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Art Statue by Theodoros Papagiannis

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References: 1. Gregory CW et al. Androgen receptor stabilization in recurrent prostate cancer is associated with hyper sensitivity to low androgen. Cancer Res 2001; 61: p2892-2898. **2.** Holzbeierlein J et al. Gene expression analysis of human prostate cancer during hormonal therapy identifies androgen-responsive genes and mechanisms of therapy resistance. Am J Path 2004; 164 (1): p217-227. **3.** Yu S-Q et al. The diverse and contrasting effects of using human prostate cancer cell lines to study androgen receptor roles in prostate cancer. Asian J Androl 2009; 11 (1): p39-48. **4.** Corey E et al. LuCaP 35: a new model of prostate cancer progression to androgen independence. Prostate 2003; 55 (4): p239-246. **5.** Loberg RD et al. Development of VCaP androgen-independent model of prostate cancer. Urol Oncol 2006; 24 (2): p161-168. **6.** ZYTIGA® - Περίληψη χαρακτηριστικών του προϊόντος. **7.** de Bono JS et al. N Eng J Med 2011; 364: p1995-2005.

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ΟΝΟΜΑΣΙΑ ΤΟΥ ΦΑΡΜΑΚΕΥΤΙΚΟΥ ΠΡΟΪΟΝΤΟΣ: ZYTIGA διακία 250 mg. **ΠΟΙΟΤΙΚΗ ΚΑΙ ΠΟΣΟΤΙΚΗ ΣΥΝΘΕΣΗ**: Το κάθε δισκίο περιέχει 250 mg οξικής αμιτραιτερόνης. Έκδοχα με γνωστές δράσεις: Το κάθε δισκίο περιέχει 189 mg λακτόζης και 6,8 mg νατρίου. Για τον πλήρη κατάλογο των εκδόχων, βλ. παράγραφο 6.1. **ΦΑΡΜΑΚΟΤΕΧΝΙΚΗ ΜΟΡΦΗ**: Δισκίο. Λευκά έως υπόλευκα δισκία ωοειδούς σχήματος με χαραγμένη την ένδειξη «AA250» στη μία πλευρά. **ΚΛΙΝΙΚΕΣ ΠΛΗΡΟΦΟΡΙΕΣ**: **Θεραπευτικές ενδείξεις**: Το ZYTIGA ενδείκνυται σε συνδυασμό με πρεδνιζόνη ή πρεδνιζολόνη για: • τη θεραπεία του μεταστατικού ανθεκτικού στον ευνουχισμό καρκίνου του προστάτη σε ενήλικες άνδρες που είναι ασυμπτωματικοί ή ήπια συμπτωματικοί μετά από αποτυχία της θεραπείας στέρησης ανδρογόνων, στους οποίους η χημειοθεραπεία δεν ενδείκνυται ακόμα κλινικά. • τη θεραπεία του μεταστατικού ανθεκτικού στον ευνουχισμό καρκίνου του προστάτη σε ενήλικες άνδρες των οποίων η νόσος έχει εξελιχθεί κατά τη διάρκεια ή μετά από θεραπεία με χημειοθεραπευτικό σχήμα που περιέχει δοσιταξέλη. **Αντενδείξεις**: - Υπερευαισθησία στη δραστική ουσία ή σε κάποιο από τα έκδοχα που αναφέρονται στην παράγραφο 6.1. - Γυναίκες που είναι ή μπορεί να είναι έγκυος. - Σοβαρή ηπατική δυσλειτουργία [Κατηγορία C κατά Child-Pugh (βλέπετε παράγραφο Ειδικές προειδοποιήσεις και προφυλάξεις κατά τη χρήση)]. **Ειδικές προειδοποιήσεις και προφυλάξεις κατά τη χρήση:** Υπέρταση, υποκαλιαιμία, κατακράτηση υγρών και καρδιακή ανεπάρκεια λόγω περίσσειας αλατοκορτικοειδών. Το ZYTIGA μπορεί να προκαλέσει υπέρταση, υποκαλιαιμία και κατακράτηση υγρών (βλέπετε παράγραφο 4.8) ως συνέπεια αυξημένων επιπέδων αλατοκορτικοειδών που προκύπτουν από την αναστολή του CYP17. Η συγχορήγηση ενός κορτικοστεροειδούς καταστέλλει την ώση της φλοιοεπινεφριδιοτρόπου ορμόνης (ACTH), οδηγώντας σε μείωση της επίπτωσης και της σοβαρότητας αυτών των ανεπιθύμητων ενέργειών. Απαιτείται προσοχή στη θεραπεία ασθενών των οποίων η υποκείμενη ιατρική κατάσταση μπορεί διακυβεύεται από τις αυξήσεις στην αρτηριακή πίεση, την υποκαλιαιμία (π.χ. σε άσους λαμβάνουν καρδιακές γλυκοσίδες), ή την κατακράτηση υγρών (π.χ. σε άσους πάσχουν από καρδιακή ανεπάρκεια), σοβαρή ή ασταθή στηθάγχη, πρόσφατο έμφραγμα του μυοκαρδίου ή κοιλιακή αρρυθμία και των ασθενών με σοβαρή νεφρική διαλειτουργία. Το ZYTIGA πρέπει να χρησιμοποιείται με προσοχή σε ασθενείς με ιστορικό καρδιαγγειακής νόσου. Από τις μελέτες φάσης 3 οι οποίες διεξήχθησαν με το ZYTIGA αποκλείσθηκαν ασθενείς με μη ελεγχόμενη υπέρταση, κλινικά σημαντική καρδιοπάθεια, όπως προκύπτει από έμφραγμα του μυοκαρδίου ή αρτηριακά θρομβωτικά επεισόδια, τους προηγούμενους 6 μήνες, σοβαρή ή ασταθή στηθάγχη ή καρδιακή ανεπάρκεια Κατηγορίας II ή IV κατά NYHA (μελέτη 301) ή καρδιακή ανεπάρκεια Κατηγορίας II έως IV (μελέτη 302) ή κλάσμα εξώθησης <50%. Στη μελέτη 302 εξαιρέθηκαν οι ασθενείς με καλπική μαρμαρυγή, ή άλλη καρδιακή αρρυθμία που απαιτούσε ιατρική θεραπεία. Η ασφάλεια σε ασθενείς με κλάσμα εξώθησης αριστερής κοιλίας < 50% ή με καρδιακή ανεπάρκεια κατηγορίας III ή IV κατά NYHA (στη μελέτη 301) ή καρδιακή ανεπάρκεια Κατηγορίας II έως IV κατά NYHA (στη μελέτη 302) δεν τεκμηριώθηκε (βλέπε παράγραφο Ανεπιθύμητες ενέργειες). Πριν από τη θεραπεία ασθενών με σημαντικό κίνδυνο για συμφορητική καρδιακή ανεπάρκεια (π.χ. ιστορικό καρδιακής ανεπάρκειας, μη ελεγχόμενη υπέρταση, ή καρδιακά επεισόδια όπως ισχαιμική καρδιοπάθεια), εξετάστε το ενδεχόμενο να γίνει αξιολόγηση της καρδιακής λειτουργίας (π.χ. ηχοκαρδιογράφημα). Πριν από τη θεραπεία με ZYTIGA, πρέπει να αντιμετωπιστεί η καρδιακή ανεπάρκεια και να βελτιστοποιηθεί η καρδιακή λειτουργία. Η υπέρταση, η υποκαλιαιμία και η κατακράτηση υγρών πρέπει να διορθώνονται και να ελέγχονται. Κατά τη διάρκεια της θεραπείας, η αρτηριακή πίεση, τα επίπεδα καλίου στον ορό, η κατακράτηση υγρών (αύξηση βάρους, περιφερικό οίδημα), και άλλα σημεία και συμπτώματα της συμφορητικής καρδιακής ανεπάρκειας πρέπει να παρακολουθούνται κάθε 2 εβδομάδες για 3 μήνες, έπειτα σε μηνιαία βάση και να διορθώνονται οι ανωμαλίες. Αξιολογήστε την καρδιακή λειτουργία όπως ενδείκνυται κλινικά, εγκαταστήστε την κατάλληλη αντιμετώπιση και εξετάστε το ενδεχόμενο της διακοπής της θεραπείας με ZYTIGA εάν υπάρχει κλινικά σημαντική μείωση στην καρδιακή λειτουργία. Ηπατοτοξικότητα και ηπατική δυσλειτουργία: Σε ελεγχόμενες κλινικές μελέτες σημειώθηκαν σημαντικές αυξήσεις στα ηπατικά ένζυμα, οι οποίες οδήγησαν στη διακοπή της θεραπείας ή σε τροποποίηση της δόσης (βλέπε παράγραφο Ανεπιθύμητες ενέργειες). Τα επίπεδα τρανσαμινασών ορού πρέπει να μετρώνται πριν από την έναρξη της θεραπείας, κάθε δύο εβδομάδες για τους πρώτους τρεις μήνες της θεραπείας και κάθε μήνα στη συνέχεια. Αν εμφανιστούν κλινικά συμπτώματα ή σημεία που υποδεικνύουν ηπατοτοξικότητα, πρέπει να μετρηθούν αμέσως οι τρανσαμινάσες ορού. Αν η ALT ή η AST αυξηθεί, απαιαδήποτε στιγμή, πάνω από το πενταπλάσιο του ανώτατου φυσιολογικού ορίου, η θεραπεία πρέπει να διακόπτεται αμέσως και η ηπατική λειτουργία πρέπει να παρακολουθείται στενά. Η επαναθεραπεία μπορεί να ξεκινήσει μόνο αφού οι δοκιμασίες ηπατικής λειτουργίας του ασθενούς επιστρέψουν στα αρχικά επίπεδα και με μειωμένο επίπεδο δόσης. Αν οι ασθενείς εμφανίσουν σοβαρή ηπατοτοξικότητα (ALT ή AST εικοσαπλάσια του ανώτατου φυσιολογικού ορίου) οποιαδήποτε στιγμή κατά τη διάρκεια της θεραπείας, η θεραπεία πρέπει να διακόπτεται και οι ασθενείς δεν πρέπει να ακολουθήσουν επαναθεραπεία. Οι ασθενείς με ενεργό ή συμπτωματική ιογενή ηπατίτιδα αποκλείσθηκαν από τις κλινικές μελέτες, επομένως δεν υπάρχουν δεδομένα, τα οποία να υποστηρίζουν τη χρήση του ZYTIGA στον πληθυσμό αυτόν. Δεν υπάρχουν δεδομένα για την κλινική ασφάλεια και αποτελεσματικότητα πολλαπλών δόσεων οδικής αμιτραιτερόνης όταν χορηγείται σε ασθενείς με μέτρια ή σοβαρή ηπατική δυσλειτουργία (Κατηγορία B ή C κατά Child-Pugh). Η χρήση του ZYTIGA πρέπει να αξιολογείται προσεκτικά σε ασθενείς με μέτρια ηπατική δυσλειτουργία, στους οποίους το όφελος προφανώς πρέπει να αντιστάθμιζει τον πιθανό κίνδυνο. Το ZYTIGA δεν πρέπει να χρησιμοποιείται σε ασθενείς με σοβαρή ηπατική δυσλειτουργία (βλέπετε παράγραφο Αντενδείξεις). Απόσυρση κορτικοστεροειδών και κάλυψη στρεσογόνων καταστάσεων: Συνιστάται προσοχή και παρακολούθηση σε περίπτωση φλοιοεπινεφριδιακής ανεπάρκειας, αν οι ασθενείς απασυρθούν από την προδνιζόνη ή πρεδνιζολόνη. Αν το ZYTIGA συνεχιστεί μετά από την απόσυρση των κορτικοστεροειδών, οι ασθενείς πρέπει να παρακολουθούνται για συμπτώματα περίσσειας αλατοκορτικοειδών (βλέπε πληροφορίες παραπάνω). Σε ασθενείς υπό πρεδνιζόνη ή πρεδνιζολόνη που βιώνουν μη συνηθισμένη στρεσογόνο κατάσταση, μπορεί να ενδείκνυται αυξημένη δόση κορτικοστεροειδών πριν, κατά τη διάρκεια και μετά από την στρεσογόνο κατάσταση. Οστική μάζα: Μείωση της οστικής μάζας μπορεί να συμβεί σε άνδρες με μεταστατικό προχωρημένο καρκίνο του προστάτη (ανθεκτικό στον ευνουχισμό καρκίνο του προστάτη). Η χρήση του ZYTIGA σε συνδυασμό με ένα γλυκοκορτικοειδές μπορεί να αυξήσει αυτή την επίδραση. Προηγούμενη χρήση κετοκοναζόλης: Σε ασθενείς που έχουν προηγουμένως λάβει θεραπεία με κετοκοναζόλη για τον καρκίνο του προστάτη, μπορεί να αναμένονται χαμηλότερα ποσοστά αντιαπόκρισης. Υπεργλυκαιμία: Η χρήση των γλυκοκορτικοειδών θα μπορούσε να αυξήσει την υπεργλυκαιμία, συνεπώς πρέπει να μετρώνται συχνά τα επίπεδα του σακχάρου στο αίμα σε ασθενείς με διαβήτη. Χορήγηση με χημειοθεραπεία: Η ασφάλεια και η αποτελεσματικότητα της ταυτόχρονης χρήσης του ZYTIGA με κυτταροτοξική χημειοθεραπεία δεν έχουν τεκμηριωθεί. Δυσανεξία σε έκδοχα: Αυτό το φαρμακευτικό προϊόν περιέχει λακτόζη. Ασθενείς με σπάνια κληρονομικά προβλήματα δυσανεξίας στη γαλακτόζη, ανεπάρκεια λακτάσης Lapp ή δυσαπορρόφηση γλυκόζης – γαλακτόζης δεν πρέπει να λαμβάνουν αυτό το φάρμακο. Αυτό το φαρμακευτικό προϊόν περιέχει περισσότερο από 1 mmol (ή 27,2 mg) νατρίου σε κάθε δόση των τεσσάρων δισκίων. Να λαμβάνεται υπόψη από ασθενείς που ακολουθούν δίαητα με ελεγχόμενες ποσότητες νατρίου. Πιθανοί κίνδυνοι: Αναιμία και αξεσουαλική δυσλειτουργία μπορεί να εμφανιστούν σε άνδρες με ανθεκτικό στον ευνουχισμό μεταστατικό καρκίνο του προστάτη συμπεριλαμβανομένων εκείνων που υποβάλλονται σε θεραπεία με ZYTIGA. Επιδράσεις στους σκελετικούς μύες: Έχουν αναφερθεί περιπτώσεις μυοπάθειας σε ασθενείς που έλαβαν θεραπεία με ZYTIGA. Ορισμένοι ασθενείς είχαν ραβδομυόλυση με νεφρική ανεπάρκεια. Οι περισσότερες περιπτώσεις εμφανίστηκαν εντός του πρώτου μήνα της θεραπείας και αποκαταστάθηκαν μετά τη διακοπή του ZYTIGA. Συνιστάται προσοχή σε ασθενείς που λαμβάνουν ταυτόχρονα φάρμακα που είναι γνωστό ότι συνδέονται με μυοπάθεια/ραβδομυόλυση. **Ανεπιθύμητες ενέργειες:** Περίληψη του προφίλ ασφάλειας: Οι συνηθέστερες ανεπιθύμητες ενέργειες που έχουν παρατηρηθεί είναι το περιφερικό οίδημα, η υποκαλιαιμία, η υπέρταση και η ουρολοίμωξη. Άλλες σημαντικές ανεπιθύμητες ενέργειες περιλαμβάνουν τις καρδιακές διαταραχές, την ηπατοτοξικότητα και τα κατάγματα. Το ZYTIGA μπορεί να προκαλέσει υπέρταση, υποκαλιαιμία και κατακράτηση υγρών στο πλαίσιο των φαρμακοδυναμικών συνεπειών του μηχανισμού δράσης του. Σε κλινικές μελέτες οι ανεμενόμενες αλατοκορτικοειδείς ανεπιθύμητες αντιδράσεις παρατηρήθηκαν συνηθέστερα στους ασθενείς που έλαβαν θεραπεία με ZYTIGA σε σχέση με τους ασθενείς που έλαβαν θεραπεία με εικονικό φάρμακο: υποκαλιαιμία 21% έναντι 11%, υπέρταση 16% έναντι 11% και κατακράτηση υγρών (περιφερικό οίδημα) 26% έναντι 20%, αντίστοιχα. Στους ασθενείς που έλαβαν θεραπεία με ZYTIGA, παρατηρήθηκε υποκαλιαιμία Βαθμών 3 και 4 κατά CTCAE (έκδοση 3.0) και υπέρταση Βαθμών 3 και 4 κατά CTCAE (έκδοση 3.0) στο 4% και 2% των ασθενών, αντιστοίχως. Οι αλατοκορτικοειδείς αντιδράσεις ήταν γενικά διναπό να αντιμετωπιστούν ιατρικά με επιτυχία. Η ταυτόχρονη χρήση κορτικοστεροειδούς μειώνει την επίπτωση και τη σοβαρότητα αυτών των ανεπιθύμητων ενεργειών (βλέπε παράγραφο Ειδικές προειδοποιήσεις και προφυλάξεις κατά τη χρήση). Συνοπτική παρουσίαση των ανεπιθύμητων ενεργειών υπό μορφή πίνακα: Σε μελέτες ασθενών με μεταστατικό πραγωρημένο καρκίνο του προστάτη που χρησιμοποιούσαν ανάλογα της ορμόνης απελευθέρωσης της ωχρινοποιητικής ορμόνης (LHRH) ή είχαν υποβληθεί προηγουμένως σε ορχιεκτομή, το ZYTIGA χορηγήθηκε σε δόση 1.000 mg ημερησίως σε συνδυασμό με χαμηλή δόση πρεδνιζόνης ή πρεδνιζολόνης (10 mg ημερησίως). Οι ανεπιθύμητες ενέργειες που παρατηρήθηκαν κατά τη διάρκεια των κλινικών μελετών με το ZYTIGA αναφέρονται στη συνέχεια ανά κατηγορία συχνότητας. Οι κατηγορίες συχνότητας ορίζονται ως εξής: πολύ συχνές (≥ 1/10), συχνές (≥ 1/100 έως < 1/10), όχι συχνές (≥ 1/1.000 έως < 1/100), σπάνιες (≥1/10.000 έως <1/1.000), πολύ σπάνιες (<1/10.000). Εντός κάθε ομάδας συχνότητας, οι ανεπιθύμητες ενέργειες εμφανίζονται με σειρά φθίνουσας σοβαρότητας.

Πίνακας 1: Ανεπιθύμητες ενέργειες που αναφέρθηκαν στις κλινικές μελέτες
Λοιμώξεις και παρασιτώσεις	πολύ συχνές ουρολοίμωξη
Διαταραχές του ενδοκρινικού συστήματος	όχι συχνές επινεφριδιακή ανεπάρκεια
Διαταραχές του μεταβολισμού και της θρέψης	πολύ συχνές υποκαλιαιμία συχνές υπεργλυκαιμία
Καρδιακές διαταραχές	συχνές καρδιακή ανεπάρκεια*, στηθάγχη, αρρυθμία, κολπική μαρμαρυγή, ταχυκαρδία
Αγγειακές διαταραχές	πολύ συχνές υπέρταση
Γαστρεντερικές διαταραχές	πολύ συχνές διάρροια συχνές δυσπεψία
Διαταραχές του ήπατος και των χοληφόρων	συχνές αυξημένη αμινοτρανσφεράση της αλανίνης, αυξημένη ασπαρτική αμινοτρανσφεράση
Διαταραχές του δέρματος και του υποδόριου ιστού	συχνές εξάνθημα
Διαταραχές του μυοσκελετικού συστήματος και του συνδετικού ιστού	όχι συχνές μυοπάθεια, ραβδομυόλυση
Διαταραχές των νεφρών και των ουροφόρων οδών	συχνές αιματουρία
Γενικές διαταραχές και καταστάσεις της οδού χορήγησης	πολύ συχνές περιφερικό οίδημα
Κακώσεις, δηλητηριάσεις και επιπλοκές θεραπευτικών χειρισμών	συχνές κατάγματα**

*Η καρδιακή ανεπάρκεια περιλαμβάνει, επίσης, τη συμφορητική καρδιακή ανεπάρκεια, τη δυσλειτουργία αριστερής κοιλίας και το μειωμένο κλάσμα εξώθησης

**Τα κατάγματα περιλαμβάνουν όλα τα κατάγματα με την εξαίρεση του παθολογικού κατάγματος

Οι ακόλουθες ανεπιθύμητες ενέργειες Βαθμού 3 κατά CTCAE (έκδοση 3.0) έχουν παρατηρηθεί σε ασθενείς που έχουν ακολουθήσει θεραπεία με ZYTIGA: υποκαλιαιμία 3%, ουρολοίμωξη, αυξημένη αμινοτρανσφεράση της αλανίνης, υπέρταση, αυξημένη ασπαρτική αμινοτρανσφεράση, κατάγματα 2%, περιφερικό οίδημα, καρδιακή ανεπάρκεια και κολπική μαρμαρυγή, 1% το καθένα. Υπερτριγλυκεριδαιμία και στηθάγχη Βαθμού 3 κατά CTCAE (έκδοση 3.0) παρατηρήθηκε σε < 1% των ασθενών. Περιφερικό οίδημα, υποκαλιαιμία, ουρολοίμωξη, καρδιακή ανεπάρκεια και κατάγματα βαθμού 4 κατά CTCAE (έκδοση 3.0) παρατηρήθηκαν σε < 1% των ασθενών. Περίγραφη επιλεγμένων ανεπιθύμητων ενεργειών: Καρδιαγγειακές αντιδράσεις: Και οι δύο μελέτες φάσης 3 απέκλειαν τη συμμετοχή ασθενών με μη ελεγχόμενη υπέρταση, κλινικά σημαντική καρδιοπάθεια, η οποία επιβεβαιώνονταν από έμφραγμα του μυοκαρδίου, ή αρτηριακά θρομβωτικά συμβάντα τους τελευταίους 6 μήνες, σοβαρή ή ασταθή στηθάγχη, ή καρδιακή ανεπάρκεια κατηγορίας III ή IV σύμφωνα με την NYHA (μελέτη 301) ή καρδιακή ανεπάρκεια κατηγορίας II έως IV (μελέτη 302) ή με μέτρηση καρδιακού κλάσματος εξώθησης < 50%. Όλοι οι ασθενείς που εντάχθηκαν στη μελέτη πάσχουν από κάποια μορφή καρδιακής νόσου και αυτοί που έλαβαν εικονικό φάρμακο έλαβαν παράλληλα θεραπεία στέρησης ανδρογόνων, κυρίως με τη χρήση αναλόγων της LHRH, η οποία έχει σχετιστεί με διαβήτη, έμφραγμα του μυοκαρδίου, αγγειακό εγκεφαλικό επεισόδιο και αιφνίδιο καρδιακό θάνατο. Η επίπτωση των καρδιαγγειακών ανεπιθύμητων ενεργειών στις μελέτες φάσης 3 σε ασθενείς που λάμβαναν ZYTIGA έναντι ασθενών που λάμβαναν εικονικό φάρμακο ήταν ως εξής: υπέρταση 14,5% έναντι 10,5%, καλπική μαρμαρυγή 3,4% έναντι 3,4%, ταχυκαρδία 2,8% έναντι 1,7%, στηθάγχη 1,9% έναντι 0,9%, καρδιακή ανεπάρκεια 1,9% έναντι 0,6%, και αρρυθμία 1,1% έναντι 0,4%. Ηπατοτοξικότητα: Έχει αναφερθεί ηπατοτοξικότητα με αυξημένη ALT, ασπαρτική τρανσαμινάση (AST) και ολική χολερυθρίνη σε ασθενείς που έλαβαν θεραπεία με το ZYTIGA. Σε όλες τις κλινικές μελέτες, οι αυξήσεις στις δοκιμασίες ηπατικής λειτουργίας (αυξήσεις της ALT ή της AST > 5 x ULN ή αυξήσεις χολερυθρίνης > 1,5 x ULN) αναφέρθηκαν στο 4% περίπου των ασθενών που έλαβαν ZYTIGA, συνήθως κατά τη διάρκεια των πρώτων 3 μηνών από την έναρξη της θεραπείας. Στην κλινική μελέτη 301, οι ασθενείς με αυξημένες τιμές ALT ή AST κατά την έναρξη της μελέτης ήταν πιθανότερο να εμφανίσουν αυξημένες τιμές στις δοκιμασίες ηπατικής λειτουργίας σε σχέση με τους ασθενείς με φυσιολογικές τιμές κατά την έναρξη της μελέτης. Όταν παρατηρήθηκαν αυξήσεις είτε της ALT είτε της AST > 5 x ULN ή αυξήσεις στη χολερυθρίνη > 3 x ULN, η χορήγηση του ZYTIGA διεκόπη προσωρινά ή οριστικά. Σε δύο περιπτώσεις σημείωθηκαν σημαντικές αυξήσεις στις τιμές των δοκιμασιών ηπατικής λειτουργίας (βλέπε παράγραφο Ειδικές προειδοποιήσεις και προφυλάξεις κατά τη χρήση). Οι δυο αυτοί ασθενείς με φυσιολογική ηπατική λειτουργία κατά την έναρξη της μελέτης, εμφάνισαν αυξήσεις στην ALT ή την AST 15 έως 40 x ULN και αυξήσεις στις τιμές της χολερυθρίνης 2 έως 6 x ULN. Κατά τη διακοπή του ZYTIGA, οι τιμές των δοκιμασιών ηπατικής λειτουργίας αμαλοποιήθηκαν και στους δύο ασθενείς και ο ένας ασθενής συνέχισε τη θεραπεία χωρίς να επανεμφανιστούν αυξήσεις. Στη μελέτη 302, παρατηρήθηκαν αυξήσεις βαθμού 3 ή 4 στην ALT ή την AST σε 35 (6,5%) ασθενείς που έλαβαν θεραπεία με ZYTIGA. Οι αυξήσεις της αμινοτρανσφεράσης αποκαταστάθηκαν σε όλους εκτός από 3 ασθενείς (2 με νέες πολλαπλές μεταστάσεις στα ήπαρ και 1 με αύξηση στην AST περίπου 3 εβδομάδες μετά την τελευταία δόση του ZYTIGA). Διακοπή στη θεραπεία λόγω των αυξήσεων των ALT και AST αναφέρθηκε στο 1,7% και 1,3% των ασθενών που λάμβαναν θεραπεία με ZYTIGA και στο 0,2% και 0% των ασθενών που λάμβαναν εικονικό φάρμακο, αντίστοιχα. Δεν αναφέρθηκαν θάνατοι λόγω ηπατοτοξικού συμβάματος. Στις κλινικές δοκιμές, ο κίνδυνος ηπατοτοξικότητας μετρίαστηκε από τον αποκλεισμό ασθενών με ηπατίτιδα κατά την έναρξη ή σημαντικές ανωμαλίες στους δείκτες της ηπατικής λειτουργίας. Στη δοκιμή 301, εξαιρέθηκαν οι ασθενείς με αρχική ALT και AST ≥ 2,5 x ULN απουσία μεταστάσεων στο ήπαρ και > 5 x ULN παρουσία μεταστάσεων στο ήπαρ. Στη δοκιμή 302 οι ασθενείς με μεταστάσεις στο ήπαρ δεν ήταν κατάλληλοι για ένταξη και οι ασθενείς με αρχική ALT και AST ≥ 2,5 x ULN εξαιρέθηκαν. Οι παθολογικές τιμές στις δοκιμασίες ηπατικής λειτουργίας που εμφανίστηκαν στους ασθενείς που συμμετείχαν στις κλινικές μελέτες αντιμετωπίστηκαν εντατικά με υποχρεωτική προσωρινή διακοπή της θεραπείας και δυνατότητα συνέχισης της θεραπείας μόνο εφόσον οι τιμές των δοκιμασιών ηπατικής λειτουργίας του ασθενούς είχαν επιστρέψει στα αρχικά επίπεδα. Οι ασθενείς με επίπεδα ALT ή AST > 20 x ULN δεν ακολούθησαν επαναθεραπεία. Η ασφάλεια της επαναθεραπείας στους ασθενείς αυτούς δεν είναι γνωστή. Ο μηχανισμός που προκαλεί ηπατοτοξικότητα δεν έχει γίνει κατανοητός. **ΚΑΤΟΧΟΣ ΤΗΣ ΑΔΕΙΑΣ ΚΥΚΛΟΦΟΡΙΑΣ**: Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Βέλγιο. **ΑΡΙΘΜΟΣ(ΟΙ) ΑΔΕΙΑΣ ΚΥΚΛΟΦΟΡΙΑΣ:** EU/1/11/714/001. **ΗΜΕΡΟΜΗΝΙΑ ΑΝΑΘΕΩΡΗΣΗΣ ΤΟΥ ΚΕΙΜΕΝΟΥ:** 25 Ιουλίου 2013. 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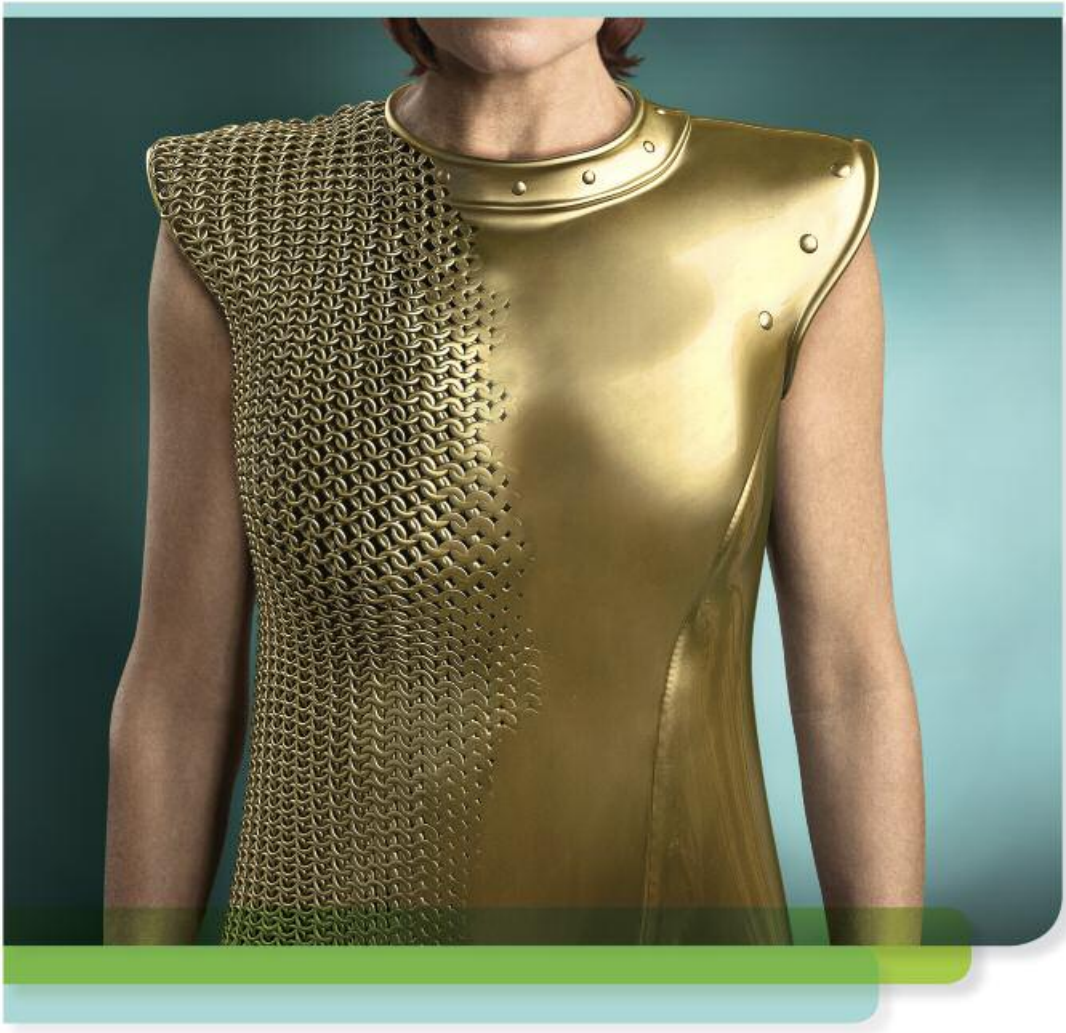

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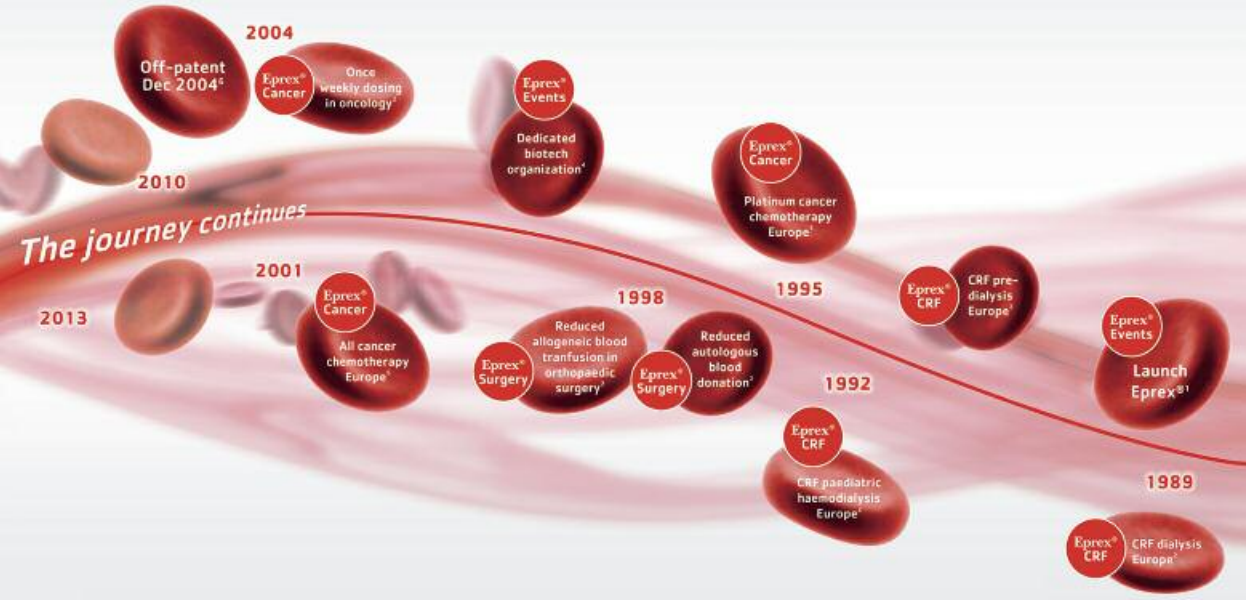

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ΠΕΡΙΛΗΨΗ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

ΟΝΟΜΑΣΙΑ ΦΑΡΜΑΚΕΥΤΙΚΟΥ ΠΡΟΪΟΝΤΟΣ: EPREX 40.000 IU/ml ενέσιμο διάλυμα σε προγεμισμένη σύριγγα. **ΠΟΙΟΤΙΚΗ ΚΑΙ ΠΟΣΟΤΙΚΗ ΣΥΝΘΕΣΗ:** Epoetin alfa*...40.000 IU/ml (336,0 μικρογραμμάρια ανά ml). Κάθε προγεμισμένη σύριγγα του 0,5 ml περιέχει 20.000 IU (168,0 μικρογραμμάρια) epoetin alfa. Κάθε προγεμισμένη σύριγγα του 1,0 ml περιέχει 40.000 IU (336,0 μικρογραμμάρια) epoetin alfa. * παράγεται σε κύτταρα Ωοθηκών Κινεζικών Χοιριδίων (Chinese Hamster Ovary, CHO) με την τεχνολογία ανασυνδυασμένου DNA. **ΦΑΡΜΑΚΟΤΕΧΝΙΚΗ ΜΟΡΦΗ:** Ενέσιμο διάλυμα σε προγεμισμένη σύριγγα. Διαυγές, άχρωμο διάλυμα. **ΚΛΙΝΙΚΕΣ ΠΛΗΡΟΦΟΡΙΕΣ: Θεραπευτικές ενδείξεις:** Θεραπεία της αναιμίας και μείωση των απαιτήσεων για μετάγγιση σε ενήλικες ασθενείς οι οποίοι υποβάλλονται σε χημειοθεραπεία για συμπαγείς όγκους, κακοήθες λέμφωμα ή πολλαπλό μυέλωμα και βρίσκονται σε κίνδυνο μετάγγισης όπως αξιολογείται με βάση τη γενική τους κατάσταση (π.χ. καρδιαγγειακή κατάσταση, προϋπάρχουσα αναιμία κατά την έναρξη της χημειοθεραπείας). Το EPREX είναι δυνατόν να χρησιμοποιηθεί για να αυξήσει την απόδοση του αυτόλογου αίματος από ασθενείς που συμμετέχουν σε ένα πρόγραμμα αυτομετάγγισης. Η χρήση του σε αυτήν την ένδειξη θα πρέπει να σταθμίζεται σε σχέση με τον αναφερόμενο κίνδυνο θρομβοεμβολικών επιπλοκών. Η θεραπεία ενδείκνυται μόνο σε ασθενείς με αναιμία μέτριας βαρύτητας (Hb 10-13 g/dl, [6,2-8,1 mmol/L], χωρίς έλλειψη σιδήρου), αν οι τεχνικές αποταμίευσης αίματος είναι ανύπαρκτες ή ανεπαρκείς, και το μείζον προγραμματισμένο χειρουργείο απαιτεί μεγάλες ποσότητες αίματος (4 ή περισσότερες μονάδες αίματος στις γυναίκες ή 5 ή περισσότερες μονάδες στους άνδρες). Το EPREX μπορεί να χρησιμοποιηθεί πριν από μείζονα προγραμματισμένα ορθοπεδικά χειρουργεία, τα οποία παρουσιάζουν υψηλά ποσοστά αναμενόμενων επιπλοκών κατά την μετάγγιση, ώστε να μειώσει την έκθεση σε αλλογενικές μεταγγίσεις αίματος σε ενήλικους ασθενείς που δεν παρουσιάζουν έλλειψη σιδήρου. Η χρήση του θα πρέπει να περιορίζεται σε ασθενείς με αναιμία μέτριας βαρύτητας (π.χ. Hb 10-13 g/dl) οι οποίοι δεν συμμετείχαν σε κάποιο πρόγραμμα αυτομετάγγισης και οι οποίοι αναμένεται να υποστούν μια απώλεια αίματος μέτριας βαρύτητας (900 έως 1.800 ml). Στο προεγχειρητικό στάδιο θα πρέπει να χρησιμοποιούνται πάντα σωστές τεχνικές διαχείρισης του αίματος. **Αντενδείξεις:** Ασθενείς που αναπτύσσουν αμιγή απλασία ερυθράς σειράς (PRCA - ερυθροβλαστοπενία) μετά από θεραπεία με οποιαδήποτε ερυθροποιητίνη δεν θα πρέπει να λαμβάνουν EPREX ή οποιαδήποτε άλλη ερυθροποιητίνη (βλέπε παράγραφο Ειδικές προειδοποιήσεις και προφυλάξεις κατά τη χρήση-Αμιγής Απλασία Ερυθράς Σειράς). Μη ελεγχόμενη αρτηριακή υπέρταση. Στους ασθενείς στους οποίους χορηγείται epoetin alfa θα πρέπει να τηρούνται όλες οι αντενδείξεις που σχετίζονται με τα προγράμματα αυτομετάγγισης. Υπερευαισθησία στη δραστική ουσία ή σε οποιοδήποτε από τα έκδοχα. Η χρήση της epoetin alfa αντενδείκνυται σε ασθενείς που είναι προγραμματισμένοι για μείζονα ορθοπεδικά χειρουργεία αλλά δε συμμετέχουν σε κάποιο πρόγραμμα αυτομετάγγισης και υποφέρουν από κάποια σοβαρή στεφανιαία, περιφερική αρτηριακή, καρωτιδική ή αγγειακή εγκεφαλική νόσο, συμπεριλαμβανομένων των ασθενών που είχαν υποστεί πρόσφατα κάποιο έμφραγμα του μυοκαρδίου ή αγγειακό εγκεφαλικό επεισόδιο. Χειρουργικοί ασθενείς οι οποίοι για οποιονδήποτε λόγο δεν μπορούν να λάβουν επαρκή προφυλακτική αντιπηκτική αγωγή. **Ειδικές προειδοποιήσεις και προφυλάξεις κατά τη χρήση:** Γενικά: Η αρτηριακή πίεση όλων των ασθενών που λαμβάνουν epoetin alfa, θα πρέπει να παρακολουθείται στενά και να λαμβάνονται όλα τα μέτρα για την ρύθμισή της. Στις περιπτώσεις της μη αντιμετωπιζόμενης, της ανεπαρκώς αντιμετωπιζόμενης ή της ανεπαρκώς ελεγχόμενης υπέρτασης, η epoetin alfa θα πρέπει να χρησιμοποιείται με πολύ προσοχή. Είναι πιθανό να απαιτείται έναρξη ή αύξηση της αντιϋπερτασικής αγωγής. Στις περιπτώσεις που δεν είναι δυνατή η ρύθμιση της αρτηριακής πίεσης, θα πρέπει να διακόπτεται η θεραπεία με epoetin alfa. Η epoetin alfa θα πρέπει να χρησιμοποιείται επίσης με προσοχή στις περιπτώσεις που οι ασθενείς πάσχουν από επιληψία ή από χρόνια ηπατική ανεπάρκεια. Οι ασθενείς με χρόνια νεφρική ανεπάρκεια καθώς και οι καρκινοπαθείς που λαμβάνουν epoetin alfa, πρέπει να ελέγχουν σε τακτά χρονικά διαστήματα τα επίπεδα της αιμοσφαιρίνης τους, μέχρι αυτά να σταθεροποιηθούν. Από τη στιγμή που τα επίπεδα της αιμοσφαιρίνης σταθεροποιηθούν ο έλεγχος πρέπει να γίνεται περιοδικά. Σε όλους τους ασθενείς, τα επίπεδα της αιμοσφαιρίνης πρέπει να παρακολουθούνται στενά λόγω πιθανού αυξημένου κινδύνου θρομβοεμβολικών επεισοδίων και μοιραίων καταλήξεων όταν τα επίπεδα της αιμοσφαιρίνης των υπό θεραπεία ασθενών είναι υψηλότερα από τα στοχευόμενα της ένδειξης χρήσης. Κατά τη διάρκεια της θεραπείας με epoetin alfa, είναι δυνατό να παρατηρηθεί μια μέτρια δοσοεξαρτώμενη αύξηση στον αριθμό των αιμοπεταλίων, η οποία να παραμένει μέσα στα φυσιολογικά όρια. Η αύξηση αυτή υποχωρεί κατά την πορεία της συνεχιζόμενης θεραπείας. Επιπλέον, έχει αναφερθεί θρομβοκυττάρωση υψηλότερη του φυσιολογικού εύρους. Συνιστάται να ελέγχεται ο αριθμός των αιμοπεταλίων σε τακτά χρονικά διαστήματα κατά τη διάρκεια των πρώτων 8 εβδομάδων θεραπείας. Όλα τα άλλα αίτια της αναιμίας (έλλειψη σιδήρου, αιμόλυση, απώλεια αίματος, έλλειψη βιταμίνης B_{12} ή φυλλικού οξέος) θα πρέπει να ληφθούν υπόψη και να γίνει η κατάλληλη αγωγή πριν την έναρξη της θεραπείας με epoetin alfa. Στις περισσότερες περιπτώσεις οι τιμές φερριτίνης στον ορό πέφτουν ταυτόχρονα με την αύξηση του όγκου συμπυκνωμένων ερυθρών. Για να διασφαλιστεί η βέλτιστη ανταπόκριση στην epoetin alfa θα πρέπει να εξασφαλιστούν επαρκείς αποθήκες σιδήρου • συνιστάται η υποκατάσταση σιδήρου με χορήγηση από του στόματος 200 – 300 mg/ημέρα σε όλους τους καρκινοπαθείς των οποίων ο κορεσμός της τρανσφερρίνης είναι κάτω από το 20%. Όλοι αυτοί οι πρόσθετοι παράγοντες της αναιμίας θα πρέπει να εκτιμηθούν προσεκτικά όταν αποφασίζεται αύξηση της δόσης της epoetin alfa σε καρκινοπαθείς. Πολύ σπάνια, έχει παρατηρηθεί εμφάνιση ή επιδείνωση της πορφυρίας σε ασθενείς που υποβάλλονται σε θεραπεία με epoetin alfa. Η epoetin alfa πρέπει να χρησιμοποιείται με προσοχή σε ασθενείς με πορφυρία. Για να βελτιωθεί η ανιχνευσιμότητα των ESA πρέπει να λαμβάνονται όλα τα απαραίτητα και πιθανά μέτρα για την εξασφάλισή της (π.χ. ακριβείς πληροφορίες που αφορούν το χρησιμοποιούμενο προϊόν πρέπει να τεκμηριώνονται με κατάλληλο τρόπο). Επιπλέον, οι ασθενείς πρέπει να αλλάζουν από έναν ESA σε άλλο μόνο υπό την κατάλληλη επίβλεψη. Αμιγής Απλασία Ερυθράς Σειράς: Πολύ σπάνια έχει αναφερθεί αμιγής απλασία ερυθράς σειράς με τη μεσολάβηση αντισωμάτων (Pure Red Cell Aplasia-PRCA) μετά από μήνες έως χρόνια υποδόριας χορήγησης epoetin. Σε ασθενείς που εμφανίζουν αιφνίδια απώλεια αποτελεσματικότητας που ορίζεται ως μείωση της αιμοσφαιρίνης (1 έως 2 g/dl ανά μήνα) με αυξημένη ανάγκη για μεταγγίσεις, πρέπει να ληφθεί ο αριθμός των δικτυοερυθροκυττάρων και να ερευνηθούν τα συνήθη αίτια της μη ανταπόκρισης (π.χ. έλλειψη σιδήρου, φυλλικού οξέος ή βιταμίνης B_{12}, δηλητηρίαση με αργίλιο, λοίμωξη ή φλεγμονή, απώλεια αίματος και αιμόλυση). Εάν ο αριθμός των δικτυοερυθροκυττάρων διορθωμένος ως προς την αναιμία (δηλαδή ο δείκτης δικτυοερυθροκυττάρων) είναι χαμηλός (< 20.000 mm³ ή < 20.000/μικρόλιτρα ή < 0,5%), τα αιμοπετάλια και ο αριθμός των λευκοκυττάρων είναι φυσιολογικά και εάν καμία άλλη αιτία απώλειας αποτελεσματικότητας δεν έχει βρεθεί, πρέπει να προσδιορισθούν τα αντισώματα έναντι ερυθροποιητίνης και να ληφθεί υπόψη το ενδεχόμενο εξέτασης του μυελού των οστών για τη διάγνωση της αμιγούς απλασίας ερυθράς σειράς. Εάν υπάρχει υποψία αμιγούς απλασίας ερυθράς σειράς με τη μεσολάβηση αντισωμάτων έναντι της ερυθροποιητίνης, η θεραπεία με EPREX πρέπει να διακοπεί άμεσα. Δεν πρέπει να χορηγηθεί καμία άλλη θεραπεία με ερυθροποιητίνες εξαιτίας του κινδύνου διασταυρούμενης αντίδρασης. Όταν ενδείκνυται μπορεί να χορηγηθεί στους ασθενείς κατάλληλη θεραπεία όπως μετάγγιση αίματος. Θεραπεία ασθενών με αναιμία προκαλούμενη από χημειοθεραπεία: Οι εποετίνες είναι αυξητικοί παράγοντες που διεγείρουν κατά κύριο λόγο την παραγωγή των ερυθροκυττάρων. Οι υποδοχείς της ερυθροποιητίνης μπορεί να εκφράζονται στην επιφάνεια μιας ποικιλίας νεοπλασματικών κυττάρων. Όπως ισχύει για όλους τους αυξητικούς παράγοντες, υπάρχει ο προβληματισμός πως οι ερυθροποιητίνες θα μπορούσαν να προάγουν την αύξηση του όγκου. Σε διάφορες ελεγχόμενες μελέτες, οι ερυθροποιητίνες δεν έχουν δείξει να βελτιώνουν τη συνολική επιβίωση ή να μειώνουν τον κίνδυνο της εξέλιξης του όγκου σε ασθενείς με αναιμία σχετιζόμενη με καρκίνο. Σε ελεγχόμενες κλινικές μελέτες, η χρήση του EPREX και άλλων παραγόντων διέγερσης της ερυθροποίησης (ESA) έχει δείξει: • μείωση του τοπικού περιοχικού ελέγχου σε ασθενείς με προχωρημένο καρκίνο κεφαλής και τραχήλου οι οποίοι υποβάλλονταν σε θεραπεία με ακτινοβολία, όταν χορηγήθηκε με στόχο μια συγκέντρωση αιμοσφαιρίνης μεγαλύτερη από 14 g/dl (8,7 mmol/l), • μειωμένη συνολική επιβίωση και αυξημένο ποσοστό θανάτων που αποδόθηκαν στην εξέλιξη της νόσου σε 4 μήνες σε ασθενείς με μεταστατικό καρκίνο του μαστού οι οποίοι υποβάλλονταν σε χημειοθεραπεία, κατά τη χορήγηση με στόχο μια συγκέντρωση αιμοσφαιρίνης 12 – 14 g/dl (7,5 – 8,7 mmol/l), • αυξημένο κίνδυνο θανάτων κατά τη χορήγηση με στόχο μια συγκέντρωση αιμοσφαιρίνης 12 g/dl (7,5 mmol/l) σε ασθενείς με ενεργή κακοήθη νόσο που δεν υποβάλλονταν ούτε σε χημειοθεραπεία ούτε σε θεραπεία ακτινοβολίας. Οι ESA δεν ενδείκνυνται για χρήση στο συγκεκριμένο πληθυσμό ασθενών. Λαμβάνοντας υπόψη τα παραπάνω, σε ορισμένα κλινικά περιστατικά η μετάγγιση αίματος πρέπει να είναι η προτιμώμενη θεραπεία για τη διαχείριση της αναιμίας σε ασθενείς με καρκίνο. Η απόφαση χορήγησης θεραπείας με ανασυνδυασμένη ερυθροποιητίνη πρέπει να βασίζεται στην αξιολόγηση του οφέλους- κινδύνου με συμμετοχή του ίδιου του ασθενή, λαμβάνοντας υπόψη το συγκεκριμένο κλινικό πλαίσιο. Οι παράγοντες που πρέπει να ληφθούν υπόψη σε αυτήν την αξιολόγηση πρέπει να περιλαμβάνουν τον τύπο του όγκου και το στάδιό του, το βαθμό της αναιμίας, το προσδόκιμο επιβίωσης, το περιβάλλον μέσα στο οποίο ο ασθενής υποβάλλεται στη θεραπεία και την προτίμηση του ασθενούς. Σε καρκινοπαθείς που υπόκεινται σε χημειοθεραπεία, η καθυστέρηση 2- 3 εβδομάδων μεταξύ της χορήγησης του ESA και της εμφάνισης των ερυθροκυττάρων που επάγονται από την ερυθροποιητίνη πρέπει να λαμβάνονται υπόψη όταν αξιολογείται εάν η θεραπεία με epoetin alfa είναι κατάλληλη (ο ασθενής βρίσκεται σε κίνδυνο να υποβληθεί σε μετάγγιση). Επειδή έχει παρατηρηθεί μια αυξημένη συχνότητα θρομβωτικών αγγειακών επεισοδίων (TVEs) σε καρκινοπαθείς που ελάμβαναν ESAs (βλέπε παράγραφο Ανεπιθύμητες Ενέργειες), αυτός ο κίνδυνος πρέπει να εξεταστεί προσεκτικά σε σχέση με το όφελος της θεραπείας με epoetin alfa, ιδιαίτερα σε καρκινοπαθείς με αυξημένο κίνδυνο θρομβωτικών αγγειακών επεισοδίων, όπως στην περίπτωση παχυσαρκίας και σε ασθενείς με προηγούμενο ιστορικό TVEs (π.χ. εν τω βάθει φλεβική θρόμβωση ή πνευμονική εμβολή). Μια ερευνητική μελέτη (μελέτη BEST) σε γυναίκες με μεταστατικό καρκίνο του μαστού σχεδιάστηκε για να καθορίσει εάν η θεραπεία με epoetin alfa που επεκτείνεται πέρα από τη διόρθωση της αναιμίας μπορεί να βελτιώσει τα αποτελέσματα της θεραπείας. Σε αυτήν τη μελέτη η συχνότητα εμφάνισης των θανατηφόρων θρομβοεμβολικών επεισοδίων ήταν υψηλότερη σε ασθενείς που ελάμβαναν epoetin alfa από αυτούς που ελάμβαναν εικονικό φάρμακο. Χειρουργικοί ασθενείς σε προγράμματα αυτομετάγγισης: Θα πρέπει να τηρούνται όλες οι ειδικές προειδοποιήσεις και οι ειδικές προφυλάξεις που σχετίζονται με τα προγράμματα αυτομετάγγισης, ειδικά η τακτική υποκατάσταση όγκου. Ασθενείς προγραμματισμένοι για μείζονα ορθοπεδικά χειρουργεία: Στους ασθενείς που είναι προγραμματισμένοι για μείζονα ορθοπεδικά χειρουργεία, το αίτιο της αναιμίας θα πρέπει, αν είναι δυνατό, να εντοπίζεται και να αντιμετωπίζεται πριν από την έναρξη της θεραπείας με epoetin alfa. Τα θρομβωτικά επεισόδια αποτελούν έναν παράγοντα κινδύνου σε αυτόν τον πληθυσμό και η πιθανότητα αυτή θα πρέπει να λαμβάνεται σοβαρά υπ' όψη σε σχέση με τα οφέλη που προκύπτουν από την θεραπεία σε αυτή την ομάδα των ασθενών. Οι ασθενείς που είναι προγραμματισμένοι για μείζονα ορθοπεδικά χειρουργεία θα πρέπει να λαμβάνουν επαρκή προφυλακτική αντιπηκτική αγωγή, καθώς είναι πιθανό, στους ασθενείς αυτούς, να παρουσιαστούν θρομβωτικά και αγγειακά επεισόδια, ειδικά στις περιπτώσεις υποκείμενης καρδιοαγγειακής νόσου. Επιπλέον, θα πρέπει να λαμβάνονται ειδικές προφυλάξεις στους ασθενείς που έχουν προδιάθεση για να αναπτύξουν εν τω βάθει φλεβική θρόμβωση (DVTs). Επιπλέον, στους ασθενείς με τιμή αναφοράς της αιμοσφαιρίνης > 13 g/dl, δεν μπορεί να αποκλειστεί η πιθανότητα η θεραπεία με epoetin alfa να συνδέεται με αυξημένο κίνδυνο μετεγχειρητικών θρομβωτικών/αγγειακών επεισοδίων. Επομένως, δεν θα πρέπει να εφαρμόζεται σε ασθενείς με τιμή αναφοράς της αιμοσφαιρίνης > 13 g/dl. Ασθενείς με χρόνια νεφρική ανεπάρκεια: Οι ασθενείς με χρόνια νεφρική ανεπάρκεια που ακολουθούν θεραπεία με EPREX με υποδόρια χορήγηση πρέπει να παρακολουθούνται τακτικά για απώλεια αποτελεσματικότητας, που ορίζεται ως απουσία ή μείωση της ανταπόκρισης στη θεραπεία με EPREX σε ασθενείς που είχαν προηγούμενα ανταποκριθεί σε αυτή τη θεραπεία. Αυτό χαρακτηρίζεται από μια εμμένουσα μείωση της αιμοσφαιρίνης παρά την αύξηση της δοσολογίας του EPREX. Αυτό το φαρμακευτικό προϊόν περιέχει λιγότερο από 1 mmol νατρίου (23 mg) ανά δόση, δηλαδή είναι ουσιωδώς 'ελεύθερο νατρίου'. **Ανεπιθύμητες ενέργειες:** Γενικά: Σε καρκινοπαθείς και σε ασθενείς με χρόνια νεφρική ανεπάρκεια η πιο συχνή ανεπιθύμητη αντίδραση φαρμάκου κατά τη διάρκεια θεραπείας με epoetin alfa είναι μια δοσοεξαρτώμενη αύξηση της αρτηριακής πίεσης ή επιδείνωση της ήδη υπάρχουσας υπέρτασης. Πρέπει να παρακολουθείται η αρτηριακή πίεση, κυρίως κατά την έναρξη της θεραπείας (βλέπε παράγραφο Ειδικές προειδοποιήσεις και προφυλάξεις κατά τη χρήση). Άλλες συχνές ανεπιθύμητες ενέργειες του φαρμάκου που παρατηρήθηκαν στις κλινικές δοκιμές με epoetin alfa είναι εν τω βάθει φλεβική θρόμβωση, πνευμονική εμβολή, επιληπτικές κρίσεις, σπασμοί, διάρροια, ναυτία, κεφαλαλγία, γριππώδης συνδρομή, πυρεξία, εξάνθημα και έμετος. Η γριππώδης συνδρομή που περιλαμβάνει κεφαλαλγίες, αρθραλγία, μυαλγία και πυρεξία μπορεί να παρουσιασθεί ιδιαίτερα κατά την έναρξη της θεραπείας. Οι συχνότητες μπορεί να ποικίλλουν ανάλογα με την ένδειξη (βλέπε πίνακα παρακάτω). Οι σοβαρές ανεπιθύμητες ενέργειες του φαρμάκου περιλαμβάνουν φλεβικές και αρτηριακές θρομβώσεις καθώς και εμβολές (συμπεριλαμβανομένων και μερικών μοιραίων καταλήξεων), όπως εν τω βάθει φλεβική θρόμβωση, πνευμονική εμβολή, αρτηριακή θρόμβωση (συμπεριλαμβανομένου του εμφράγματος του μυοκαρδίου και της ισχαιμίας του μυοκαρδίου), αμφιβληστροειδική θρόμβωση και αναστομωτική θρόμβωση (συμπεριλαμβανομένης της συσκευής αιμοκάθαρσης). Επιπλέον, έχουν αναφερθεί σε κλινικές δοκιμές με epoetin alfa αγγειακά εγκεφαλικά επεισόδια (συμπεριλαμβανομένου του εγκεφαλικού έμφρακτου και της εγκεφαλικής αιμορραγίας) και παροδικά ισχαιμικά επεισόδια. Έχουν αναφερθεί ανευρύσματα. Έχουν αναφερθεί αντιδράσεις υπερευαισθησίας συμπεριλαμβανομένων περιπτώσεων εξανθήματος, κνίδωσης, αναφυλακτικής αντίδρασης και αγγειονευρωτικού οιδήματος. Υπερτασική κρίση με εγκεφαλοπάθεια και επιληπτικές κρίσεις, που απαιτούσαν άμεση προσοχή του ιατρού και εντατική ιατρική φροντίδα, έχουν επίσης παρουσιασθεί κατά τη διάρκεια της θεραπείας με epoetin alfa, ασθενών με προϋπάρχουσα φυσιολογική ή χαμηλή αρτηριακή πίεση. Πρέπει να δίδεται ιδιαίτερη προσοχή σε αιφνίδια οξεία κεφαλαλγία που προσομοιάζει με ημικρανία επειδή μπορεί να αποτελεί πιθανό προειδοποιητικό σημείο. Αμιγής απλασία της ερυθράς σειράς με τη μεσολάβηση αντισωμάτων έχει αναφερθεί πολύ σπάνια σε < 1/10.000 περιπτώσεις ανά ανθρωποέτη μετά από μήνες έως χρόνια θεραπείας με EPREX (βλέπε παράγραφο Ειδικές προειδοποιήσεις και προφυλάξεις κατά τη χρήση). Το συνολικό προφίλ ασφαλείας του EPREX αξιολογήθηκε σε 142 άτομα με χρόνια νεφρική ανεπάρκεια και σε 765 άτομα με καρκίνο τα οποία συμμετείχαν σε ελεγχόμενες με εικονικό φάρμακο, διπλά τυφλές εγκεκριμένες κλινικές δοκιμές. Οι ανεπιθύμητες ενέργειες του φαρμάκου που αναφέρθηκαν από ≥ 0,2% των ατόμων υπό θεραπεία με EPREX, από αυτές τις κλινικές δοκιμές, από επιπλέον κλινικές δοκιμές και από την εμπειρία μετά την κυκλοφορία του προϊόντος αναφέρονται παρακάτω ανά κατηγορία οργάνου συστήματος και συχνότητα. Οι συχνότητες καθορίζονται ως: Πολύ συχνές (≥ 1/10), συχνές (≥ 1/100, < 1/10), όχι συχνές (≥ 1/1.000, < 1/100), σπάνιες (≥ 1/10.000, < 1/1.000), πολύ σπάνιες (< 1/10.000). Μια συχνότητα καθορίζεται ως μη γνωστή εάν η ανεπιθύμητη ενέργεια του φαρμάκου δεν αναφέρθηκε στις διπλά τυφλές, ελεγχόμενες με εικονικό φάρμακο εγκεκριμένες κλινικές δοκιμές ή όταν η συχνότητα δεν μπορεί να εκτιμηθεί με βάση άλλα διαθέσιμα δεδομένα.

Εντός κάθε ομάδας συχνότητας, οι ανεπιθύμητες ενέργειες του φαρμάκου παρατίθενται κατά σειρά μειούμενης σοβαρότητας. Κατηγορία Οργάνου Συστήματος: Διαταραχές του Αιμοποιητικού και του Λεμφικού Συστήματος. Συχνότητα: Όχι συχνές. Θρομβοκυττάρωση (καρκινοπαθείς). Συχνότητα μη γνωστή: Αμιγής απλασία ερυθράς σειράς με τη μεσολάβηση αντισωμάτων[1]. Θρομβοκυττάρωση (ασθενείς με χρόνια νεφρική ανεπάρκεια). Κατηγορία Οργάνου Συστήματος: Διαταραχές του Ανοσοποιητικού Συστήματος. Συχνότητα: Συχνότητα μη γνωστή. Ανεπιθύμητη Αντίδραση Φαρμάκου: Αναφυλακτική αντίδραση. Υπερευαισθησία. Κατηγορία Οργάνου Συστήματος: Διαταραχές του Νευρικού Συστήματος. Συχνότητα: Πολύ συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Κεφαλαλγία (καρκινοπαθείς). Συχνότητα: Συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Σπασμοί (ασθενείς με χρόνια νεφρική ανεπάρκεια). Κεφαλαλγία (ασθενείς με χρόνια νεφρική ανεπάρκεια). Συχνότητα: Όχι συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Εγκεφαλική αιμορραγία[2]. Σπασμοί (καρκινοπαθείς). Συχνότητα: Συχνότητα μη γνωστή. Ανεπιθύμητη Αντίδραση Φαρμάκου: Αγγειακό εγκεφαλικό επεισόδιο[2]. Υπερτασική εγκεφαλοπάθεια. Παροδικά ισχαιμικά επεισόδια. Κατηγορία Οργάνου Συστήματος: Οφθαλμικές Διαταραχές. Συχνότητα: Συχνότητα μη γνωστή. Ανεπιθύμητη Αντίδραση Φαρμάκου: Αμφιβληστροειδική θρόμβωση. Κατηγορία Οργάνου Συστήματος: Αγγειακές διαταραχές. Συχνότητα: Συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Εν τω βάθει φλεβική θρόμβωση[2] (καρκινοπαθείς). Υπέρταση. Συχνότητα: Συχνότητα μη γνωστή. Ανεπιθύμητη Αντίδραση Φαρμάκου: Εν τω βάθει φλεβική θρόμβωση[2] (ασθενείς με χρόνια νεφρική ανεπάρκεια). Αρτηριακή θρόμβωση. Υπερτασική κρίση. Κατηγορία Οργάνου Συστήματος: Διαταραχές του Αναπνευστικού Συστήματος, του Θώρακα και του Μεσοθωράκιου. Συχνότητα: Συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Πνευμονική εμβολή[2] (καρκινοπαθείς). Συχνότητα: Συχνότητα μη γνωστή. Ανεπιθύμητη Αντίδραση Φαρμάκου: Πνευμονική εμβολή[2] (ασθενείς με χρόνια νεφρική ανεπάρκεια). Κατηγορία Οργάνου Συστήματος: Διαταραχές του Γαστρεντερικού. Συχνότητα: Πολύ συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Ναυτία. Συχνότητα: Συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Διάρροια (καρκινοπαθείς). Έμετος. Συχνότητα: Όχι συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Διάρροια (ασθενείς με χρόνια νεφρική ανεπάρκεια). Κατηγορία Οργάνου Συστήματος: Διαταραχές του Δέρματος και του Υποδόριου Ιστού. Συχνότητα: Συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Εξάνθημα. Συχνότητα: Συχνότητα μη γνωστή. Ανεπιθύμητη Αντίδραση Φαρμάκου: Αγγειονευρωτικό οίδημα. Κνίδωση. Κατηγορία Οργάνου Συστήματος: Διαταραχές του Μυοσκελετικού Συστήματος, του Συνδετικού Ιστού και των Οστών. Συχνότητα: Πολύ συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Αρθραλγία (ασθενείς με χρόνια νεφρική ανεπάρκεια). Συχνότητα: Συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Αρθραλγία (καρκινοπαθείς). Συχνότητα: Όχι συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Μυαλγία (καρκινοπαθείς). Συχνότητα: Συχνότητα μη γνωστή. Ανεπιθύμητη Αντίδραση Φαρμάκου: Μυαλγία (ασθενείς με χρόνια νεφρική ανεπάρκεια). Κατηγορία Οργάνου Συστήματος: Συγγενείς και Οικογενείς/Γενετικές Διαταραχές. Συχνότητα: Συχνότητα μη γνωστή. Ανεπιθύμητη Αντίδραση Φαρμάκου: Πορφυρία. Κατηγορία Οργάνου Συστήματος: Γενικές Διαταραχές και Καταστάσεις της Οδού Χορήγησης. Συχνότητα: Πολύ συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Πυρεξία (καρκινοπαθείς). Γριππώδης συνδρομή (ασθενείς με χρόνια νεφρική ανεπάρκεια). Συχνότητα: Συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Γριππώδης συνδρομή (καρκινοπαθείς). Συχνότητα: Συχνότητα μη γνωστή. Ανεπιθύμητη Αντίδραση Φαρμάκου: Φάρμακο μη αποτελεσματικό. Περιφερικό οίδημα. Πυρεξία (ασθενείς με χρόνια νεφρική ανεπάρκεια). Αντίδραση της θέσης ένεσης. Κατηγορία Οργάνου Συστήματος: Έρευνες. Συχνότητα: Συχνότητα μη γνωστή. Ανεπιθύμητη Αντίδραση Φαρμάκου: Αντίσωμα κατά ερυθροποιητίνης θετικό[1]. Κατηγορία Οργάνου Συστήματος: Κακώσεις, Δηλητηριάσεις και Επιπλοκές Θεραπευτικών Χειρισμών. Συχνότητα: Συχνές. Ανεπιθύμητη Αντίδραση Φαρμάκου: Αναστομωτικές θρομβώσεις συμπεριλαμβανομένης της συσκευής αιμοκάθαρσης (ασθενείς με χρόνια νεφρική ανεπάρκεια).

[1]Η συχνότητα δεν μπορεί να εκτιμηθεί με βάση τις κλινικές δοκιμές.
[2]Συμπεριλαμβανομένων των περιπτώσεων με μοιραία έκβαση.

Ασθενείς με χρόνια νεφρική ανεπάρκεια: Σε ασθενείς με χρόνια νεφρική ανεπάρκεια, επίπεδα αιμοσφαιρίνης μεγαλύτερα των 12 g/dl μπορεί να σχετισθούν με υψηλότερο κίνδυνο καρδιαγγειακών συμβαμάτων, περιλαμβανομένου θανάτου (βλέπε παράγραφο Ειδικές προειδοποιήσεις και προφυλάξεις κατά τη χρήση). Αναστομωτικές θρομβώσεις έχουν παρουσιαστεί σε ασθενείς σε αιμοκάθαρση, κυρίως σε αυτούς που έχουν την τάση για υπόταση ή σε αυτούς που το αρτηριοφλεβικό συρίγγιο παρουσιάζει επιπλοκές (π.χ. στενώσεις, ανευρύσματα κ.λ.π.). Καρκινοπαθείς: Έχει αναφερθεί μία αυξημένη συχνότητα εμφάνισης θρομβοεμβολικών συμβαμάτων σε καρκινοπαθείς που λαμβάνουν ESAs, συμπεριλαμβανομένης της epoetin alfa (βλέπε παράγραφο Ειδικές προειδοποιήσεις και προφυλάξεις κατά τη χρήση). Χειρουργικοί ασθενείς: Σε ασθενείς που έχουν προγραμματιστεί για μείζον ορθοπεδικό χειρουργείο, με αρχικά επίπεδα αιμοσφαιρίνης μεταξύ 10 έως 13 g/dl, η συχνότητα εμφάνισης θρομβωτικών/αγγειακών συμβαμάτων (τα περισσότερα από τα οποία ήταν εν τω βάθει φλεβική θρόμβωση) στο συνολικό πληθυσμό των ασθενών των κλινικών δοκιμών εμφανίσθηκε να είναι παρόμοια για τις διάφορες δοσολογικές ομάδες της epoetin alfa και του εικονικού φαρμάκου, παρόλο που η κλινική εμπειρία είναι περιορισμένη. Επιπλέον, σε ασθενείς με αρχικά επίπεδα αιμοσφαιρίνης > 13 g/dl, η πιθανότητα να συσχετισθεί η θεραπεία με epoetin alfa με έναν αυξημένο κίνδυνο για μετεγχειρητικά θρομβωτικά/αγγειακά συμβάματα δεν μπορεί να αποκλεισθεί. **ΚΑΤΟΧΟΣ ΤΗΣ ΑΔΕΙΑΣ ΚΥΚΛΟΦΟΡΙΑΣ:** JANSSEN-CILAG Φαρμακευτική ΑΕΒΕ, Λ. Ειρήνης 56, 151 21 Πεύκη, Αθήνα. Τηλ. 210 80 90 000. **ΑΡΙΘΜΟΣ ΑΔΕΙΑΣ ΚΥΚΛΟΦΟΡΙΑΣ:** EPREX Ενέσιμο διάλυμα 20.000 IU/0,5 ML PF.SYR: 1101/11.01.2010. EPREX Ενέσιμο διάλυμα 40.000 IU/1 ML PF.SYR: 1100/11.01.2010. **ΗΜΕΡΟΜΗΝΙΑ (ΜΕΡΙΚΗΣ) ΑΝΑΘΕΩΡΗΣΗΣ ΤΟΥ ΚΕΙΜΕΝΟΥ:** 18 Φεβρουαρίου 2011. **ΤΡΟΠΟΣ ΔΙΑΘΕΣΗΣ:** Περιορισμένη ιατρική συνταγή. Η διάγνωση και/ή έναρξη της θεραπείας γίνεται σε νοσοκομείο και μπορεί να συνεχίζεται και εκτός νοσοκομείου υπό την παρακολούθηση ειδικού ιατρού.

ΣΥΣΚΕΥΑΣΙΕΣ/ ΤΙΜΕΣ:

Περιεκτικότητα	Μέγεθος Συσκευασίας	Νοσοκομειακή Τιμή	Λιανική Τιμή
40.000 IU/ML	FL x 1 PF.SYR	219,73	270,64
40.000 IU/ML	FL x 4 PF.SYR	878,91	986,71
20.000 IU/0,5 ML	FL x 1 PF.SYR	116,32	146,58

Για περισσότερες πληροφορίες παρακαλούμε επικοινωνήστε με την εταιρεία Janssen-Cilag Φαρμακευτική Α.Ε.Β.Ε., Λ. Ειρήνης 56, 151 21 Πεύκη, τηλ. 210 80 90 000.

Content

Invitation Letter

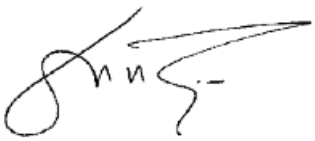
Dear Colleagues,

It is a great honor and pleasure for me, as President of the Congress, to announce the 3rd Mediterranean Multidisciplinary Oncology Forum (MMOF) Congress, to be held in the capital of Greece, Athens, in October 24-26, 2013.

This 3rd congress is following on previous important scientific endeavors of MMOF in the Mediterranean area. Our aim is to provide an International Forum for discussion, to share new developments and knowledge for the diagnosis and treatment of cancer and to exchange stimulating ideas for the advancement of oncology research and care in our area.

A prestigious faculty of oncology experts from many countries and representing various disciplines, including medical oncology, radiotherapy, oncological surgery, breast surgery, molecular biology, oral oncology etc. has been assembled to review and analyze current state-of-the-art issues and hot topics regarding many types of neoplasias. The Congress will feature round tables, invited lectures, panel discussions of challenging cases, scientific debates, oral presentations, poster viewing sessions and special workshops for Young Oncologists. The program will also encompass a special noteworthy event, the "SKIN CANCER DAY'', an entire morning devoted to the latest developments in Melanoma and Skin Cancer, discussed and presented by world opinion leaders in this field.

We are looking forward to welcoming you in the beautiful city of Athens, to experience and delight in the civilization, the hospitality and the beauties of the city and to share and benefit from a dynamic and innovative scientific event.



Dimitrios J. Bafaloukos, MD
President of the MMOF Congress

Organizing Committee - (Board of Directors of MMOF)

Congress President – Vice President of MMOF
Dimitrios Bafaloukos, Greece

Honorary President
Paris Kosmidis, Greece

President
Gokhan Demir, Turkey

General Secretary
Helena Linardou, Greece

Educational Committee Chairs
Ourania Nikolatou-Galitis, Greece
Pinar Saip, Turkey

Multidisciplinary Oncology Committee Chair
George Asimakopoulos, Greece

Treasurer
Ourania Nicolatou-Galitis, Greece

Mediterranean Executive Officer
Marina Garassino, Italy

Members
Haluk Onat, Turkey (past Vice-President)
Idris Yucel, Turkey

Local Organizing Committee

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Dimitrios Bafaloukos

Members:
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I. Athanasiadis
I. Boukovinas
A. Boutis
A. Christopoulou
A. Dimopoulos
D. Kanaloupiti
M. Karamouzis
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P. Papakostas
F. Poulakaki
M. Tolia

Scientific Committee

Chairmen:
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Nazim Serdar Turhal, Turkey
Hussein Khaled, Egypt

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T. Abdelhamid, Egypt
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G. Basaran, Turkey
R. Berardi, Italy
A. Boleti, UK
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P. Dimovelis, Greece
H. El-Zawahry, Egypt
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Scientific Program

Thursday 24th October 2013

Makedonia Hall

14:00-16:00	Registrations
14:00-16:00	**NRs Committee Meeting** Chair: ***O. Khorshid (EG) - E. Razis (GR)***
16:00-17:30	**Young MMOF - Educational and fellowship opportunities for young Medical Oncologists in Europe and USA** Chairs: ***I. Mountzios (GR) - M. Garassino (IT) - A. Zeeneldin (EG)*** Young Meditteranean Oncologists: what can ESMO do for you? ***S. Banerjee (UK)*** How to write a successful fellowship application for ESMO/ASCO. ***D. Krikelis (GR)*** Practical tips from a former fellow. ***I. Mountzios (GR)***
17:30-19:00	**The revolution in prostate and renal cancer** Chairs: ***D. Mavroudis (GR) - N. Kentepozidis (GR) - S. Bavbek (TR)*** The robotic era in renal and prostate surgical oncology. ***V. Poulakis (GR)*** Renal Cancer: treatment choices among available algorithms. ***E. Boleti (UK)*** Castration-resistant prostate cancer: choosing among available options - the new treatment paradigm. ***C. Massard (FR)***
19:00-19:30	**Keynote Lecture** Chairs: ***H. Linardou (GR) - P. Saip (TR) - O. Khorshid (EG)*** Oncology progress, financial crisis and the cancer patient. ***P. Kosmidis (GR)***
19:30-20:30	**Opening Ceremony** Chairs: ***D. Bafaloukos (GR) - G. Demir (TR)*** Welcome addresses **Opening lecture** Medical Humanities in the Mediterranean. ***N. Tsironis (GR)***
20:30	Reception

Pella-Mycenae Hall

16:00-16:30	**Cancer Nursing Symposium** **Lecture** Chairs: ***A. Foutouloglou (GR) - V. Papara (GR)*** Health related quality of life. ***D. Papageorgiou (GR)***

Pella-Mycenae Hall

16:30-18:00	**Round Table** **Cancer patients and quality of life: from diagnosis to treatment and beyond** Chairs: ***A. Papadouri (GR) - E. Robanos (GR) - A. Tarabikou (GR)***
	Defining quality of life. ***M. Lavdaniti (GR)***
	Quality of life through the cancer trajectory. ***E. A. Çitak (TR)***
	Assessment tools and management of quality issues. ***G. Doga (GR)***
	The oncology nursing impact in improving quality of life. ***S. Kav (TR)***

Friday 25th October 2013

Makedonia Hall

Skin cancer day *Sponsored by* Roche Bristol-Myers Squibb

	Session I Chairs: ***D. Bafaloukos (GR) - H. Gogas (GR)***
09:00-09:15	Introduction - welcome by the Chairs
09:15-09:45	Molecular diagnosis of melanoma (Incidence, genes, RAF/NRAS/CKIT testing). ***S. Murray (UK)***
09:45-10:15	Immunotherapy of melanoma. ***H. Gogas (GR)***
10:15-10:45	Redefining treatment of metastatic melanoma. From chemo to personalized targeted therapies. ***P. Chapman (USA)***
10:45-11:00	Coffee break
	Session II Moderators: ***A. Polyzos (GR) - A. Testori (IT)***
11:00-12:00	Optimizing today's management of metastatic melanoma: A Case-Based approach (expert panel, case presentation, discussion, voting)
	Expert Panel: ***K. Frangia-Tsivou (GR), G. Demir (TR), H. Gogas (GR), D. Bafaloukos (GR)***
	Case Presenters: ***F. Stavridi (GR), I. Boukovinas (GR), A. Testori (IT)***
12:00-12:30	Coffee break
	Session III Chairs: ***V. Georgoulias (GR) - A. Katsabas (GR)***
12:30-13:00	Resistance to targeted therapy in melanoma and how to overcome it: opportunities and challenges. ***H. Linardou (GR)***
13:00-13:30	Future directions for metastatic melanoma. ***P. Chapman (USA)***
13:30-14:00	Targeting Hedgehog as a novel therapeutic approach to basal cell carcinoma. ***A. Stratigos (GR)***

Friday 25th October 2013

Makedonia Hall

14:00-15:30	Lunch
15:30-16:00	**Lecture** Chairs: ***D. Kanaloupiti (GR) - T. Demesticha (GR) - H. Nina (AL)*** Palliative and supportive care in oncology. ***V. Barbounis (GR)***
16:00-17:00	**Metastasectomy in cancer: when and for who?** Chairs: ***E. Samantas (GR) - N. Üskent (TR) - A. Sevinç (TR)*** Metastasectomy in colorectal cancer: medical oncology overview. ***N. Allahloubi (EG)*** Metastasectomy in other solid tumors: is there any role for a local approach in generalised disease? ***C. Dervenis (GR)*** Liver radio-frequency ablation and chemo-embolization: indications and limitations. ***G. Papageorgiou (GR)***
17:00-17:30	Coffee break
17:30-19:30	**Lung cancer: current clinical controversies in multidisciplinary management** Chairs: ***P. Kosmidis (GR) - S. Pleština (CR) - G. Samonis (GR)*** Molecular profiling and genomics: where are we and where are we going? ***G. Metro (IT)*** Is T4 disease always unresectable? ***L. Rosso (IT)*** Second-line treatment: targeted agents or chemotherapy? ***R. Gaafar (EG)*** Maintenance therapies: are they worth the trouble? ***E. Haspinger (IT)***
19:30	**«*Paris Kosmidis Award*» and Lecture** Chairs: ***H. Onat (TR) - T. Economopoulos (GR)*** Personalised cancer treatment: fulfilling the promise or still a challenge? ***F. Ciardiello (IT)***

Pella-Mycenae Hall

14:30-15:30 **Interactive case forum**

Chairs: ***E. Galani (GR) - A. Ardavanis (GR)***

Advances in the management of HER-2 positive metastatic breast cancer.

Sponsored by gsk do more feel better live longer

15:30-17:00 **Oral Presentation I "Translational research"**

Chairs: ***P. Gouveris (GR) - S. Turhal (TR) - G. Makris (GR)***

O1: DETECTION OF TOPOISOMERASE II ALPHA (TOPOIIA) IN HEPATOCELLULAR CARCINOMA RELEVANT TO RESPONSE TO CHEMOTHERAPY

H. El-Zawahry[1], M. Mourad[2], R. Zaki[3], A. Gaber[1], Y. Sallam[1], M. Saber[1]

1. Professor of Medical Oncology National Cancer Institute Cairo University, Egypt, 2. Professor of Pathology, National Cancer Institute, Cairo University, Egypt, 3. Lecturer of Medicine Faculty of Medicine Zagazig University, Egypt

O2: EVALUATION OF VASCULAR ENDOTHELIAL GROWTH FACTOR AS PROGNOSTIC MARKER IN HEPATOCELLULAR CARCINOMA TREATED BY LOCOREGIONAL THERAPY

H. Ramadan[1], H. Alzawahry[1], N. Algarem[2], H.Sedrak[2], M. Esmat[2]

1. Medical Oncology Department, NCI, Cairo University, Egypt, 2. Internal Medicine Department, Faculty of Medicine, Cairo University, Egypt

O3: GLOBAL MICRORNA PROFILING IN FAVORABLE PROGNOSIS SUBGROUPS OF CANCER OF UNKNOWN PRIMARY (CUP) DEMONSTRATES NO SIGNIFICANT EXPRESSION DIFFERENCES WITH METASTASES OF MATCHED KNOWN PRIMARY TUMORS

G. Pentheroudakis[1], Y. Spector[2], **D. Krikelis**[3], V. Kotoula[4], E. Meiri[2], V. Malamou-Mitsi[5], G. Fountzilas[3], M. Sanden[6], N. Pavlidis[1], H. Benjamin[2], R. Aharonov[2]

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O4: EPHRIN A2 AS A POTENTIAL PREDICTIVE BIOMARKER OF PATIENTS WITH ADVANCED COLORECTAL CANCER TREATED WITH CETUXIMAB

A. Strimpakos[1], G. Pentheroudakis[2], V. Kotoula[3], W. De Roock[4], G. Kouvatseas[5], P. Papakostas[6], T. Makatsoris[7], D. Papamichael[8], A. Andreadou[9], J. Sgouros[10], A. Zizi- Sermpetzoglou[11], A. Kominea[12], E. Razis[13], E. Galani[14], D. Pectasides[15], S. Tejpar[16], K. Syrigos[17], G. Fountzilas[9]

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O5: PROGNOSTIC SIGNIFICANCE OF PHENOTYPES IN OPERATED STAGE IIIC, PATHOLOGICAL N3A, BREAST CARSINOMA PATIENTS

I. Turker, Ü. Yalçıntaş Arslan, Ü. Üyetürk, Ö. Uysal Sönmez, K. Helvacı, B. Budakoğlu, Ö. Bal, O. Eşbah, A. S. Ekinci, N. Alkış, B. Öksüzoğlu

Dr. Abdurrahman Yurtaslan Oncology Training and Research Hospital, Medical Oncology Department, Ankara, Turkey

O6: NIK AND BCL3 IN NSCLC PATIENTS: UNVEILING AN UNEXPECTED RELATION

F.I. Dimitrakopoulos[1], A. Antonacopoulou[1], A. Kottorou[1], S. Maroussi[1], I. Koukourikou[1], C. Scopa[2], D. Dougenis[3], H. Papadaki[4], H. Kalofonos[1]

1. Molecular Oncology Laboratory, Medical School, University of Patras, Greece, 2. Department of Pathology, Medical School, University of Patras, Greece, 3. Department of Cardiothoracic Surgery, Medical School, University of Patras, Greece, 4. Department of Anatomy, Medical School, University of Patras, Greece

O7: KI67 BUT NOT P53 PREDICTS RESISTANCE TO ADJUVANT TAMOXIFEN IN LUMINAL POSTMENOPAUSAL BREAST CANCER PATIENTS

Y. M. Ismail[1], MD, MRCP, H. M. El-Zawahry[1], MD, M. M. Saber[1], MD, N. M. Allahlouby[1], MD, A. A. Zeeneldin[1], MD, N. H. Aly El-Din[3], MD, N. M. Mokhtar[2], PhD

1. Medical Oncology-Hematology Department, National Cancer Institute, Cairo University, Egypt, 2. Pathology Department, National Cancer Institute, Cairo University, Egypt, 3. Cancer Epidemiology and Biostatistics Departments, National Cancer Institute, Cairo University, Egypt

O8: KI67 MEASURED AFTER NEOADJUVANT ENDOCRINE THERAPY IN ESTROGEN RECEPTOR POSITIVE PRIMARY BREAST CANCER

H. El-Zawahry[1], **A. Diyaa**[1], O. Mansour[1], N. Mokhtar[2], H. Abdallah[3], H.Ali[1]

1. Medical Oncology Department, National Cancer Institute (NCI), Cairo University, Egypt, 2. Surgical Pathology Department, National Cancer Institute (NCI), Cairo University, Egypt, 3. Surgical Oncology Department, National Cancer Institute (NCI), Cairo University, Egypt

Pella-Mycenae Hall

...Oral Presentation I "Translational research"

O9: BIOMARKERS OF BENEFIT FROM CETUXIMAB-BASED THERAPY IN METASTATIC COLORECTAL CANCER: INTERACTION OF EGFR LIGAND EXPRESSION WITH RAS/RAF, PIK3CA GENOTYPES

G. Pentheroudakis[1], V. Kotoula[2,3], W. De Roock[4], G. Kouvatseas[5], P. Papakostas[6], **T. Makatsoris**[7], D. Papamichael[8], I. Xanthakis[9], J. Sgouros[10], D. Televantou[3], G. Kafiri[11], A. C. Tsamandas[12], E. Razis[13], E. Galani[14], D. Bafaloukos[15], I. Efstratiou[16], I. Bompolaki[17], D. Pectasides[18], N. Pavlidis[1], S. Tejpar[4], G. Fountzilas[9]

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O10: GENE EXPRESSION SIGNATURES PREDICTIVE FOR BEVACIZUMAB BENEFIT IN PATIENTS WITH METASTATIC COLON CANCER: A TRANSLATIONAL RESEARCH STUDY OF THE HELLENIC COOPERATIVE ONCOLOGY GROUP (HeCOG)

G. Pentheroudakis, E. Fountzilas,V. Kotoula, G. Fountzilas, **D. Krikelis**

Greece

Saturday 26th October 2013

Makedonia Hall

09:30-10:00	**Lecture** Chairs: ***G. Asimakopoulos (GR) - D. Rologis (GR)*** Challenges and disparities in oncology practice across the Mediterranean Sea: the scientific and cultural map. ***M. Kinay (TR)***
10:00-11:00	**Symposium: targeted therapies - challenges for the future** Chairs: ***F. Ciardiello (IT) - H. Kalofonos (GR) - S. Yalcin (TR)*** The quest for biomarkers, next generation techniques. ***N. Normanno (IT)*** Resistance to targeted agents and ways around it. ***M. Taron (SP)***
11:00-11:30	Coffee break
11:30-13:00	**Breast Cancer: current state-of-the-art** Chairs: ***C. Markopoulos (GR) - H. Khaled (EG) - C. Andreadis (GR)*** What is new for DCIS/ LCIS? ***E. Mamounas (USA)*** Luminal breast cancer: from biology to treatment. ***M. Ignatiadis (BE)*** Beyond trastuzumab: new options for HER-2 positive breast cancer. ***H. El-Zawahry (EG)*** New advances in radiotherapy: is less better? ***A. Dimopoulos (GR)***
13:00-14:00	**Breast cancer workshop: cutting-edge evolutions in local management** Chairs: ***G. Zografos (GR) - B. Berkarda (TR) - O. Aktan (TR)*** Management of the axilla: sentinel node biopsy versus nothing. ***E. Mamounas (USA)*** Latest approaches in breast cancer surgery. ***F. Poulakaki (GR)*** Consensus guidelines in surgical management of early breast cancer. ***G. Zografos (GR)***
14:00-15:00	Lunch
15:00- 16:00	**The role of HPV in cancer** Chairs: ***D. Skarlos (GR) - C. Christodoulou (GR)*** HPV as a prognostic and predictive factor in head and neck cancer. ***A. Psyrri (GR)*** HPV and cervical cancer: prevention and management. ***I. Athanasiadis (GR)***

Makedonia Hall

16:00-17:30 **Advances and controversies in colorectal cancer**
Chairs: ***G. Demir (TR) - P. Papakostas (GR) - M. El Serafi (EG)***

First-line therapy in CRC: choosing among expanding options.
T. Makatsoris (GR)

Biological agents for CRC: new insights, old players and what is coming. ***G. Demir (TR)***

Colorectal liver metastases: how to select the optimal management.
M. El Serafi (EG)

17:30 **Closing ceremony and awards**
Chairs: ***H. Linardou (GR) - I. Mountzios (GR) - S. Turhal (TR)***

Pella-Mycenae Hall

09:00-10:30 **Oral Presentation II**
"Clinical practice and supportive care in oncology"
Chairs: ***G. Aravantinos (GR) - A. Christopoulou (GR) - A. Koumarianou (GR)***

O11: INFERIOR ALVEOLAR NERVE INVOLVEMENT IN BISPHOSPHONATE RELATED OSTEONECROSIS OF THE JAW (BRONJ) – A CASE SERIES

T. Weissman[1], T. Lazarovici[1], N. Porat[1], R. Yahalom[1], O. Peleg[1], N. Yarom[1,2]

1. Department of Oral and Maxillofacial Surgery, Sheba Medical Center, Israel, 2. Department of Oral Pathology and Oral Medicine, School of Dental Medicine, Tel-Aviv University, Israel

O12: TREATMENT AND PREVENTION OF BISPHOSPHONATE-ASSOCIATED OSTEONECROSIS OF THE JAWS: 2009-2012

E. Papadopoulou[1], O. Nicolatou-Galitis[1], E. Razis[2], E. Vardas[1], T. Sarri[1], E. Gatou[1], M.C. Kyrtsonis[3], P. Repousis[4], I. Athanasiadis[5], D. Bafaloukos[6]

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O13: SMILEON: SUPPORTING INNOVATIVE LEARNING APPROACHES THROUGH MOBILE INTEGRATION IN THE WORKPLACE - ONCOLOGY NURSING: EXPERIENCES FROM SIX EUROPEAN COUNTRIES

S.Kav[1], E.A.Citak[1], A.Karahan[1], P. Fernandez[2], M. Montserrat[2], A. Sedano[2], A. Company[2], A. Milani[3], M. Markova[4], J. Fendrychová[4], K. Lokar[5], M. Bernot[5], M. Matkovic[5], A. Blazeviciene[6], A. Vaskelyte[6]

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O14: FACTORS DETERMINING SURVIVAL IN PATIENTS DIAGNOSED WITH ADVANCED INOPERABLE OR METASTATIC NON-SMALL CELL LUNG CANCER

N. Yasar [1], A. G. Mert[2], N. S. Dinc[2], D. Aydin[2], T. Korkmaz[2], K. Aydın[2], H. Odabas[2], S. Yüksel[2], O. Ercelep[2], M. Gumus[2], M. Aliustaoglu[2], S.Cihan[1], S.Keskin[1]

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O15: GEMCITABINE, DEXAMETHASONE AND CISPLATIN (GDP REGIMEN) AS FIRST SALVAGE TREATMENT OF PATIENTS WITH REFRACTORY OR RELAPSED DIFFUSE LARGE B CELL NON HODGKIN LYMPHOMA

T. Abdel Hamid[1], M. Saber[1], F. Abu-Taleb[2], A. Bahnassy[3], M. Fawzy[2], N. Ali El Din[3]

1. Medical Oncology Department, NCI, Egypt, 2. Medical Oncology Department Zagazig University, Egypt , 3. Pathology and Biostatistic Departments, NCI, Egypt

O16: THERAPY-RELATED MYELOID NEOPLASMS: REPORT OF THE ITALIAN NETWORK ON SECONDARY LEUKEMIAS

L. Fianchi[1,*], M.T. Voso[1], A. Candoni [2], G. Gaidano[3], M. Criscuolo[1], G. Specchia[4], E.M. Pogliani[5], B. Monarca[6], L. Maurillo[7], C. Mecucci[8], M. Breccia[9], F. Aversa[10], P. Musto[11], M. Rondoni[12], C. Fozza[13], R. Invernizzi[14], A. Spadea[15], S. Fenu[16], G. Buda[17], M. Gobbi[18], V. Santini[19], S. Mancini[20], A. Molteni[21], L. Pagano[1], **G. Leone**[1]

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Pella-Mycenae Hall

Oral Presentation II "Clinical practice and supportive care in oncology"

O17: SOME EPIDEMIOLOGIC FEATURES OF CUTANEOUS MELANOMA IN ALBANIA IN THE PERIOD 2008 – 2011

X. Doci[1], A. Sallaku[2], H. Nina[2]

1. Durres Regional Hospital, Department Dermatology, Albania, 2. University Hospital Center "Mother Theresa", Oncology Hospital, Albania

O18: TOXICITY CAN PREDICT SURVIVAL BENEFIT OF METRONOMIC CHEMOTHERAPY IN METASTATIC BREAST CANCER

M.M. Hussein[1], R.M. Gaafar[1], A.M. Abdel-Wareth[1], W.A. Ahmed[2], S.E. Salem[1], E.M. Abdel-Salam[2]

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O19: TREATMENT OF LOCALLY ADVANCED (HIGH RISK) PROSTATE CANCER (PCA) BY A COMBINATION OF HORMONAL THERAPY, BRACHYTHERAPY AND EXTERNAL BEAM IRRADIATION

D. Katsochi, V. Skouteris, M. Metsinis, G. Kollias, E. Koutsouveli, M. Skouteris, A. Dounis

Radiation Oncology Center and Prostate Brachytherapy Center of Diagnostic and Therapeutic Center of Athens, "Hygeia" Hospital, Athens, Greece

O20: ENZALUTAMIDE (ENZA) IN HEAVILY PRETREATED PATIENTS WITH BONE METASTATIC CASTRATION RESISTANT PROSTATE CANCER (MCRPC) RESISTANT TO ANDROGEN BIOSYNTHESIS INHIBITOR (ABI) TREATMENT. THE HELLENIC EXPERIENCE OF THE NAME PATIENT ACCESS PROGRAM (NPAP)

E. Bournakis[1], **R. Gyftaki**[1], E Kafantari[1], E. Razis[2], G. Rigakos[1], K. Stravodimos[3], D. Mitropoulos[3] A. Bamias[1], M.A. Dimopoulos[1], E. Efstathiou[1]

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13:00-14:00 **Oral Oncology: new and emerging oral complications in targeted therapies**

Chairs: ***G. Koumakis (GR) - M. Trichas (GR)***

Maintenance of bone health in oncology patients receiving denosumab and risk for jaw osteonecrosis: prevention and management. ***C. A. Migliorati (USA)***

Stomatitis related to mTOR Inhibitors and other targeted therapies. ***O. Nicolatou-Galitis (GR)***

Saturday 26th October 2013

Pella-Mycenae Hall

15:00-17:00 **1st MMOF Workshop on Jaw Osteonecrosis in Medication**

Organizers: ***Cesar A. Migliorati, Ourania Nicolatou-Galitis***

Chairs: ***G. Samelis (GR) - N. Yarom (IL) - R. A. Mendes (PT)***

Session 1

Theories and clinical data on pathogenic mechanisms.
O. Nicolatou-Galitis (GR)

Management strategies. ***N. Yarom (IL)***

Avoid or perform the dental extraction? ***C. A. Migliorati (USA)***

Session 2

Case presentations.
E. Papadopoulou (GR), E. Vardas (GR), K. Bektaş-Kayhan (TR), J. Beck-Mannagetta (AU), Y. Zadik (IL), O. Nicolatou-Galitis (GR), C. A. Migliorati (USA), R. A. Mendes (PT), S. Jarjoura (IL)

Endorsed by the International Society of Oral Oncology, ISOO
A Certificate of Attendance will be given.

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General Information

Organized by the
Mediterranean Multidisciplinary Oncology Forum (M.M.O.F.)

Congress website
www.medmof2013.com

Congress Dates
24-26 October 2013

Congress Venue

Divani Caravel Hotel
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Athens 16121, Greece
Tel.: +30 210 7207000
Fax: +30 210 7236683

Language
The official language of the Congress is English.

Audiovisual – Technical Support
All meeting rooms will be equipped with data video projectors, laser pointers etc, for power point presentations. Technical Support Center will be available outside the meeting rooms. Technical staff will assist with the presentations. All speakers are kindly requested to submit their presentation at least 1 hour prior to their scheduled presentation.

Accreditation
The 3rd Congress of the Mediterranean Multidisciplinary Oncology Forum will receive accreditation from the European Society for Medical Oncology (ESMO) and the Panhellenic Medical Society.

Name badges
All registered participants will receive name badges, which are kindly requested to wear at all times. Each badge will have a barcode for monitoring the hours of attendance.

Certificate of Attendance
All registered participants who have attended at least 60% of the total program hours will receive a certificate of attendance from the Secretariat Desk after the closing ceremony.

Registration Cost

Type of Registration	
MMOF, ESMO Members	250€
Non-MMOF Members	350€
Dentists, Junior Oncologists, Nurses	100€
Daily registration ticket	100€
Medical Students	free

Registration cost includes:

- Admission to all conference sessions & exhibition area
- Congress proceedings – material, certificate of attendance
- Coffee breaks
- 2 lunches
- Welcome Reception

Full payment is required for all registrations.

Registration for medical students includes:

- Admission to all conference sessions & exhibition area
- Coffee breaks
- Certificate of attendance

Accommodation Cost

Limited number of rooms has been pre-booked at the Divani Caravel Hotel with special conditions for the Congress' participants.

Congress Venue	Single Room
Hotel Divani Caravel *(cost for 2 nights)*	240€

Extra night cost	Single Room
Hotel Divani Caravel	120€

Option date for hotel bookings, September 10th 2013.

Please visit the site www.medmof2013.com to download the booking form in order to guarantee and confirm your reservation.

Congress Secretariat

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Abstracts

Oral Presentations

O1: DETECTION OF TOPOISOMERASE II ALPHA (TOPOIIA) IN HEPATOCELLULAR CARCINOMA RELEVANT TO RESPONSE TO CHEMOTHERAPY

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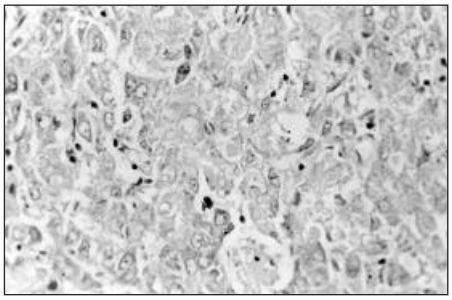
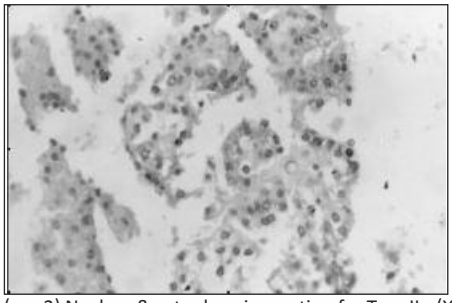
Introduction: Hepatocellular cancer (HCC) is resistant to chemotherapy and did not show survival benefits after systemic combination chemotherapy. This make the search for any biomarker is extremely important to help for improvement the response of this dull disease.
Purpose: We conduct this study to evaluate the relation between TopoIIα level in the liver tumor tissue and response to therapy mainly Doxorubicin. Correlation between clinico-pathological features and overall survival relevant to expression TopoIIα may help as a prognostic and predictive biomarker in HCC.
Rustles: The study included 50 HCC patients, who were diagnosed and treated in the NCI, Cairo University. The mean age was 54.5 years; 47 of them were males and 3 females. Doxorubicin 50 mg/ m2 every 3 weeks was given for 3 cycles and the response was evaluated according to Response Evaluation Criteria in Solid Tumors (RECIST).
Overexpression of TopoIIα was fond in 19/50(38%) and was negative in 31/50(76%). No CR was seen after treatment with doxorubicin, while PR was 8/50(16%), SD 21/50(42%) and PD 21/50 (42%). There was a significant correlation between Topo IIα and the response to the chemotherapy (P=0.001) (Table1). The study showed significant correlation between Topo IIα and OS; 8 months for overexpression compared to 20 months in negative expression (figs1).

(Table 1) correlation between topoisomerase II alpha Expression and response to the therapy:

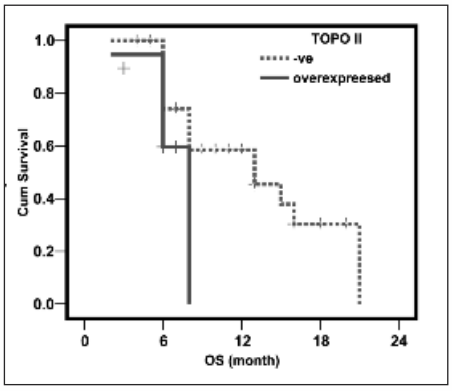
Topoisomerase II Alpha expression	Response			Total No.
	SD	PD	PR	
	No %	No%	No%	
- ve	16 51.6	15 48.4	0 0	31
+ ve	5 26.3	6 31.6	8 42.1	19
p-value	0.07	0.24	0.001**	



(sec.1) Focal nuclear positivity of TopoII α (X-200 DAB chromogen)



(sec.2) Nuclear & cytoplasmic reaction for TopoIIα (X-100 DAB chromogen)



(fig.1) OS according to TopoIIα; negative 20 months and overexpression 8 months (p=,001)

Conclusion: Evaluation of the level TopoIIα in liver tissue showed a significant correlation to both response to therapy and survival in 50 HCC patients. Topo IIα is a promising prognostic and predictive factor that together with others factors; tumor size, pathological grade may help for more personalized therapy in f HCC.

O2: EVALUATION OF VASCULAR ENDOTHELIAL GROWTH FACTOR AS PROGNOSTIC MARKER IN HEPATOCELLULAR CARCINOMA TREATED BY LOCOREGIONAL THERAPY

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Background: Overall HCC rates as the seventh most common malignancy in males and the ninth most common in females (El-Serag HB, 2004). Hepatitis C virus mostly plays both an indirect role in tumor development by increasing the risk of HCC through promotion of fibrosis and cirrhosis and a direct role in hepatic carcinogenesis (El-Nady GM et al., 2003).Recent publications have indicated that angiogenesis is essential in tumor growth and progression, including that of HCCs, which have a high level of vascularization. The expression of VEGF in typical cancerous tissues of HCC is significantly higher than those in the normal liver (Huang GW et al., 2005).

Aim: To highlight the rule of locoregional therapy in management of HCC and its impact on VEGF corresponding to radiological work up and patient quality of life.

Patients and methods: This prospective non-randomized study included 40 patients with HCC presented to NCI, Cairo University, in the period between September 2010 and February 2011. Serum sample was collected for VEGF at presentation and one month after procedure done during follow up including follow up with ultrasound and AFP.

Results: There were 34 males (85.0%) and 6 females (15.0%) their ages ranged from 54 and 69 years with a median of 61 years. 32 patients were child A (80%) and 8 were child B (20%) classification. HCC etiology was related to HBV in 7 patients (17.5%) and HCV in 33 patients (82.5%), according to AJCC/UICC staging system 13 patients (32.5) were stage IIIA and 27 patients (67.5) were stage II. All patients divided into 2 groups (group A) 20 patients underwent chemoembolization and (group B) 20 patients received intralesional alcohol injection. There is no significance correlation between age, virology, performance, status, staging, child Pugh and type of local therapy to response. Although was a significance regarding sex {male patients showed significant response compared to female patient (p-value was 0.018). There was a significance between tumor size and AFP level either before treatment or after to response of local therapy. Significantly higher level of VEGF was found in those with base line alpha fetoprotein≥400ng/ml. There was no significant correlation between age, sex and performance status and VEGF level either before or after intralesiona alcohol injection. There was significant increase in VEGF level after local therapy in both groups.

Conclusion: Finally based on the previous results VEGF can predict the aggressiveness of the disease and outcome after local treatment. This fact together with the radiological response may help the decision for shifting to systemic therapy or continuing the local therapy. Patients have persistent high level of VEGF after local therapy may gain benefits from adding anti-VEGF.

O3: GLOBAL MICRORNA PROFILING IN FAVORABLE PROGNOSIS SUBGROUPS OF CANCER OF UNKNOWN PRIMARY (CUP) DEMONSTRATES NO SIGNIFICANT EXPRESSION DIFFERENCES WITH METASTASES OF MATCHED KNOWN PRIMARY TUMORS

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6. Rosetta Genomics Inc., Philadelphia, PA, USA

No data exist on biologic differences between Cancer of unknown primary (CUP) and metastatic solid tumors of known primary site. We assigned a primary tissue of origin in 40 favorable CUP patients (A: serous peritoneal carcinomatosis n = 14, B: axillary adenocarcinoma n = 8, C: upper squamous cervical adenopathy n = 18) by means of a 64-microRNA assay. Subsequently, we profiled the expression of 733 microRNAs (miRs) in the CUP cases and compared results with metastases from 20 ovarian carcinomas, 10 breast adenocarcinomas, 20 squamous head neck or lung tumors. In the Peritoneal CUP versus Ovarian (Known Primary Metastases) KPM comparison, a total

of 12 miR were significantly differentially expressed: higher than twofold expression difference in CUP was seen only for miR-513a-5p (3.7-fold upregulated) and miR-483-5p (2.5-fold upregulated), while miR-708 exhibited a twofold downregulation. In the Breast CUP versus Breast KPM comparison, only miR-29c that were downregulated in CUP by 2.7-fold satisfied the FDR threshold. miR-30e and miR-27b, downregulated in ovarian CUPs versus KPMs, were also non-significantly downregulated in breast CUP by 2.0- and 1.4-fold respectively. Six miRs, which belong to the 17-92 oncocluster showed a trend of upregulation in Breast CUP versus Breast KPM cases. A CUP signature remains elusive.

O4: EPHRIN A2 AS A POTENTIAL PREDICTIVE BIOMARKER OF PATIENTS WITH ADVANCED COLORECTAL CANCER TREATED WITH CETUXIMAB

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Introduction: Patients with colorectal cancer (CRC) with wild-type KRAS are often treated with the endothelial growth factor receptor (EGFR) monoclonal antibody cetuximab. Despite the presence of this specific biomarker in almost half of patients, most of them do not benefit from this biological treatment. Eph receptors are interacting proteins playing role in cell-to-cell communication, adhesion, migration and invasion as well as in regulation of vasculature development and angiogenesis.

Purpose: In search of other mediators affecting EGFR treatment outcome we explored the role of ephrin A2 (EphA2) receptor expression as predictor of cetuximab benefit. Tumor biopsy samples from 226 patients with CRC treated with cetuximab were studied for mRNA expression of insulin growth factor binding protein 2 (IGFBP2), insulin growth factor receptor 1 (IGF1R), cMET, EphA2, human epidermal growth factor receptor 2 (HER2), HER3, and HER4 by means of RT-PCR.

Results: Of the 226 patients evaluable for exploratory analysis, 222 had complete follow-up data. The univariate analysis revealed the following significant adverse prognostic factors for risk of death: high EphA2 mRNA levels (hazard ratio [HR], 1.61; P ΄Ο .015), high HER2 mRNA levels, and high IGF1R mRNA levels. Low EphA2 tumor expression was significantly associated with objective response to cetuximab therapy. In multivariate analysis of a broad biomarker panel, factors with independent prognostic value included EphA2 mRNA levels (HR, 1.67; P ΄Ο .029), high amphiregulin (AREG) mRNA levels in KRAS wild-type tumors (HR, 0.17; P < .0001), and high epiregulin (EREG) mRNA levels (HR, 0.38; P ΄Ο .006).

Conclusion: High Eph2A receptor expression in CRC was associated with a worse outcome in patients treated with cetuximab-based therapy. Our results require prospective validation in treated and control CRC patients in order to confirm its predictive or potential prognostic role.

O5: PROGNOSTIC SIGNIFICANCE OF PHENOTYPES IN OPERATED STAGE IIIC, PATHOLOGICAL N3A, BREAST CARSINOMA PATIENTS

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Introduction and Purpose: Aim of this retrospective study was to evaluate the prognostic significance of phenotypes in patients (pts) for operated stage IIIC breast carcinoma who had ≥10 lymph node positive (pathological N3a)

Material and method: Medical records of 242 operated breast cancer patients with ≥10 axillary lymph node involvement whose tumors were assessed for hormone receptor (HR) and Human Epidermal Growth Factor Receptor 2 (HER2) status were evaluated retrospectively.

Results: Median age was 49 (21-78) years. Median follow-up was 40 (5-182) months. The proportion of breast cancer phenotypes was 50.4% HR+/HER2-, 41.3% HER2+ and 8.3% triple negative (TN). At the time of analysis, 129 patients had recurrent disease and 92 patients died. The percentage of recurrent disease in patient subgroups were as follows: 52.0% for HR+/HER2-, 55.6% for HER2+, and 50.0% for TN. Tumor size has been shown to have a negative correlation with overall survival(OS) (log-rank p=.015). Although DFS of HR+/HER2- group was relatively longer than others, it did not reach statistically significance (log-rank p=.102). Adjuvant trastuzumab have a strong impact on DFS for pts with HER2+ tumors (p=.014). Survival after recurrence were significantly shorter in pts with TN tumors as compared to HR+/HER2- ones (p=.03). But, there was no a significant difference between HR+/HER2- and HER2+ groups (p=.863). Patients with HR+/HER2- tumor had a significantly longer 5-year survival rate than HER2+ and TN groups (70.0%, 48.0% and 42.0%, respectively; log-rank p=.012). In multivariate analysis, only breast cancer subtypes were found to be independent prognostic factors with a significant negative influence on OS in pts who had ≥10 axillary lymph node metastasis (p=0.003,HR:1.37;95%CI: 1.11-1.70).

Conclusion: HR+/HER2- breast cancer patients have still got a better prognosis than TN and HER2+ ones even if they had entensive axillary lymph node metastasis. Prognosis of HER2+ locally advanced BC has changed in the era of adjuvant trastuzumab therapy.

Key words: *Stage IIIC breast cancer, breast cancer fenotypes, prognosis*

O6: NIK AND BCL3 IN NSCLC PATIENTS: UNVEILING AN UNEXPECTED RELATION

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Background: Classical and alternative pathways of NF-κB have become objects of detailed research in the last years, although, little is known of the possible role of NIK and BCL3 in carcinogenesis. The aim of this study was on the one hand to define the relation of the BCL3 snp rs8100239 with NSCLC and its association with BCL3 protein expression and on the other hand to determine the possible relation of BCL3 and NIK expression levels with clinicopathological data and 2- and 5-year survival rates.

Material and methods: Using the tag-Snps selection and evaluation algorithms, Tagger and Sysnps, we chose the rs8100239 polymorphism of BCL3. We used 294 blood specimens and FFPE normal tissue specimens from patients with NSCLC and 280 blood specimens from healthy donors. DNA isolation was performed using commercial extraction kits. Samples were genotyped using real-time PCR. Immunohistochemical analysis for BCL3 and NIK proteins were performed on 130 FFPE tissue specimens (120 tumor and 10 tumor-adjacent normal tissues) from the same NSCLC patients.

Results: Although no difference was found in allele frequencies between patients and healthy controls (p=0.297), patients of stage II, carrying a T allele, displayed 2- and 5-year survival benefit compared to patients with AA genotype (p<0.001). BCL3 was detected both in the cytoplasm and nucleus in neoplastic tissues, whereas in non neoplastic tissues no immunostaining was noticed (p<0.001). Higher BCL3 nuclear expression levels were correlated with A allele carriage (p=0.042). Furthermore, small tumors had higher BCL3 nuclear expression levels (p=0.009). In addition, cytoplasmic expression of BCL3 was associated with grade (p=0.002), relapse rate (p=0.05), histological subtype (p=0.031) and disease stage (0.045). NIK immunopositivity was limited in cytoplasm of cancer cells with healthy tissues having no staining (p<0.001). Furthermore, NIK cytoplasmic expression was corre-

lated with the location of primary lesion (p=0.032), histological subtype (p=0.002), infiltration of the lymph nodes (p=0.021) and relapse rate (p=0.029). Also, NIK cytoplasmic levels were associated with BCL3 nuclear immunostaining status (p=0.012). No correlation was found between 2- or 5-year survival and NIK and BCL3 expression levels.
Conclusions: The deregulation of the alternative NF-kB pathway in NSCLC seems to play a crucial role in the development and progression of the disease. Further studies to elucidate this role now appear warranted.

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O7: KI67 BUT NOT P53 PREDICTS RESISTANCE TO ADJUVANT TAMOXIFEN IN LUMINAL POSTMENOPAUSAL BREAST CANCER PATIENTS

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Background: Breast cancer (BC) is a major health problem in Egypt & worldwide. The biology of the tumor as assessed by proliferation markers & molecular subtyping is now a major prognostic and predictive variable. The purpose of this study was to correlate the clinical outcome of luminal postmenopausal BC patients receiving adjuvant tamoxifen with the expression of Ki67 and p53.
Methods: A total of 70 hormone- receptor positive postmenopausal BC patients receiving adjuvant tamoxifen were included in this prospective cohort study held at the Egyptian National Cancer Institute between July, 2007 and March, 2012. Ki67 and p53 were assessed on original paraffin-embedded blocks using immunohistochemistry (IHC) methods.
Results: At a median follow-up of 53 months (range 34-70 months), 22 patients (31%) experienced tumor recurrence either loco-regional or distant in 5.7 and 30%, respectively. The 2-, 3- and 5-year disease-free survival (DFS) and overall survival (OS) rates were 91, 84, 59% &100, 98, 77%, respectively. The median Ki67 value was 22.5% (IQR, 10-50%). DFS was significantly worse with higher TNM stage, lower ER expression and higher Ki67 values. Median Ki67 values were significantly higher in patients who developed early relapse on tamoxifen (≤ 24 months) compared to the non-relapsed cases in the same period. OS was significantly worse in patients with Ki67 values ≥ 30%. The latter was an independent predictor of recurrence on multivariate analysis. The median p53 value was 0% (IQR 0-5%). p53 did not significantly impacted DFS or OS.
Conclusion: High Ki67 expression is predictive of poor prognosis and early resistance to adjuvant tamoxifen in luminal postmenopausal BC patients. We recommend considering Ki67 as one of the risk factors that guide decisions of adjuvant endocrine treatment in this subset of patients.

***Key Words**: Breast cancer, postmenopausal, adjuvant tamoxifen, Ki67, p53, NCI, Egypt.*

O8: KI67 MEASURED AFTER NEOADJUVANT ENDOCRINE THERAPY IN ESTROGEN RECEPTOR POSITIVE PRIMARY BREAST CANCER

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Introduction: Neoadjuvant endocrine therapy (NET) using aromatase inhibitors (AIs) has emerged as an accepted approach in postmenopausal women with strong HR-positive disease. The Ki-67 has shown promising results in predicting response and long-term outcome to neoadjuvant chemotherapy and hormonal studies. The aim of this study is to evaluate efficacy of neoadjuvant AI to induce clinical and pathological response & to correlate Ki-67 level with clinical benefit.
Patients & methods: This is a prospective study including 52 consecutive postmenopausal females with newly diagnosed LABC, hormone receptor positive & HER2 status negative presented to the Medical Oncology Department NCI, Cairo University during the

period from October 2010 to October 2011. Patients were treated with neoadjuvant AI (Letrozole) daily for 4 months & followed for at least 1 year. Ki-67 was measured in all tumour biopsies before treatment & postoperatively in patients responded to NET.

Results: Out of the 52 patients 49 were evaluable, clinical response rate was 71.5% (35/49), progressive disease was 22.4% (11/49), while stable disease was 6.1% (3 /49). The mean Ki-67 measured postoperatively in patients responded to NET was 26.1± 19.3 compared to 48.6 ± 28.6 preoperatively (p<0.001). There was a statistically significant difference in response rate between patients with low (<14%) versus high level ki-67 (p=0.05). After a median follow up of 19 months the event free survival (EFS) for responding patients was 24.4±0.8 month. Regarding the 2 years EFS, there was a statistically significant difference between patients achieving clinical response and non-responders (P=0.01), while there was no statistically significant difference between patients with high (≥14) or low level of ki-67.

Conclusion: Neoadjuvant endocrine therapy using AI could be as an alternative to conventional chemotherapy in post-menopausal women with strong hormone receptor positive breast cancers. The Ki-67 could be used as predictive marker of response to NET.

O9: BIOMARKERS OF BENEFIT FROM CETUXIMAB-BASED THERAPY IN METASTATIC COLORECTAL CANCER: INTERACTION OF EGFR LIGAND EXPRESSION WITH RAS/RAF, PIK3CA GENOTYPES

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Background: More than half of patients with KRAS-wild type advanced colorectal cancer (CRC) fail anti-EGFR monoclonal antibodies. We studied EGFR-axis messenger RNA (mRNA) expression and RAS, RAF, PIK3CA mutations in order to identify additional biomarkers of cetuximab efficacy.

Methods: Previously genotyped (KRAS, NRAS, BRAF, PIK3CA mutations) formalin-fixed paraffin-embedded tumour biopsies of 226 cetuximab-treated CRC patients (1st to 3rd line therapy) were assessed for mRNA expression of epidermal growth factor receptor (EGFR) and its ligands EGF, Transofrming Growth Factor-a (TGFA), Amphiregulin (AREG) and Epiregulin (EREG) with real time quantitative PCR. Mutations were detected in 72 (31.9%) tumours for KRAS, in 6 (2.65%) for BRAF, in 7 (3.1%) for NRAS and in 37 (16.4%) for PIK3CA.

Results: Only PIK3CA mutations occasionally coexisted with other gene mutations. In univariate analysis, prognostic significance for survival (from metastases until death) was seen for BRAF mutations (Hazard Ratio HR 8.1, 95% CI3.4-19), codon 12-only KRAS mutations (HR 1.62, 95% CI 1.1-2.4), high AREG mRNA expression only in KRAS wild type CRC (HR 0.47, 95% CI 0.3-0.7) and high EREG mRNA expression

irrespective of KRAS mutation status (HR 0.45, 95% CI 0.28-0.7). EREG tumoural mRNA expression was significantly associated with a 2.26-fold increased likelihood of objective response to cetuximab therapy (RECIST 1.1). In multivariate analysis, favourable predictive factors were high AREG mRNA in KRAS wild type tumours, high EREG mRNA, low Ephrin A2 receptor mRNA. Cetuximab-treated patients with AREG-low KRAS wild type CRC fared very poorly, their survival being similar to KRAS mutant CRC. Patients with KRAS codon 13 or other non-codon 12 mutations had a median survival (30 months, 95% CI 20–35) similar to that of patients with KRAS wild-type (median survival 29 months, 95% CI 25–35), in contrast to patients with KRAS codon 12 mutations who fared worse (median survival 19 months, 95% CI 15–26).
Conclusions: BRAF and codon 12 KRAS mutations predict for adverse outcome of CRC patients receiving cetuximab. AREG mRNA reflects EGFR signalling in KRAS wild type tumours, predicting for cetuximab efficacy when high and failure when low. EREG may have a prognostic role independent of KRAS mutation.

O10: GENE EXPRESSION SIGNATURES PREDICTIVE FOR BEVACIZUMAB BENEFIT IN PATIENTS WITH METASTATIC COLON CANCER: A TRANSLATIONAL RESEARCH STUDY OF THE HELLENIC COOPERATIVE ONCOLOGY GROUP (HECOG)

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Background: Bevacizumab, an antibody neutralizing Vascular Endothelial Growth Factor (VEGF), is licensed for the management of patients with advanced colon cancer. However, tumor biomarkers identifying the molecular tumor subsets most amenable to angiogenesis modulation are lacking.
Patients and Methods: We profiled expession of 24526 genes by means of whole genome 24K DASL (cDNA-mediated, Annealing, Selection and Ligation) arrays, (Illumina, CA) in 18 bevacizumab-treated patients with advanced colon cancer (Test set). Genes with strong correlation to 8-month Progression-free status were studied by means of qPCR in two independent colon cancer cohorts: 49 patients treated with bevacizumab+chemotherapy (Validation set) and 72 patients treated with chemotherapy only (Control set). Endpoints were best tumor response before metastasectomy (ORR) and Progression-Free Survival (PFS).
Results: Five genes were significantly correlated to 8-month Progression-free status in the Test set: overexpression of KLF12 and downregulation of AGR2, ALDH6A1, MCM5, TFF2. In the two independent datasets, irinotecan- or oxaliplatin-based chemotherapy was administered as first-line treatment and metastasectomies were subsequently applied in 8-14% of patients. The complex gene expression profile of all-low tumor (ALDH6A1+TFF2+MCM5) was strongly associated with ORR in the Validation set (ORR 85.7%, p=0.007), but not in the Control set (ORR 36.4%, p=0.747). The Odds Ratio for response for the all-low tumor (ALDH6A1+TFF2+MCM5) profile versus any other ALDH6A1+TFF2+MCM5 profile was 14.99 (p=0.018) in the Validation set but only 0.86 (p=0.84) in the Control set. The tumor expression profile of (KLF12-high+TFF2-low) was significantly associated with PFS only in the Validation set: bevacizumab-treated patients with (KLF12-high + TFF2-low) tumors had superior PFS (median 14 months, 95% CI 2-21) compared to patients with any other (KLF12+TFF2) expression profile (median PFS 7 months, 95% CI 5-10, p=0.021). The Hazard Ratio for disease progression for (KLF12-high + TFF2-low) versus any other KLF12+TFF2 expression profile was 2.92 (p=0.03) in the Validation and 1.29 (p=0.39) in the Control set.
Conclusions: Our «three-stage» hypothesis-generating study suggests two gene signatures associated with bevazicumab benefit in patients with advanced colon cancer. Further validation in independent cohorts is warranted.

O11: INFERIOR ALVEOLAR NERVE INVOLVEMENT IN BISPHOSPHONATE RELATED OSTEONECROSIS OF THE JAW (BRONJ) – A CASE SERIES

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Aims: Osteonecrosis of the Jaw is a known side effect of long-term Bisphosphonate use. Since its first description by Marx in 2003, thousands of cases were published detailing the main sign and symptoms of the condition that range from pain, exposed bone, suppuration, swelling, to extra-oral fistula, oro-antral communication and even pathological jaw fractures. However, very few descriptions exist in the literature regarding the involvement of the inferior alveolar nerve (IAN) in BRONJ.
Methods: A total of nine consecutive BRONJ patients with symptoms of IAN involvement are presented. Data on demographics, medical background, type and

duration of BP use, symptoms of nerve injury and treatment outcome were recorded.

Results: All of the nine patients were female with an average age of 68. The underlying disease was breast cancer (N=4), multiple myeloma (N=3), and osteoporosis (N=2). Three of the patients used Pamidronate, 2 zoledronate, 2 were prescribed both Pamidronate and zoledronate, and 2 patients have used Alendronate.

Dento-alveolar surgery was the inciting event of BRONJ in 7 patients, while 2 cases have developed spontaneously. All 9 patients met the stage 3 criteria for BRONJ.

The involvement of the IAN was manifest as paresthesia in 7 patients and as severe neuropathic pain in 2 patients. The neuropathic pain was treated with Carbamazepine (Tegratol) in 1 patient and with Pregabalin (Lyrica) in the other patients with good response in both patients. Complete recovery of the IAN was noted in one patient and partial recovery was noted in 3 patients with paresthesia following long term antibiotics.

Conclusions: BRONJ of the mandible might cause IAN injury manifesting as paresthesia or neuropathic pain of the lower lip and chin. Long-term antibiotics may beneficial in cases of paresthasia while in cases were IAN injury results in neuropathic pain Carbamazepine or Pregabalin therapy is suggested.

O12: TREATMENT AND PREVENTION OF BISPHOSPHONATE-ASSOCIATED OSTEONECROSIS OF THE JAWS: 2009-2012

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Introduction: ONJ if not diagnosed early can seriously affect patients' quality of life.

Purpose: To present our experience in the treatment and prevention of bisphosphonate-related jaw osteonecrosis for 2009-2012.

Patients-Methods: Two hundred fifty seven patients were evaluated between 2009-2012. Underlying diagnosis was multiple myeloma (48.2%), breast cancer (26.8%), lung cancer (8.6%) and other malignancies. Patients had received zoledronic acid (71.6%), or other bisphosphonates for a median time of 31.5 months. Ninety patients presented with osteonecrosis. Tooth extraction preceded osteonecrosis in 63.8% of the cases. One hundred sixty five patients were referred for prevention of osteonecrosis, before/after the initiation of bisphosphonates. Oral care included clinical/ radiographic evaluation, patient education and hygiene measures.

Results: The 90 osteonecrosis patients (stage 0 n=33, 36.7%, stage I n=24,26.7%, stage II n=27, 30%, stage III n=6, 6.7%) were treated with long-term antibiotics, continuous or with treatment-free intervals. Ozone oil was locally applied biweekly in 24 patients. Today, 13 patients (14.4%) have healed, 25 (27.8%) are stable, without pain, and 44 (48.9%) are asymptomatic, but with minor mucosal inflammation. Of the 33 patients with ONJ stage 0, 11 progressed to ONJ stage I (3 following dental extractions), 9 healed (4 after dental extraction) and 11 showed partial remission. Of the 165 patients, who were included in the prevention protocol, 164 patients continue their bisphosphonate therapy, while 1 patient (0.6%) developed osteonecrosis after one dental extraction due to caries.

Conclusion: Increasing awareness and improved management has led to lower prevalence (0.6%) of osteonecrosis, earlier diagnosis and favorable outcomes.

O13: SMILEON: SUPPORTING INNOVATIVE LEARNING APPROACHES THROUGH MOBILE INTEGRATION IN THE WORKPLACE - ONCOLOGY NURSING: EXPERIENCES FROM SIX EUROPEAN COUNTRIES

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Introduction: Use of mobile technology can allow the learning process to be facilitated outside and beyond the classroom contexts in which most oncology nursing training currently takes place.
Purpose: To develop a new approach to learning in the oncology nursing field based on the use of mobile devices that facilitate the integration of learning into their daily professional practice, so as to ensure that theoretical knowledge is fully connected to practical skills.
The project has involved needs analysis, development of appropriate learning methodology and mobile toolkit to support it. The project duration is 24 months and a consortium includes institutions from the Czech Republic, Italy, Lithuania, Slovenia, Spain, and Turkey. Two pilots were carried out: the first pilot focuses principally on the validation of the learning approach, while the second paid attention to exploitation and sustainability issues and the possible extension of the approach to other contexts. Sixty six nurses from partnering countries were involved into first and second pilots. Data were collected via both quantitative and semi-structure questionnaires.
Results: Needs analysis performed by semi-structured interview (n=75) and quantitative survey among 201 nurses. Pharmacotherapy, acute conditions and procedures in oncology nursing were listed as top priority areas for learning. These integrated in a manual describing the approach and example activities to be used in the methodological implementation. The software toolkit developed initially for Android-based devices. Nurses indicated that this approach was useful and it was excellent choice for learning, it was relevant and effective. They suggested some technical applications such as space for discussion under documents or photos, list of latest news, email notification daily activities etc.
Conclusions: Tablet has been very useful in training; chat has been challenging for communication and to share some knowledge. Using these devices, nurses were able to communicate in real time in the work place and access relevant content according to their needs.
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O14: FACTORS DETERMINING SURVIVAL IN PATIENTS DIAGNOSED WITH ADVANCED INOPERABLE OR METASTATIC NON-SMALL CELL LUNG CANCER

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Introduction: Lung cancer is the leading cause of cancer related death worldwide .Accordingly, the prognostic factors are important for patients with advanced NSCLC at the time of diagnosis.
Purpose: We evaluated the effect of elevated serum lactate dehydrogenase (LDH) and low serum hemoglobin (hb) levels on outcomes of patients diagnosed with advanced disease.
Material and Methods: 617 patients, who were diagnosed with advanced NSCLC between the years 2008 – 2012, were assessed retrospectively. The effects of age, gender, PS, weight loss, serum LDH and hb levels at the time of diagnosis were investigated. The selected cut-off value for LDH was 375 U/l and for hb was 11 g/dl.
Results: Median follow-up period was 15 months (3-64), and median age was 61 years (28 - 86). 87% of patients were male and in 69% of patients, PS was 0 – 1. 54% of patients had weight loss, 83% of patients were smokers. 25% of patients had the adenocarcinoma, 32% of patients had the squamous cell carcinoma, no sub- type has been determined in other patients. In 42% of patients, serum LDH levels were ≥ 375 U/l, in 41% of patients, hb levels were <11 g/dl. Median overall survival was found as 14 months (SE: 1, 95% CI: 12-16.). In univariate analysis, female gender, PS of 0 – 1, age of <60 years, no weight loss were found to be effective on survival positively (respectively, p=0.043, p=0.0001, p=0.0001, p=0.0001), and no statistically significant effect of LDH and hb levels were detected. In multivariate analysis, PS of 0 – 1 and weight loss were found as factors with prognostic significance (respectively, p=0.0001, p=0.0001).
Conclusion: We could not demonstrate the effect of serum LDH and hb levels on outcomes of patients with advanced NSCLC but we found that PS and weight loss were independent prognostic factors.

O15: GEMCITABINE, DEXAMETHASONE and CISPLATIN (GDP REGIMEN) as FIRST SALVAGE TREATMENT of PATIENTS with REFRACTORY or RELAPSED DIFFUSE LARGE B CELL NON HODGKIN LYMPHOMA

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Background: Many chemotherapy regimens have been used for patients with refractory or relapsed DLBCL. No regimen has demonstrated superiority to another in this setting. Specific markers could predict the response to certain agents.
Aim: to evaluate the response of GDP regimen in relapsed and refractory DLBCL patients and to assess ribonucleotide reductase subunit M1 (RRM1) as a possible predictor marker to Gemcitabine response.
Patients and Method: Patients with Relapsed or refractory DLBCL after one previous anthracycline-containing chemotherapy regimen were treated with the GDP regimen. RRM1 was assessed by immunohistochemistry in 55 cases and its expression was correlated to treatment outcome. Patients who could not proceed to stem cell transplantation (SCT) were followed for chemotherapy response and their results are presented.
Results: The study included 70 patients with a median age of 40 years (range 18-73). At start of GDP, 19 patients (27.1%) were refractory and 51 (72.9%) were relapsed. After 4 cycles of treatment, 42 patients achieved CR, with a CR rate of 60% (95% CI: 53–68%). The median DFS was 6 months (95% CI: 5 to7 months), this DFS didn't include patients who underwent auto SCT. After a median follow-up of 20 months (range 6 to 30 months), the median OS of the patients who achieved CR was not reached, while those who didn't achieve CR had a median OS of 27.4 months (p= 0 .01). Correlation between response and the pretreatment prognostic factors including IPI score or any of its elements, previous line of chemotherapy, time to relapse and status at time of salvage were studied with only significant difference in response to GDP between patients with refractory and those with relapsed disease (CR= 21.1% versus 60% respectively, p < 0.001). There was significant correlation between RRMI study results and response to GDP, 30/31 cases with low RRM1 expression achieved CR (96.8%) while only 7/24 cases with high expression achieved CR (29.2%), (p=□ 0.001). No significant relation could be found between RRM1 expression and DFS.
Conclusion: GDP regimen is active for patients with refractory or relapsed DLBCL however, the duration of response is short and high-dose therapy with SCT support is the reference postremission treatment. RRM1expression can predict response to Gemcitabine-based chemotherapy.

Key words: *Refractory, relapsed DLBCL - GDP regimen*

O16: THERAPY-RELATED MYELOID NEOPLASMS: REPORT OF THE ITALIAN NETWORK ON SECONDARY LEUKEMIAS

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Background: In 2001, the World Health Organization (WHO) recognized therapy-related myeloid neoplasms (t-MN) as a distinct entity including acute myeloid leukemia (AML) and myelodisplastic syndromes (MDS). At present, about 10% of all AML patients have a previous history of exposure to chemotherapy and/or radiation for a primary malignancy or autoimmune disease.
Aims: In 2009, we initiated through a Web-database an epidemiological registry, with the purpose of collecting t-MN observed at Italian Hematological or Oncological Divisions. Demographic and clinical information on individuals with t-MN were included in the database whose access was restricted to selected users and was password-protected.
Methods: Between May 2009 and December 2012 a total of 275 patients observed at 21 Italian Centers [119 males and 154 females; median age 64 years (range 24-88 years)] with secondary leukemia were registered in the web-database. Patients were diagnosed with a t-MN between 1999 and 2012, with 246 cases arising after chemo or radiotherapy for a primary malignancy or immunosuppressive therapy for an autoimmune disease, while in 29 cases leukemia represented a second cancer in patients treated for a primary malignancy with surgery alone.
Results: The primary malignancy (PM) was a hematological neoplasm in 115 cases (42%), a solid tumor in 152 cases (55%), an autoimmune disease in 8 patients (3%). Thirteen patients (5%) had a history of two or more previous cancers. Among hematological malignancies, the most frequent PM were lymphoproliferative diseases (83/115 cases), while breast cancer (62/152 cases) was the most frequent primary solid tumor. In particular, hematological PM were: 83 lymphoprolipherative diseases (62 Non Hodgkin and 17 Hodgkin lymphoma, 4 chronic lymphocytic leukemia); 12 Multiple myeloma; 1 Acute lymphoblastic leukemia; 4 Acute myeloid leukemia (acute promielocytic leukemia in 2 cases). There were also 15 patients with a previous history of myeloproliferative neoplasms (10 Myelofibrosis; 3 polycitemia vera; 2 essential thrombocythemia). Sites of primary solid tumors were: 62 Breast; 37 Urogenital (17 prostate; 7 bladder; 1 kidney; 7 uterus; 5 ovarium) ; 17 Colon-rectal; 11 Lung; 7 Thyroid; 6 CNS; PM were localized at sites uncommon for t-MN in 11 patients (1 stomach, 4 skin, 4 oropharynx; 2 sarcoma); 1 unknown. Eigth patients had previously received mmunosuppressive therapy for a rheumatologic disease (5 with mitoxantrone and 3 with methotrexate). Two-hundred-eight patients had previously received chemotherapy for their primary malignancy, associated to radiotherapy in 79 cases. RT represented the only primary treatment in 38 cases. Median latency between PM and t-MN was 6.6 years (range 0.2-48). No differences were observed in age of patients (p=0.09) or in the median latency (p 0.20) between t-MN after lymphoprolipherative diseases or after breast cancer.
According to morphology, t-MN were classified as 172 AML, 97 MDS and 6 ALL.
Kariotype was available for 188 patients only and was unfavorable in 65 patients (complex in 51 patients including del(7) in 36 cases; 14 cases with isolated del(7)]. A recurrent chromosomal translocation was present in 12 patients only [3 t(8;21), 8 t(15;17) and 1 inv(16)]. One-hundred-forty-eight patients received chemotherapy for t-MN, while the hypomethylating drug Azacitidine was administered to 54 patients. Fifty-four patients underwent bone marrow transplantation (39 allogeneic and 15 autologous). Median OS from the t-MN diagnosis was 9.4 months (range 0.2-128+).
Summary / Conclusion: The incidence of t-MN is rising as a result of the increasing number of cancer survivors. Lymphoprolipherative diseases and breast cancer result as the most common primary malignancies at risk of developing this disorder.

O17: SOME EPIDEMIOLOGIC FEATURES OF CUTANEOUS MELANOMA IN ALBANIA IN THE PERIOD 2008 - 2011

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Introduction: The first step towards the implementation of prevention strategies for Cutaneous Melanoma it is the evaluation of the problem's magnitude and the features of the population involved.
Purpose: For these reasons we conducted an epidemiologic study of the patients diagnosed with CM in the

period 2008-2011 in the Oncologic Hospital and Dermatology Clinic in UHC in Tirana and Durres Hospital.
The elaboration of the data was done with the Simple Descriptive Analysis and Multiple Regression.
Results: There was noticed a raising of the incidence of CM after the year 2010 ($p<0.05$)
Mean age in total is 54.4 SD 14.6. There was not noticed any difference in mean age amongst male and female.
According to the age group, the most affected age group was 40-59 years with a frequency 46.6%.
The most affected anatomic region in total was the truncal region (33%), the most affected region in the females was that of the lower extremities, whereas the most affected region in men was the truncal region, the ocular region and the mucosal region. It is more possible that the differences in topography reflect genetic differences such as the distribution of the nevi.
Conclusion: The secondary prevention of CM saves lifes. Therefore it is important to evaluate the trend of the distribution of this disease in the population, to make possible the implementation of prevention strategies.

O18: TOXICITY CAN PREDICT SURVIVAL BENEFIT OF METRONOMIC CHEMOTHERAPY IN METASTATIC BREAST CANCER

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Background: Metronomic chemotherapy has shown efficacy in patients with metastatic breast cancer. We therefore tested the efficacy and toxicity of metronomic chemotherapy in pretreated metastatic breast cancer (MBC).
Patients and Methods: This prospective phase II study was conducted at medical oncology department of NCI, Cairo in the period between July 2008 till July 2011. The study included 50 cases of heavily pretreated MBC who received metronomic chemotherapy in the form of continuous oral cyclophosphamide 50 mg/day and oral methotrexate 2.5 mg twice day1&2 every week. The primary end point was time to progression (TTP) while secondary end points were response rate, overall survival (OS), safety and impact of treatment on VEGF.
Results: Forty eight patients were assessed. One case achieved complete response (CR) and 10 cases had partial response (PR) while 19 patients had stable disease (SD) with ORR of 22% while CBR was 45.5%. Median TTP was 5 months (95% CI 2.7 to 7.3) while median OS was 7 months (95% CI 5.1 to 8.9) with a median follow up period of 7 months (ranging from 1 to 33 months). Patients with negative progesterone receptors, ECOG PS I, achieving CR or PR and suffering from leucopenia, neutropenia and anemia due to treatment had significant prolonged TTP while patients with initial early stage at the time of diagnosis of breast cancer, receiving < 5 previous treatment lines, achieving response and experienced anemia with metronomic treatment had significant superior OS. In multivariate analysis, patients achieved CR and PR, PS I, time interval since initial diagnosis till starting metronomic chemotherapy and anemia were independent prognostic factors for longer TTP. Initial stage at presentation, number of previous treatment lines and response were independent prognostic factors for overall survival. No significant difference between the median level of VEGF at baseline and after 3 months. The median percentage of reduction of VEGF after 3 months from baseline was very minimal 0.17%. In multivariate analysis, the median level of VEGF at baseline or after 3 months as well as the median percentage of reduction was not correlated with TTP or OS.
Conclusions: Metronomic chemotherapy is an attractive way of treatment being effective and less toxic. There is certain groups seem to benefit from this treatment especially those with good PS, achieved response and who experienced toxicity with treatment. Further larger trials are warranted to assess this approach early in the course of the disease and with other more active agents.

Key words: *Metronomic chemotherapy, MBC, efficacy, toxicity*

O19: TREATMENT OF LOCALLY ADVANCED (HIGH RISK) PROSTATE CANCER (PCA) BY A COMBINATION OF HORMONAL THERAPY, BRACHYTHERAPY AND EXTERNAL BEAM IRRADIATION

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Introduction: Locally advanced PCa still remains a treatment challenge for both urologists and radiation oncologists. The last 13 years, our center treats this difficult group of patients (pts) with a combination treatment regimen, composed of hormonal therapy, brachytherapy and external beam irradiation (EBRT).
Purpose-Methods: The purpose of this study is to present our treatment results with a median follow up of 5 years. 219 pts (2000-2013) were offered the

seed implantation technique, called Real Time. Pts were classified as high risk, because they possessed at least one of the following criteria: PSA>20ng/ml, Gleason score 8-10 or c. stage>T2c. All of them were treated with 9 months of hormonal therapy (bicalutamide and LHRH-a), 3 neo-adjuvant, partial implant of prostate (prescription dose 107Gy) and supplemental EBRT (45Gy in daily fractions of 1.8Gy). All pts had negative CT and bone scan for metastatic disease. CT based postimplant dosimetry was estimated at 1 month after brachytherapy. Disease free survival was calculated using 2 different definitions, if PSA<0.5ng/ml and according to Phoenix (nadir+2).

Results: Median patient age was 67 years (44-83), and median PSA before treatment 8.5ng/ml. Median follow up time was 5 years (0.2-11). C. stage was ≤T2b in 28pts, T2c in 57pts and ≥T3a in 134pts. Gleason score was ≤6 in 100pts, 7 in 83pts and 8-10 in 36pts. Median seeds implanted were 55 (34-84). Disease free survival in 7 years was 90% for PSA<0.5ng/ml and 95% for Phoenix definition.

Complications: 79.5% with no urinary symptoms, 15.9 % with mild, 3.7% with moderate, and 0.9% with severe. 8.2% (18pts) had mild proctitis (grade 1 or 2) but no patient presented with grade 3 or 4 proctitis. Sexual function symptom score was completed by 188pts.

Conclusions: Our trimodality regimen shows excellent treatment results in high risk prostate cancer pts, higher than any other monotherapy option available today. It appears to be safe, offering pts a good quality of life with minor side effects.

020: ENZALUTAMIDE (ENZA) IN HEAVILY PATIENTS WITH BONE METASTATIC CASTRATION RESISTANT PROSTATE CANCER (MCRPC) RESISTANT TO ANDROGEN BIOSYNTHESIS INHIBITOR (ABI) TREATMENT. THE HELLENIC EXPERIENCE OF THE NAME PATIENT ACCESS PROGRAM (NPAP)

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Background: The novel antiandrogen Enzalutamide following its FDA approval for docetaxel treated mCRPC patients was made available in the European Union through a Name Patient Program. This is a preliminary report of the Hellenic Experience in far advanced mCRPC patients(pts) focusing on those resistant to ABIs in an effort to identify and target 'androgen signaling addicted' disease.

Material and Methods: Patients (pts) have progressive mCRPC with serum testosterone ≤ 50 ng/dL. Pts receive oral ENZA 160 mg QD. Pts are monitored at 4 week intervals with liver function, electrolytes, CBC, and physical examinations and agreed to serial Bone Marrow biopsy and use of archived tissue for molecular characterization by immunohistochemistry [Androgen Receptor (AR)- N, AR-C19, ARV7,CYP17, ERG, Glucorticoid receptor, pSrc, pmet,Ki67] and qPCR for AR copy number assessment. Disease is assessed clinically, by serum markers (PSA, alkaline phosphatase) and by imaging (bone scan, CT scan).

Results (preliminary): Since July 2012, 20 men who have initiated ENZA treatment within the NPAP had received prior ABIs [Abiraterone Acetate 15, Orterenol 7, (Both 2)]. Median age is 76 yrs (range 64-85), PS-ECOG 2 (range 0-3), baseline PSA concentration 120 ng/ml (range 3.1-552.1) and LDH > normal limit in 8/20 (40%). Gleason Score (GS) at diagnosis was ≥ 8 in 13/20 (65%). Thirteen (65%) had ≥ 20 bone lesions, 8/20 (40%) lesions in lymph nodes, 4/20 (20%) visceral metastases and 6/15 (40%) had confirmed bone marrow infiltration. All but two pts have received prior chemotherapy [7 (41%) ≥ 2 lines]. To date maximum PSA decline ≥ 50% is observed in 9/20 (45%) evaluable pts (on treatment ≥ 12 weeks and primarily refractory if discontinued earlier. Self-reported PS improvement 4/8 (50%) evaluable pts. No Grade ≥ 3 adverse events are reported. Primary Resistance to ENZA (discontinuation in ≤ 8 ms correlates with primary resistance to ABIs (p 0.05) but not with Gleason Score ≥ 8 or LDH above normal limit.

Conclusions: ENZA is well tolerated in a cohort of heavily pretreated far advanced m-CRPC patients and appears in this preliminary report to benefit a subset of pts resistant to prior ABI treatment. Primary Resistance to androgen signaling inhibition appears consistent for both reagents. Further follow up and a planned molecular characterization of archived bone marrow infiltrating tumors will help guide selection of this population.

Poster Presentations

Clinical Oncology Practice

P1: WHICH ONE OF HORMONOTHERAPY OR CHEMOTHERAPY IS PREFERED IN STAGE IA BREAST CANCER?

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Introduction: When planning the adjuvant therapy, the toxicities and the significance in recurrence risk should be evaluated correctly, because of low recurrence rate of stage IA breast cancer. In our country, the gen expression profile testing isn't standart so the adjuvant treatment has been planned according to clinicopathological paramateres. Herein, we retrospectively analyzed an important paremeteres in deciding adjuvant chemotherapy and factors related with disease free survival (DFS) in stage IA breast cancer.

Material and methods: We evaluated 347 stage IA breast cancer patients, who had been treated and followed in three different Medical Oncology Center. After surgery, the patients with breast tumor <2cm without axillary lymph node metastasis were included. The chi-square then logistic regression analysis was performed to detect relationship between the clinicopathological parameters and adjuvant chemotherapy. In addition prognostic parameters were analyzed by using univariate analysis for DFS.

Results: The median age and follow-up time were 52 (25-86) and 22.6 (1-113) months respectively. Over 40% of the patients were premenopause. Nearly, tumors were seen same frequency in both right and left breast, but 2 patients had bilateral breast cancer. The 5 years DFS and overall survival (OS) rates were 87.9% and 98.7%, respectively but the median DFS couldn't be reached. While the age, estrogen receptor(ER), HER2 and triple negative tumor were related with DFS, LVI, perineural invasion (PNI), HER2, triple negative tumor and recurrence were related with OS ($p<0.05$). Furthermore, age, menopausal status, multicentricity, grade, tumor size, necrosis, ER, triple negative tumor, HER2 were found to be related adjuvant chemotherapy preference ($p<0.05$). All these parameters, in addition to LVI and PNI were independent parameters for chemotherapy by logistic regression analysis.

Conclusions: In deciding adjuvant therapy in stage IA breast cancer, which can be chemotherapy or hormonotherapy, clinicopathological factors and thinking about both advantages and toxicities of therapies, should be in mind.

P2: BREAST CANCER FOLLOW UP - RECURRENCES

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Aim of study: Aim of this work was to study the characteristics of tumor that influence in appearance of loco regional recurrence; Correlations between recurrence and distant metastasis.

Material & Methods: In this study we analyzed 125 patients with loco regional recurrence for a period of 7 years. Their treatment was performed from 2004 to 2010 in Oncology Surgery Service at University Hospital Center "Mother Teresa", Tirana. The follow-up of the patients was performed until January of 2012.

For these cases we have study:

Anatomical localization and frequencies of recurrences dependent of different factors at initial diagnosis.

Frequencies of recurrences dependent to the extent of axillary node and hormonal receptor status.

Correlation between recurrence and distant metastasis.

Results & Conclusions: Appearance of loco regional recurrence depends mainly by the characteristics of tumor at initial diagnosis: skin infiltration, tumor size T > 4cm and the extent of axillary node; hormonal receptor status, etc.

Loco regional recurrences precede metastasis. Correlation of tumor attitudes at diagnostic moment & initial treatment with appearance of recurrence must be taken in consideration for the follow up of patient & protocol treatment. Recurrence appearance on thoracic wall in our study: 60% of cases when T > & = 4 cm, 77% of cases when N +, 70% of cases when hor-

monal receptor are negative.
The appearance of recurrence in 85% of cases within first 3 years shows very clearly this correlation.
Key words: *recurrence, breast, cancer*

P3: QUALITY OF INFORMED CONSENT IN BREAST CANCER SURGERY: A CLINICAL AUDIT CYCLE

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Aim: Informed consent is as a matter of crucial importance before every surgical operation, especially in surgical oncology, as it also carries a distinct symbolic substance between the patient and the surgical team. Patients need to fully understand the aim, risks and consequences of the operation to which they will be submitted, especially when in terms of elective surgery, such as breast cancer surgery. We conducted a clinical audit in order to evaluate the level of information given to a sample of breast cancer patients during the procedure of obtaining the informed consent before their scheduled operation.
Material and Methods: In the first phase of the audit, we included 18 breast cancer patients. After obtaining the informed consent, a 10-point questionnaire was distributed, evaluating the extent of the patients' understanding of the aim of the operation, the level of information concerning the potential complications, as well as the patients' perceptions concerning the adequacy of time given to express their enquiries and the attitude of the medical staff that was engaged in the consenting process. After evaluating the initial results, we completed the audit cycle distributing the same questionnaires in another 18 breast cancer patients.
Results: During the first phase of the audit, 4/18 patients reported moderate satisfaction with the adequacy of the information they received regarding the aim of the operation, while 2/18 felt that they had insufficient time to express their enquiries concerning the details of the operation and the postoperative plan. Moreover, 3/18 believed that they did not receive sufficient information regarding the potential postoperative complications, while 2/18 expressed that the medical staff was not keen to address their general concerns. In the second phase of the audit, all patients marked as excellent the amount of information about the aim of the operation and the possible complications. Finally, 2/18 noted that there was insufficient time to discuss the details of the postoperative plan and 1/18 marked that the medical staff consenting was not keen to address their general concerns.
Conclusions: Constant evaluation of the performance in the process of obtaining informed consent is of paramount importance. Especially when it comes to surgical oncology, the patients should have the space and time needed to express their concerns, since the operation could dramatically impact on their quality of life. The regular distribution of feedback questionnaires after the completion of the consenting process could improve the clinical practice and build a relationship of trust between the patient and the surgical team.

P4: INFLUENCE OF MAMMOGRAPHY SCREENING ON METASTASIS AT THE TIME OF DIAGNOSIS: DOES MAMMOGRAPHY SCREENING BENEFIT BETWEEN 40-50 YEARS

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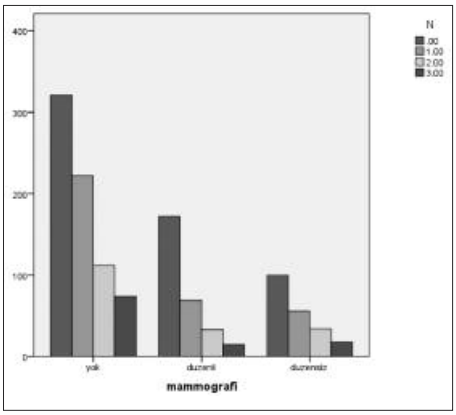
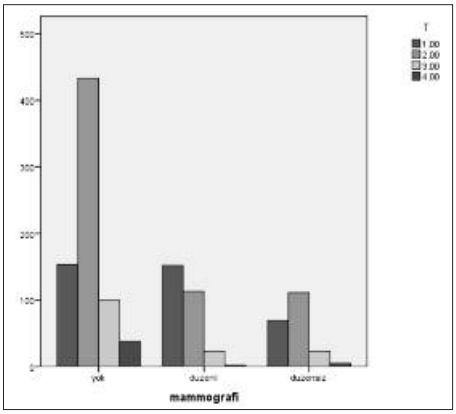
Introduction: Plain mammography is an important screening method for the early diagnosis of breast cancer. The effect of breast cancer screening on mortality is now debated. In the past studies it has been accepted that mammography screenings lower mortality rates, however, it has become arguable by new developments both in treatments methods and in chemotherapy field. In this study we research the ratios of mammography screening in Turkey and its effects on tumor size, lymph node involvement, and metastasis ratios.
Materials and Methods: We questioned 1624 pre- and post-menopausal breast cancer patients from Hacettepe University and Gaziantep University. The patients divided into 3 groups: never screened, irregularly screened and regularly screened by mammography. All patients we selected had already undergone mastectomy and axillary dissection. Demographic features, hormone profiles and pathological stages were noted.
Results: Mammography screening ratios in Turkey were: 66% never screened 19% regularly and 14% irregularly screened. In 40-50 years group, tumor sizes at the time of diagnosis were significantly low in regularly screened patients (p=0.0001). However, we found no effect on lymph node metastasis ratios in

this group. More importantly, mammography screenings do not affect the ratios of metastasis at diagnosis in this group. In the group above 50 years mammography affects tumor size, lymph node involvement and metastasis ratios significantly ($p<0.05$). In multivariate analyses the factors that influence metastasis were mammography and grade in >50-years group. Hormone and Her2 status showed no effect on metastasis. In 40-50 years group none of these variables significantly affected the metastasis status at diagnosis.

Discussion: It is obviously seen that mammography screening ratios is insufficient in Turkey. The most important finding in our study is mammography does not reduce metastasis ratios in 40-50 years group. The other important finding is the factors that influence metastasis differ according to age.



Picture 1



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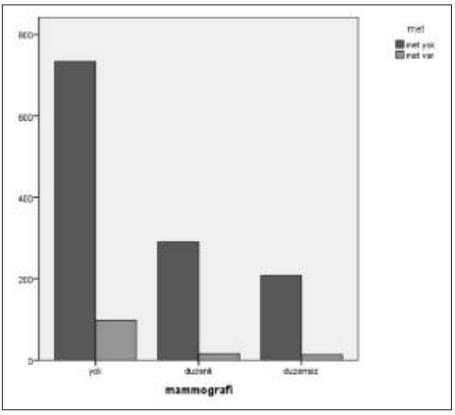

Picture 3

P5: OLDER AGE IS a poor PROGNOSTIC FACTOR ON SURVIVAL of LUNG CANCER

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Introduction: Despite all efforts at management, prognosis of advanced lung cancer is extremely poor, with median survival of approximately only one-year. The ratios of cancer patients older than 70 years have significantly increased among the cancer patient populations.

Purpose: To investigate the clinical importance of being elderly in lung cancer.

Material and methods: The data of 110 patients with histologically confirmed lung cancer who were treated and followed up in our clinic were recorded from their medical charts.

Results: There were 100 (91%) male patients with a median age of 54 (35-88) years. Majority of the patients had non-small cell lung cancer (84%) and metastatic stage (56%). The proportion of chemotherapy responders was lower in elderly patients ($p=0.01$) and also these patients were more anemic than younger patients ($p=0.02$). Majority of the deaths occurred in the elderly patients ($p=0.01$). The median overall survival of elderly patients was significantly shorter than younger patients (37.8 *v* 57 weeks) ($p=0.009$). The 1-year survival rates in younger and elderly patients were 67.3% and 55.0%, respectively. Older age had also kept its significance ($p=0.023$) in multivariate analysis. Among the elderly patients, stage of the disease and serum LDH levels had significant impact on survival. Elderly patients diagnosed with small cell lung cancer had worse outcome than

those with non-small cell lung cancer (p=0.009). In addition, elderly patients with elevated serum LDH levels survived shorter than those with normal values (p=0.042).

Conclusions: Older age is one of the major prognostic factors influencing the survival of lung cancer. Therefore, elderly patients should be interpreted differently in clinical practice.

P6: EXERCISE CAPACITY AND CARBON MONOXIDE DIFFUSING CAPACITY DURING EXERCISE AS PROGNOSTIC MARKER OF LUNG RESECTION IN NSCLC

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Introduction: We measured FEV(1) ,FVC, maximal oxygen uptake (Vo(2)max) ,maximal workload (Wmax) achieved during incremental exercise testing. We used single-breath Dlco technique to determine Dlco at rest (RDlco) and during steady-state exercise at 80% of Wmax, and the increase in Dlco from rest to exercise. We calculated the predicted postoperative values for all the above parameters using the preoperative test data and the extent of functioning bronchopulmonary segments resected, and compared the results with the actual 1-year postoperative results

Twenty two patients undergoing lung resection were studied preoperatively and 1-year postoperatively.

Purpose: To evaluate the effect of lung resection on lung function and exercise capacity values, including diffusion capacity of the lung for carbon monoxide (Dlco), during exercise, and to determine if exercise capacity is better prognostic marker than DLCO

Results: Following lung resection, there was a significant reduction in FEV(1), FVC, and Dlco with decreases of 14%, 16%, and 22% predicted, respectively. There were also significant decreases in Vo(2)max per kilogram of 2.5 mL/min/kg (11% of predicted Vo(2)max) and in Wmax of 10 W (6% of predicted Wmax). However, (80%-R) Dlco did not significantly decrease after lobectomy but decreased after pneumonectomy. The calculated PPO values significantly underestimated postoperative values after pneumonectomy but were acceptable for lobectomy.

Conclusions: Exercise tests may be better indicators of functional capacity after lung resection than measurements of FEV(1) and FVC or Dlco. These results calculated by estimating the functional contribution of the resected segments, are comparable with those obtained using ventilation-perfusion lung scanning.

P7: MAINTENANCE TREATMENT WITH PEMETREXED AFTER CRYOTHERAPY AND MICROVASCULAR INTERVENTION IN NON-SMALL CELL LUNG CANCER: A CASE REPORT

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A 69-years-old gentleman presented with sever dyspnea was diagnosed with lung adenocarcinoma, EGFR –ve, stage IV disease (malignant pleural effusion) in March 2012. Through pleuroscopy, biopsies from the costal pleura and asbestos free Talk powder pleurodesis was done after drainage of pleural effusion. Then, first-line systemic treatment included six cycles of Gemcitabine- Cisplatin was initiated, stable disease was achieved. Cryotherapy of the lung mass and Microvascular intervention using 1000 mg of Pemetrexed and microvascular particles was done with near complete remission. Maintenance therapy with Pemetrexed was given from October 2012 to May 2013. Pemetrexed was well tolerated with mild toxicity. At present, the patient is still on monthly Pemetrexed maintenance therapy and in complete remission proved by PET-CT. Given the poor prognosis of patients with advanced lung cancer, maintenance treatment with Pemetrexed during the remission state of the disease may improve progression-free survival and overall survival should be assessed.

Patients and Methods: On February 2012, a 69-year-old gentleman named M.S.M suffered from dyspnea, chest X-Ray and C.T. Chest revealed massive pleural effusion on left side, thoracoscopy was done in LT 5th intercostal space midaxillary line, which revealed thickened parietal pleura with multiple wall nodules on the costal and diaphragmatic pleura, visceral pleura was normal, Biopsies from the costal pleura and pleural effusion were taken for histopahological and cytological assessment and 3 gm. asbestos free Talk powder insufflation was done. Insertion of indwelling catheter and removal of the intercostal tube was done.

Pathology and Cytology: Bronchogenic moderately differentiated adenocarcinoma.

On 20/3 / 2012, PET-CT study was done and revealed that positive PET –CT study for FDG avid metabolically left bronchial bronchogenic carcinoma with metastatic

mediastinal lymphadenopathy and malignant pleural effusion (Stage IV).
He received 3 cycles of gemzar , cisplatin with stable disease response, he continued 3 more cycles of same line of chemotherapy with stable disease response evident by PET –CT done on 26/7/2012, EGFR was negative.
On 25 Aug 2012, patient presented to FuDa Cancer Hospital, various checkups were taken. The results of the blood routine test, urine routine test, stool routine test, hepatic function test, renal function test, coagulation function test as well as electrocardiogram did not indicate any abnormality, and following treatments were given.
Cryotherapy and biopsy under general anesthesia guided by CT scan were performed on Sep 3 2012. Four tissues were taken from tumor for pathological test, and then seven 1.47 mm cryoprobe (Endocare Inc., Cry care System, Irvine, CA, USA) were inserted. Following images generated were used to monitor the cry probes advance toward the mass for better spatial definition and the minimization of probe artifact. The probe was advanced through the center of the mass until the tip was positioned along its distal inner border. The Joule-Thompson principle-based cryo-system was activated for freezing. Every cycle consisted of 10 min of freezing followed by 5 min of thawing. Three freezing –Thawing cycles were performed. Ice ball size was anticipated to increase until it completely enveloped the mass and the edge extended 5- 10 mm beyond the mass. The course was successful.
Microvascular intervention was undergone on Sep 10th 2012, microvascular particles and 1000 mg Pemetrexed were used. The imaging showed there was staining in cancerous masses. The course was successful.
The patient is currently in stable conditions except bearing premature. His last result of blood test showed: BC 5.58, HGB 11, and PLT 144.
On Oct 18th 2012, micro vascular intervention was underwent, feeding artery for the tumor was chosen, during which 1000 mg of Pemetrexed and microvascular particles were infused. The course was successful.
After 4 weeks monthly 1000 mg Pemetrexed was received and continued till now.
On 12 Jan 2013, PET –CT was done and revealed negative follow up study.

P8: ADVANCED MALIGNANT PLEURAL MESOTHELIOMA: THE NEED FOR NEW PROGNOSTIC FACTORS

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Background: Malignant pleural mesothelioma is a lethal disease and hence the strong need for identifying new prognostic factors.
Methods: This is a retrospective study including all eligible patients with advanced malignant pleural mesothelioma (MPM) presenting to National Cancer Institute, Cairo University. Neutrophil lymphocyte (N/L) ratio was assessed before second line chemotherapy.2.5 was used as the cutoff point. Endpoints were assessment of correlation between N/L ratio and clinical response (CR), progression free survival (PFS) and overall survival (OS).
Results: 52 patients (19 stage III and 33 stage IV) MPM were included and followed up during the period from July 2009 till November 2012 with a median follow up period of 2.6 months. 87.5% of patients with N/L ratio > 2.5 showed progressive disease versus 91.7% in patients with N/L ratio <2.5. (P-value=0.66).6 months PFS was 11% for patients with N/L ratio > 2.5 versus 14% for patients with N/L ratio <2.5. (P-value =0.001). 6 months OS was 72% for patients with N/L ratio > 2.5 versus 66% for patients with N/L ratio <2.5. (P-value =0.4).
Conclusion: N/L ratio is a potential prognostic marker for advanced MPM treated with second line chemotherapy.

P9: IS IT POSSIBLE TO LIVE LONGER WITH METASTATIC SIGNET RING CELL CARCINOMA?

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Introduction: The incidence of the diffuse gastric cancer and particularly signet-ring cell carcinoma (SRC) has been increasing. SRC typically presents with a more advanced stage at diagnosis and carries a worse prognosis.
Purpose: To review the clinical characteristics and treatment approaches of survivors with metastatic SRC of the stomach.
Methods: This study is a retrospective analysis of 6 patients (4 women and 2 men) who lived ≥ 2 years with the diagnosis of metastatic SRC. Median age of patients was 48.6 years (41-59). Five patients underwent total gastrectomy and 4 of them received adjuvant chemoradiotherapy. Two patients were metastatic at the time of diagnosis.
Results: Omentum and lymph nodes were the most common sites of recurrence. Epirubicine, oxaliplatine

and capecitabine/5Flourouracil combination was the most common used 1st line treatment schema. Five out of 6 patients are still in remission. Four of them cured completely after 1st line chemotherapy. One patient achieved complete remission after 2nd line chemotherapy. Three patients received maintenance treatment with capecitabine. One patient with lung, lymph nodes and peritoneal metastases at the time diagnosis, received 3 lines of therapy. Although pulmonary nodules and lymph nodes disappeared after 2nd and 3rd lines of chemotherapy, 4th line of chemotherapy has been started due to progression of peritoneal dissemination. Mean overall survival and progression free survival was 48.6 months (24-75 months) and 34.4 months (6- 71 months).

Conclusion: Despite the studies that point out inherent chemoresistance and poor prognosis of SRC, long-term survival can be possible in patients with metastatic SRC. Epirubicine based schemas seem to be more active. Obviously, biological behaviors of SRC need further investigations.

P10: OPHTHALMOLOGICAL METASTASES IN GASTRIC CANCER: REPORT OF A CASE AND REVIEW OF THE LITERATURE

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Purpose: Most of the Ophthalmological secondary growths occur in breast or lung cancer patients. We report an unusual case in a gastric cancer patient.

Methods: A 48-year-old female post gastrectomy(27/07/2011) for T3 N3M0 adenocarcinoma of gastroesophageal junction & subsequent adjuvant (08/09/2011 till 31/03/2012) chemotherapy (6 CDF cycles) & locoregional radiotherapy of 45 Gy, firstly experienced liver relapse in October 2012, which was treated with Cyber-knife. Her re-evaluation, in January 2013, although in asymptomatic status & negative CT scan, due to elevated serum values of Ca 19-9 included PET scan to clarify the inconsistency. A few peritoneal implants & a soft tissue mass paravertebrally, at T4-T6 invasion & total skeleton infiltration were documented. Radiotherapy of T2-T8 of 30Gy & 1rst Line Chemotherapy with Epirubicin/Xeloda/ Oxaliplatin/Zometa were initiated. Two months later she claimed photopsia, blurred vision & optic acuity deterioration of right eye. Thorough examination showed visual reduction of 7/10. CT & U/S imaging assessment of implied eye showed 2 neoplastic masses in the right fundus. The funduscopy revealed the tissues – in the peripapillary & upper temporal area. The optic papilla was well defined & macula remained intact. All findings were compatible.No special therapy was given.Two months later post 3 cycles chemo, the patient's optic acuity remained stable & no remarkable imaging CT change was recorded.

Further acuity reduction (3/10) was presented post a month & a new funduscopy, revealed a retina & macular detachment.

The patient underwent radiation of 30 Gy in the right eye with gradual amelioration of optic acuity.

Conclusion: Cancer patients complaining of symptoms impaired vision, diplopia etc, it is necessity to exclude ocular or orbital metastatic disease with thorough multidisiplinary ophthalmological exploration for an early diagnosis of tumoral spread or relapse. A proper treatment is expected to prolong their overall survival

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P11: HEPATOBILIARY CANCERS: THE EXPERIENCE OF A SINGLE ONCOLOGY CENTRE

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Background: Hepatobiliary cancers are the second most common primary liver tumor. The resectability rate is extremely low due to the diagnosis time beyond surgery. Curative resection is the most effective treatment, associated with prolonged disease-free survival. The objective of this study was to review our clinical experience.

Methods: A retrospective chart review identified 24 consecutive patients (pts) undergoing treatment in the Oncology Department between 4/2007-6/2013, stage ≥ T2N1 ή ≥ T3NO. Clinical data were collected & summarized.

Results: During the study period 24 pts with hepatic

bile duct adenocarcinoma were recorded (extrahepatic 13, gall bladder /duct 6, ampula Vater 5)
The patients; 18 (75%) male, 6 (25%) female, median age 64 (39-77) y & ECOG 1 (0-2). Five had liver metastatic lesions. The main symptom was: right upper abdominal pain, weight loss, painless jaundice, low back pain, persistent fever & cholangiec crisis in 10,(42%) 5(21%), 4,(16.5%) 3(12.5%), 2 (8%), 1(4%) & 1(4%), respectively. Six (25%) claimed itch, 3(12.5%), stool discoloration & hyper pigmentation urine, while 4(16.5%) pts had palpable liver.
Laboratory tests on the diagnosis revealed abnormal liver function (direct bilurubin ± elevated alkaline phosfatase ± elevated γGT) 21(87.5%) pts
Coagulation abnormal test was recorded in 12(50%) & mild transaminase elevation in 6(25%). Median value of CEA marker recorded was 5 (0.4-1103) ng/ml and CA 19.9,in 22 pts with Lewis Ag (+), 2154 (4-60000) U/ml.
Imaging tests (CT/MRI with intravenous contrast in 24(30%), MRCP/ERCP in 8(33%), PET in 5(21%) & sonovue in 4(16.5%) pts), showed hepatic abnormality.
Diagnosis was stated with Whipple excision in 5 (21%), or at the meantime of open cholocystectomy in 4(16.5%) and wedge liver excision in 1 (4%). Histological test of FNA suspicious tissue, guided by CT in 14(58%) or ultrasound in 5 (21%) pts.
Conclusions: Hepatobiliary malignancies present as primary liver tumor with a variety of symptoms and need individualized diagnostic and therapeutic approach.

P12: THERAPEUTIC APPROACH OF HEPATOBILLIARY MALIGNANCIES. ONE SINGLE'S CENTRE CLINICAL EXPERIENCE

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The aim of the study was to document characteristics, side effects and mortality in patients (pts) admitted in our Department with hepatobiliary malignancies.

Methods: Prospectively 24 pts with adenocarcinoma of hepatic bile duct were recorded (extrahepatic 13,gall bladder /gall duct 6,ampula Vater 5) having been treated in the Oncology Department of Evaggelismos Hospital between 4/2007-6/2013,stage ≥ T2N1 ή ≥ T3NO. The pts were 18 (75%) male, 6 (25%) female, median age 64 (39-77)y & ECOG 1 (0-2).
Patients: The pts were treated therapeutically with 1rst line chemotherapy combination CDDP – Gemcitabine 18 (75%)], or with Carboplatin - Gemcitabine 6 (25%)]. In 14(58%) pts chemotherapy was combined with radiotherapy of 50 Gy.
Median PFS for the recorded pts was 8(3-58) mo, for the pts with M1 disease 4 (3-7) mo and for the 5 Whipple resected pts 14 (10-58) mo.
One patient 42y with adenocarcinoma of ampulla Vater, early stage T3NoMo, is still alive in complete response post 40+mo, although treated for her 2nd malignancy of the ovaries recently appeared. The rest 23, post relapse documentation underwent 2nd line chemo Oxaliplatin based. The PFS documentated was 6 (3 - 39+) mo.
Among them a 72 years old man with adenocarcinoma of ampulla Vater, early stage T3NoMo, in complete response. Still alive 6(25%) pts.
Stable disease have 2 & 4 in deteriorating disease, undergoing palliative care. The 16 pts died had median survival of 11 (4-64) mo.
Conclusions: Curative resection is the only therapy that can achieve long-term survival. All other therapeutic approaches (i.e., adjuvant or neoadjuvant therapy) should be evaluated to improve results.

P13: NATURAL HISTORY OF UNTREATED HEPATOCELLULAR CARCINOMA IN EGYPT: A RETROSPECTIVE COHORT STUDY

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Background: hepatocellular carcinoma (HCC) is a common cancer worldwide as well as in Egypt with hepatitis C and B, alcohol and aflatoxins being the commonest risk factors.
Aim: the objective of this study was to assess the prognostic factors affecting overall survival (OS) of untreated HCC in Egypt.
Methods: This retrospective study was conducted at Tanta Cancer Center (TCC), Egypt where 1009 HCC

cases who received no specific therapy were identified. The impact of possible prognostic factors on OS was assessed using the log-rank test (univaraite analyses) and Cox regression method (multivariate analysis).

Results: The median OS of untreated HCC in Egypt is 107 days (95% CI: 91.3-122.7). The 1, 3, 6, 12, 24 months OS rates were 92, 58, 38, 25, and 14%, respectively. Female gender, absence of fatigue, Child-Pugh A, single tumors, tumor diameter ≤5cm, absence of distant metastases, and AFP ≤ 400 ng/l had significantly better OS (p<0.5 for all). However, none was an independent prognostic factor for OS in multivariate analyses. Sensitivity analysis of OS excluding various groups that may significantly affect survival (sole hospital visit, less than 7 days of follow up, and very good prognosis patients) showed that OS did not changed markedly.

Conclusions: overall survival in untreated HCC in Egypt is very short. Many factors interact to produce this dismal survival.

Key words: *Untreated hepatocellular carcinoma, Egypt, prognosis, survival*

P14: A STUDY OF COLONIC ADENOMATOUS POLYPS AND THE RISK FACTORS FOR MALIGNANT TRANSFORMATION IN ALBANIA

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Background: Almost all colorectal cancers arise exclusively from neoplastic polyps. The tendency toward malignant change is determined by histologic type, size, and degree of atypicality of adenoma. Early detection and resection of neoplastic polyps of the colon are essential to prevent the malignization.

Aim: The aim of our study was to determine the frequency of colorectal adenoma and the risk factors for malignization in our daily practice.

Methods: Between January of 2010 and January of 2013, 938 colonoscopies were performed. The patients with colorectal polyps were chosen for the analysis of this study. The polyps characteristics were investigated to determine the risk factors for malignization.

Results: In our study there were 197 (21%) patients with 392 colorectal polyps. Snare resection during colonoscopy underwent 384 (97%) of them. From all of them 229 (58.4 %) were neoplastic polyps and 163 (41.6 %) non neoplastic. Among neoplastic polyps, 138 (60.3 %) were tubular adenomas, 25 (10.9 %) were tubulovillous adenomas, and 19 (8.3 %) were villous adenomas. We found 47 (20.5%) polyps with adenocarcinoma, 25 (53.2 %) were found in patients older than 50 years of age and in polyps larger than 2 cm in diameter.

Conclusions: We concluded that the tubular adenomas were the neoplastic polyps more frequently found and the patient age, polyp size and morphology were the more statistically significant risk factors for malignization in our study.

P15: OXALIPLATIN-INDUCED HEARING LOSS IN A PATIENT WITH METASTATIC COLON CANCER

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Introduction: Neuropathy is the most common known side effect of oxaliplatin, but oxaliplatin-induced hearing loss is very rare.

Case Report: A- 64-year old female patient applied to our oncology clinic with the diagnosis of metastatic colon cancer. She has no comorbid disease and drug use. In the colonoscopic evaluation, there was an infiltrative, but not obstructive mass involving sigmoid colon and histopathologic examination of the endoscopic biopsy specimen from the mass was consistent with adenocarcinoma. PET/CT scan showed sigmoid pimary tumor and multiple metastatic lesions with a maximum diameter of 6 cm involving both lobes of the liver. In kras mutation analysis there was no codon 12/13/61 mutation. Modified FOLFOX6 [oxaliplatine 85 mg/m2 IV day 1, 5-fluorouracil (5-FU) 400 mg/m2 IV bolus day 1, leukovorin 200 mg/m2 IV day 1, 5-FU 2400 mg/m2 IV continuous infusion (over 46 hours) every 2 weeks] and cetuximab (500 mg/m2 IV day 1, every 2 weeks) was started. After the third cycle she admitted with the complaint of progressive hearing loss. Audiometric test results were consistent with bilateral sensorineural hearing loss. Oxaliplatin was removed from the chemotherapy regimen permenantly because of oxaliplatin-induced hearing loss and steroid therapy was started, but there was no recovery of hearing functions on following months.

Conclusion: Although no autotoxic event was reported in the large trials evaluating oxaliplatin in combination with other chemotherapeutic agents, there were three case report in the literature and one of these three patient experienced permanent hearing

loss. Oxaliplatin-induced autotoxicity can be irreversible therefore oncologists should be aware of this rare, but potentially severe side effect.

P16: DOCETAXEL-BASED SYSTEMIC CHEMOTHERAPY IN ELDERLY TURKISH MEN WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (mCRPC): AN OBSERVATIONAL STUDY IN A SINGLE INSTITUTION

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Introduction and purpose: Treatment with docetaxel in combination with prednisolone is the standard first-line treatment in patients with metastatic castration-resistant prostate cancer (mCRPC). The aim of this study was to determine the efficacy and safety of docetaxel-based systemic chemotherapy in elderly Turkish men with mCRPC.
Material and methods: We retrospectively reviewed the clinical records of 98 patients with mCRPC who were treated with docetaxel-based systemic chemotherapy at a single institution between December 2004 and June 2013. Patients were placed into 2 groups: Group 1 consisted of 40 patients aged ≤ 70 years, and Group 2 consisted of 58 patients aged > 70 years. All patients received docetaxel (75 mg/m^2) once every 3 weeks and prednisolone (5 mg) twice daily. The efficacy and tolerability of this therapy were analyzed.
Results: In these 98 patients, the median age was 68 years, and serum value of prostate specific antigen (PSA) prior to docetaxel-based chemotherapy was 87.4 ng/ml. An overall PSA response ≥50% was achieved in 61 patients (62.5%). In 29 patients (29.6%), overall PSA response was ≥75%. The median overall survival (OS) of the total population was 16 months. Of all patients, 18 patients (18.4%) experienced grade 3 anemia, and 8 patients (8.2%) experienced grade 3 neutropenia. The PSA response ≥50% rates were 52.5% and 68.9%, and the OS rates were 14 months and 16 months, respectively. These rates and the drug-related toxicity were not different between two groups.
Conclusions: These findings suggests that docetaxel-based systemic chemotherapy is clinically feasible in elderly Turkish men considering the cancer control and safety associated with this therapy.

P17: THE IMPACT OF BODY MASS INDEX ON THE RESPONSE TO DOCETAXEL TREATMENT IN PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

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Introduction: Treatment with docetaxel in combination with prednisolone is the standard first-line treatment in patients with metastatic castration-resistant prostate cancer (mCRPC). The aim of this study was to determine the impact of body mass index (BMI) on the response to docetaxel treatment in patients with mCRPC.
Material and methods: We retrospectively reviewed the clinical records of 98 patients with mCRPC who were treated with docetaxel-based systemic chemotherapy at a single institution between December 2004 and June 2013. Of 98 patients, 25 Patients (25.5%) with a normal or lower BMI (<25 kg/m^2) were categorized as Group 1 and 73 patients (74.5%) with an overweight or greater BMI (≥25 kg/m^2) were categorized as Group 2. All patients received docetaxel (75 mg/m^2) once every 3 weeks and prednisolone (5 mg) twice daily. The efficacy and tolerability of this therapy were analyzed according to groups.
Results: In these 98 patients, the median age was 68 years, and serum value of prostate specific antigen (PSA) prior to docetaxel-based chemotherapy was 87.4 ng/ml. An overall PSA response ≥50% was achieved in 61 patients (62.5%). In 29 patients (29.6%), overall PSA response was ≥75%. The median overall survival (OS) of the total population was 16 months. Of all patients, 18 patients (18.4%) experienced grade 3 anemia, and 8 patients (8.2%) experienced grade 3 neutropenia. The PSA response ≥50% rates were 60% and 63%, and the OS rates were 19 months and 16 months, respectively. These rates and the drug-related toxicity were not different between two groups.
Conclusions: These findings suggest that the BMI has not a significant effect on the response to docetaxel and on the drug-related toxicity in patients with mCRPC.

P18: A TESTICULAR GERM CELL TUMOR WHICH PRESENTS WITH ENDOBRONCHIAL METASTASIS: CASE REPORT

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Introduction: Endobronchial metastasis of extrapulmonary malign tumors are extremely rare. Most common primary tumors which do endobronchial metastasis are breast, renal and colorectal cancers. Here we will present a case of germ cell tumor which has done endobronchial metastasis and presented with shortness of breath.

Case Presentation: A 30 years old male patient attended to the hospital with complaints of shortness of breath, cough and back pain. On chest X-ray there were bilateral mass lesions. Computed tomography of thorax showed a mass filling anterior mediastinum and metastatic mass lesions on both lungs. Because of severe respiratory distress bronchoscopy was done and multiple obstructing endobronchial lesions were seen. Bronchoscopic interventions to overcome these obstructions were done accordingly. The patient was refered to our department after the pathologic examşnation reported a germ cell tumor. On testicular examination and ultrasonography there was a mass in right testis. Positron Emission Tomography revealed a mass filling anterior mediastinum and paraaortic field, left jugular, multiple mediastinal lymph nodes, bilateral multiple lung metastasis and right acetabular lesion with FDG uptakes of SUVmax ranging between 10-21. Right radical orchiectomy was done to the patient whose shortness of breath was releaved after bronchoscopic intervention. On pathologic examination there was mixed germ cell tumor (50% classical seminoma, 20% embriyonel carcinoma, 30 % necrosis). Tumor was pT2. Bronchoscopic biopsy was examined again and it was embryonal carcinoma. Bleomycin-Etoposide-Cisplatin chemotherapy protochol was started on postoperative fifth day. Now the patient is free of symptoms and taken second cycle of chemotherapy.

Conclusion: Endobronchial metastasis of testicular germ cell tumors are rare. We should make genital examination that is usually missed as a part of physical examination especially in a young patient presenting with lung metastasis. So that we can diagnose and start treatment witout loosing time especially in case of such a highly chemosensitive tumor.

P19: OVARIAN CANCER METASTASIS TO INTRAMAMMARY LYMPH NODE, CASE REPORT

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Breast cancer is the second and ovarian cancer is the fifth leading cause of cancer-related death among women. Occurrence of ovarian cancer and breast cancer may be either synchronous or metachronous. Ovarian cancer is usually associated with pelvic, peritoneal and lymph node metastases. Metastasis to breast is relatively rare in ovarian cancer. This case report presents a patient diagnosed with synchronous ovarian epithelial carcinoma and ductal carcinoma in situ and who developed ovarian cancer metastasis to intramammary lymph node 4 years after the ovarian cancer diagnosis. The lung graphy and computed tomography performed in the 68-year old female patient with the complaint of coughing revealed pleural effusion, and the subsequent cytological examination demonstrated malignant cytology. Following the screening tests, the mass detected in her left breast was excised, and total abdominal hysterectomy for adnexal masses, bilateral salpingo-oophorectomy, pelvic lymph node sampling and omentectomy were performed during the same session. Following the histopathological and immunohistochemical examinations, the patient was diagnosed with mixed form carcinoma in situ of the breast and bilateral malignant serous ovarian tumor. A chemotherapy program was initiated for the patient, and during her follow-up at 4 years after the ovarian cancer diagnosis mammography and mammary ultrasonography revealed a suspicious lesion in the right breast, for which excisional biopsy was performed by marking. Histopathological and immunohistochemical examinations of the surgical specimen demonstrated WT-1 positive staining and GCDFP-15 negative staining in tumor cells. The patient was diagnosed with intramammary lymph node metastasis of the malignant serous tumor. Due to the differences in prognosis and possible alterations in treatment, it is important to differentiate the second primary breast cancer and metastasis to breast tissue in patients diagnosed with ovarian cancer.

P20: A GESTATIONAL TROPHOBLASTIC DISEASE TREATED SUCCESSFULLY WITH AN ALTERNATIVE CHEMOTHERAPY: A CASE REPORT

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Introduction: Gestational trophoblastic disease comprises a spectrum of diseases which have variable malignancy potential. Cases which are not resulted in spontenous remission, persistent or which require chemotherapy are accepted as GTD. Treatment modalities in GTD's include single agent or multi agent combined, systemic or intrathecal chemotherapies, surgical procedures and local radiotherapies.
Case Report
A 37 year old woman referred to gynecologist with vaginal bleeding. After suction evacuation was performed twice; due to the persistance of the high B-hcg, methothrexate and leucovorin were administered. Inspite of the treatment, B-hcg has not decreased and she has referred to oncology department. There was no metastasis. Although MAC and EMA-CO are the most common protocols for the high risk GTN's; due to the unresponsiveness to the previous methothrexate administration, high toxicity and the reason that actinomycin-D is not available in our country; TP/TE (paclitaxel-cisplatin/paclitaxel-etoposide) has been chosen. Beta HCG levels have decreased gradually and it has measured as <2 IU/L at the end of treatment.
Discussion: When datas upon the treatment of GTN's have been considered, it is seen that the first line treatment chosen for non metastatic and low risk metastatic GTD's is single agent methotrexate or actinomycin D using one as an alternative to the other in case there is seen resistance or toxicity; and if the remission is not obtained, combined therapy is considered. Because of the high and severe toxicity incidence of combined multi agent chemotherapy protocols, most of the patients are died due to the treatment. Although MAC is the oldest protocol, recently the protocols of EMA-CO and EP/EMA, the response rates of which are higher, are preferred most frequently.
Conclusion: In our case, good response to TP/TE protocol has been revealed and it has seen that this protocol must be situated as one of the first line therapies.

P21: PAZOPANIB TREATMENT OF RENAL CELL CARCINOMA: A SINGLE CENTRE EXPERIENCE

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Introduction: Renal cell carcinoma (RCC) accounts for approximately 3% of adult malignancies. At diagnosis, approximately 30% of patients with renal carcinoma present with metastatic disease. Pazopanib is an oral multitargeted tyrosine kinase inhibitor that targets VEGFR-1 through 3, PDGFR, and c-kit. We present here our experience with pazopanib 800 mg once daily treatment in patients with RCC.
Purpose: The patients' data was statistically analyzed using SPSS software version 17.0 for Windows.
Results: Median age was 62 years: 61.5% male, 38.5% female. ECOG PS score 1 was found in 8 patients, PS 2 in 4 patients, PS 3 in 1 patient. At diagnosis, 7 patients were metastatic stage. Five of these patients had only lung metastasis, 2 patients had lung and hepatic metastasis. Four patients had nephrectomy and metastasectomy. Ten patients (77%) had intermediate prognostic factors. All patients received pazopanib after cytokin treatment. Side effects included: grade1 nausea/vomiting in 8 patients, grade 1 diarrhea and mucositis in 6 patients, grade 1 asthenia in 6 patients, grade 2 asthenia in 5 patients, grade 1 hypertension in 5 patients, grade 3 hypertension in 1 patients, grade 1 hypothyroidism in 6 patients, grade 1 anemia in 4 patients, grade 1 rash in 2 patients, hand and foot syndrome in 2 patients, grade 1 elevated liver function test results in 1 patient. In our follow-up, we made dose reductions for 6 patients and interrupted therapy for 3 patients. Median follow-up was 7 months. Four patients were dead. We haven't detected any progression in surviving patients yet.
Conclusions Antiangiogenic approaches in the treatment of RCC are essential. In our experience, pazopanib appears to have good clinical effects, manageable side effects and good patient tolerance. Targeted therapy is becoming more important in oncology and in the future cancer treatment needs to be more patient specific.

P22: MERKEL CELL CARCINOMA OF THE HEAD AND NECK: 12 YEARS OF CLINICAL EXPERIENCE AND PRINCIPLES OF MANAGMENT

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Background: Merkel cell carcinoma (MCC) is a rare and aggressive type of non-melanoma cutaneous malignancy with high recurrence and mortality rates. Approximately more than one half of MCCs arise in the head and neck region. Oral and Maxillofacial (OMF) surgeons are among health care providers, who may first encounter this disease.
Purpose: This study aims to review the experience of the Oral and Maxillofacial Surgery Department of Theageneion Anticancer Hospital of Thessaloniki in terms of oncological management of patients with primary MCC in the head and neck region (MCCHN). Moreover, this presentation includes an overview of contemporary literature data related to diagnosis, epidemiology, histopathology, staging, treatment approach considerations, outcomes, prognosis, and postoperative monitoring of MCCHN.
Material and Methods: An electronic search of the patient database of Theageneion Anticancer Hospital was carried out using the following keywords: Merkel Cell Carcinoma, cutaneous neuroendocrine carcinoma, primary neuroendocrine carcinoma of the skin, and the ICD-10-code of MCC. Over a 12 year period, six cases of primary MCCHN were identified. Patients' medical charts and records, as well as clinical and telephone follow-ups were used to obtain the necessary medical information. All the collected data were screened for patients' age and sex, tumor site and TNM stage, surgical and adjuvant treatment, recurrence, disease related deaths, follow-up, and survival.
Results: The mean age of six patients was 71.17 years. The follow-up periods ranged from 4 to 151 months (median follow-up 43 months). The treatment modalities included surgery alone or surgery followed by adjuvant radiotherapy or concurrent radiotherapy and chemotherapy. One female patient died because of the advanced stage of disease. The other five survived and remained disease-free over a mean follow-up period of 50.8 months.
Conclusions: MCC is a very rare and aggressive skin malignancy. At the present time, there is no optimal treatment protocol. The appropriate management requires early and accurate diagnosis as well as a multidisciplinary team approach. This study suggests that MCCHN cases should be managed by a hospital oncologic council which consists of various specialties such as dermatologists, OMF surgeons, otolaryngologists-head and neck surgeons, radiation-oncologists, oncologists, pathologists, radiologists, and speech pathologists.

P23: IPILUMUMAB INDUCED HERPES ZOSTER INFECTION

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Case Report: A 54-year-old male patient with no known medical comorbidities presented to the us after resection of a nevus on the right lumbar region due to color changes and shape irregularities. The pathology report denoted a superficial melanoma which prompted re-resection and sentinel lymph node dissection. Due to the sentinel lymph node biopsy returning with cancer diagnosis, an axillary dissection was also performed. Final diagnosis was melanoma with T3bN2M0 stage. Patient subsequently underwent interferon treatment for one year. In April, 2013, or five months into the interferon treatment, multiple lung metastases were detected. Biopsy confirmed the metastases in the lungs. Brain metastases was also found in a cranial MRI, and this was followed by cranial radiotherapy and temazolamide treatment. Because of the severe site pains in the chest, a chest CT was performed which showed progression of the metastases. Paclitaxel, carboplatin, and ipilumumab treatments were planned. There was partial regression noted in the radiologic studies after the third cycle of the chemotherapy. Three weeks after the third cycle of the chemotherapy, vesicular and bullous skin lesions with erythema were detected along the left lumbar dermatome distribution (Figure). Diagnosis was compatible with herpes zoster. After cessation of intravenous medications for one week, patient was placed on pregabalin due to the continuation of neuropathic pain. After one more week, the noted skin lesions were cleared.
Conclusion: Although Ipilumumab is an effective chemotherapy agent, there are significant side effects because of the known T-cell hyperstimulation. The most frequent side effects are malaise, diarrhea, itching, and skin sloughing. Immunosuppression with steroids may be needed to treat the side effects of this medication. Lethal side effects from severe autoim-

mune reactions have been described in 13% of patients (colitis, hepatitis, and endocrine dysfunction). The appearance of herpes zoster infection, a known disorder related to T-cell dysfunction, being an unexpected side effect due to this immunotherapy was found to be interesting and worthwhile reporting, especially given that there are no similar reports in the literature.

P24: LEPTOMENINGEAL METASTASES FROM CUTANEOUS MELANOMA: SINGLE CENTER EXPERIENCE

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Introduction: Brain metastases (BM) are among the most devastating and debilitating complications of melanoma, the third most common tumor to metastasize to the brain. The reported incidence of BM is 10%-40%, but there is higher reported incidence at autopsy (12% – 73%) and the discovery of asymptomatic BM on brain imaging studies is frequent. Leptomeningeal metastases (LM) from melanoma has a relentlessly progressive clinical course.

Purpose

To present the clinical features, management options, treatment and survival outcomes of a series of cases with leptomeningeal metastases among patients with metastatic melanoma seen in our clinic.

Results: We retrospectively analysed the clinical data of serial cases with LM from melanoma presented in our clinic since 2009. Seven patients, 6 male and 1 female, diagnosed with cutaneous melanoma, aged 34 to 67 years (median age 50 years) were identified. AJCC stage at initial melanoma diagnosis varied from IA to IV, with ulceration in 5 cases, while B-RAF was mutated in 5 of 6 cases tested. Brain metastases (BM) were present at diagnosis of stage IV disease in 3 cases while the other 4 developed BM after a median of 2.6 months. The median time from initial melanoma diagnosis to development of BM was 4.8 years (range 0-19.2 years), 6 of the patients presented with neurological symptoms and 1 had intratumoral hemorrhage. Four patients were treated with WBRT and 2 with radio-surgery. At the time of BM all seven patients had extracranial metastases. Three patients received Temozolomide- based chemotherapy and 3 B-RAF inhibitors. Median time from detection of BM to the development of leptomeningeal metastases was 8 months (range 1-28 months). All patients underwent lumbar puncture and positive cerebrospinal fluid cytology as well as abnormal LDH levels were shown in all patients. Median survival time from detection of BM was 7.9 months (range 2-29 months) and from LM detection only 1.2 months (range 0.5-3 months). In all seven cases best supportive care was offered after the LM diagnosis with no further systemic treatment.

Conclusions: Leptomeningeal melanomatosis is an incapacitating complication of melanoma. Our series and review of the literature show that outcomes for patients with LM are extremely poor. With recent treatment advances, patients with metastatic melanoma survive longer and the advent of LM seems more common. To improve outcomes for these patients, further therapeutic options are required, targeting both the systemic and CNS disease.

P25: CUTANEOUS SIDE EFFECTS OF BRAF AND MEK INHIBITORS: A CASE SERIES.

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Introduction: The development of targeted therapies has initiated a new era in the management of melanoma. Inhibitors of the RAS-RAF-MEK-ERK pathway have taken the center-stage with rapid clinical development. Vemurafenib, Dabrafenib and Trametinb were recently approved by regulatory agencies, following impressive clinical benefit over standard chemotherapy. However, these agents are also associated with frequent cutaneous adverse events, potentially affecting patients' quality of life and treatment, and representing a toxicity profile distinct from cutaneous toxicities of other targeted agents.

Purpose: To characterize and analyse the type of, as well as frequency of presentation of cutaneous effects

in patients with metastatic melanoma receiving BRAF or MEK inhibitors.

Results: We retrospectively reviewed a case series of 41 patients with metastatic melanoma who received BRAF (vemurafenib or dabrafenib) or MEK inhibitors (Trametinib), from 2011 to 2013 (mean age 52.8 years, range 30-79 years). Median duration of treatment was 4 months (range 0.5-24 months). Twenty-three patients received Vemurafenib, 16 patients received Dabrafenib, 2 patients received Trametinib. Cutaneous toxicity was recorded according to Common Toxicity Criteria grading system (NCI CTC v.4), except for hyperkeratosis and squamoproliferative lesions that cannot be assessed with this system.

Skin toxicity was observed in 20/23 Vemurafenib patients, 10/16 Dabrafenib patients, 1/2 Trametinib patients. The following toxicities were documented: of 23 patients treated with Vemurafenib, 4 reported **pruritus**, **photosensitivity** was developed in 5 (22%), **skin rash** in 7 (30%), **dry skin** in 3, **alopecia in** 5 (22%), and **hyperkeratosis** in 6 (26%). **Squamo-proliferative lesions** included keratoacanthoma (1 patient), verrucous keratosis (1 patient), verruca vulgaris (2 patients), skin papillomas (warts) (11 patients, 48%). Of 13 patients treated with Dabrafenib, 1 developed p**hotosensitivity**, 2 **dry skin**, 3 **hyperkeratosis**, 1 patient had **eye lashes loss**, and 1 **onycholysis**. **Squamo-proliferative lesions** included 1 keratoacanthoma in the 3rd month of treatment and skin papillomas in 5/16 patients (31%), all in the 1st month. Finally, of 2 patients treated with Trametinib, 1 developed grade 3 papulopustular **rash.** There was no case of therapy discontinuation due to skin toxicity associated with BRAF and MEK inhibitors.

Conclusions: Multiple cutaneous side effects were frequently observed in our case series of melanoma patients during treatment with BRAF and MEK inhibitors. Some of those are very specific for BRAF inhibitors and cannot be assessed with the current toxicity criteria grading systems. Photosensitivity, rash and squamo-proliferative lesions were common, and occurred within the first 2 months of treatment. No cases of SCC were seen in our series and skin toxicity did not lead to treatment discontinuation. Further studies are warranted to elucidate the frequency, timing and mechanisms associated with these cutaneous effects, while patients receiving B-RAF and MEK inhibitors should undergo regular full body examinations.

P26: BEVACIZUMAB AND IRINOTECAN IN THE TREATMENT OF RECURRENT MEDULLOBLASTOMA IN THE ADULT, A CASE REPORT

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Introduction: Adult medulloblastoma accounts for less than 1% of adult intracranial tumors, the peak age is between 20 and 35 years, after which the incidence steadily declines. The current standard of care includes resection, radiation and chemotherapy.

Several pre-clinical studies have reported the relationship of medulloblastoma and angiogenesis.

Materials and methods: We described a 32 years old woman with recurrent medulloblastoma. Her clinical history began in June 2003; she developed symptoms of raised intracranial pressure with dizziness, vomiting and headache. A brain CT-scan revealed a tumor in the pontocerebellar region. The patient underwent a complete surgical resection, confirmed by a postsurgery imaging, and the diagnosis of desmoplastic medulloblastoma was performed. After that, she received a craniospinal irradiation with a total dose of 54Gy.

After 8-years period of event-free follow-up, in February 2011 a radiographic surveillance showed recurrent disease in the cerebellum region involving the brainstem, vermis and the fourth ventricle, then she underwent a second but partial surgery.

In April 2011, she started a treatment with Bevacizumab at a dose of 5 mg/kg and Irinotecan at a dose of 125 mg/m^2 every 14 days.

Results: After a median of two months of systemic treatment (from April to June 2011) she performed a partial response by radiological evaluation, followed by thirteen months of stable disease (from June 2011to July 2012), in a total of fifteen months of control disease.

During this long term of treatment, no severe side effects or major toxicities were present, and the quality of life was good.

Conclusion: Targeting VEGF signaling may represent a new therapeutic option in the treatment of recurrent medulloblastoma of adults**.**

Bevacizumab and Irinotecan regimen can become an interesting treatment option with less toxic profile then conventional chemotherapy, thus further investigations may explore antiangiogenic regimens in important clinical trials with a consistent number of patients.

P27: FEBRILE NEUTROPENIA IN A HEMATOLOGY DEPARTMENT

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Chemotherapy –induced neutropenia remains the major predisposing factor to infection in hematology patients. Febrile neutropenia (FN) has increased risk of bacteremia associated with significant morbidity.
Purpose: To investigate the causative organisms in febrile neutropenic patients between May 2012 and February 2013.
Results: 137 episodes of FN were evaluated in 55 (29 men and 26 women) patients with median age 82 (53-91 years) and 68(33-100 years) respectively. Underlying diseases were: myelodysplastic syndrome 20 (36.3%), acute myeloid leukemia 11 (20.0%), non Hodgkin lymphoma 18 (32.7%), multiple myeloma 3 (5.4%), myelohyperplastic syndrome 3 (5.4%). 77(56.2%) episodes of FN had no apparent clinical focus of infection. Clinically documented infections were detected in 60 (43.8%) febrile episodes: bacteremia was documented in 14(23.3%), urinary tract infection in 26(56.5.9%), pulmonary infection in 11 (23.9%), fungal infection in 7(15.2%), central venous catheter infection in 2(0.4%). The isolated pathogens were shown in table1. The leading pathogen was Coagulase negative staphylococci (CNS) followed by E.Coli. Mortality of FN episodes occurred in 2 patients attributable to multidrug resistant Klebsiella pneumonia.

*Table 1.*Microorganisms from positive cultures

Bacteria	N/%		N/%		N/%
Gram+	32(53.33%)	Gram-	22(36.6%)	Fungi	6(10%)
Coagulase negative staphylococci (CNS)	14	E.Coli	8	C.albicans	6
St. aureus	3	Klebsiella spp	3		
Streptococcus spp.	7	Pseudomonas spp.	2		
Enterococcus spp.	4	Acinobacter spp.	3		
C. jeikenium	2	Stenotrophomonas maltofilia	1		
Corynebacterium	2	Enterobacter cloacae	2		
		Serratia	2		
		Haemophilus influenzae	1		

Conclusions: There is a predominance of gram + bacteria. Among the gram-positives, CNS (60%), were the prevalent bacteria, which is comparable to the reported results from different centers. The study of the etiological agents and the flora of each unit must be used to direct the initial and empiric antimicrobial treatment and to develop strategies to minimize the occurence of resistant pathogens.

P28: METACHRONUS SECOND PRIMARY MALIGNANCY (SPM) IN HEMATOLOGY PATIENTS

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The prevalence of SPM has been reported varying between 0.73% and 11.7%. Involved factors for developing SPM are: first primary cancer itself, genetics, environment exposures, improvements in survival and better treatment.
Purpose: To estimate occurrence of SPM in hematology patients.
Results: A total of 602(338men, 264 women) patients with median age 58y (43-82) and a male to female ratio 1.6:1, admitted in our unit, were retrospectively evaluated between January 2010 and May 2013. Metachronus (more than 6 months after first primary malignancy) SPM developed 11 (1.82%) patients, 7 (2.07%) men and 4 (1.51%) women. 7/11 cases were associated with a first hematologic malignancy and 4/11 with solid tumor. 5/11 cases had diagnosis lung cancer as primary or second malignancy. 7/11 patients had treatment for the first malignancy and 4/11 did not receive any treatment (Table1).

*Table 1.*Clinical data of patients with SPM

			FIRST CANCER	PRIMARY		SECOND CANCER	PRIMARY	
No	Gender	Age at diagnosis	Diagnosis	Treatment	Interval	Diagnosis	Treatment	OS
1	M	57	MPN/PV	Hydroxyurea Blood apheresis	[illegible]	Lung cancer	Palliative	[illegible] Death
2	M	55	B-CLL	-	79m	Lung cancer	Surgery	54m
3	M	81	MDS/RARS-T/AMML	Erythropoietin Hydroxyurea	18m	Lung cancer	Palliative	18m Death
4	M	81	MDS/CMML		23m	Lung cancer	Palliative	3m
5	F	54	Lung cancer	Surgery/RT	91m	MDS/RAEB-I	Azacitidine	[illegible]
6	M	73	Prostate cancer	RT/HRT	14m	MDS/RCMD	-	18m
7	F	49	Melanoma	Surgery Interferon	216m	Gastric MALT B-NHL	R/CVP	[illegible]
8	F	58	B-CLL	-	156m	Breast cancer	Surgery/CT/RT/HRT	165m
9	F	[illegible]	[illegible]	Cisplatin Adriamycin Surgery	[illegible]	Hodgkin disease	ABVD	[illegible]
10	M	82	MDS	Erythropoietin	24m	Gastric MALT B-NHL	Rituximab Leukeran	[illegible]
11	M	76	B-CLL	-	120m	MDS/CMML	Azacitidine	144m

OS: Overall survival m: month

Conclusions: The risk of developing metachronus SPM among hematology patients was low in our series. Based on small numbers, an unexpected presence of solid tumors was reported whereas lung cancer was the commonest site of tumor.

P29: MINIMAL RESIDUAL DISEASE DETECTION AT END OF INDUCTION IN EGYPTIAN ADULT ACUTE MYELOID LEUKEMIA PATIENTS

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Background: The achievement of complete hematologic remission (CR) is used as predictor for treatment response in patients with myeloid leukemia (AML).However <5% blasts in the bone marrow does not reflect the presence of tumor burden precisely. Minimal residual disease (MRD) in the first complete remission (CR1) may play a critical rule in assessment of treatment response and prediction of subsequent relapse.
Patients and Methods: Leukemia associated immunophenotyping (LAIP) for 73 patients with denovo AML monitored at diagnosis , day 14 and day28 post-induction by multiparametric flow cytometry (MFC).
Results: CR achieved in 60(82%) patients and 13(18%) patients did not. Among the 60(80%) patients who achieved CR 9 (15%) were MRD negative and 51(85%) were MRD positive at day14. Significant association between MRD detection and disease free survival (DFS) using 0.01% cut off value (P=.015). Day 28 post induction show highly significant association between MRD and DFS using 0.01% cut off value (P=0.001) as 38(63%) patients were MRD negative and (27%) were positive.
Significant association between MRD detection and overall survival (50 month) at day 14 and day 28 (P=0.02, P=0.001) respectively using cut off value 0.01%. MRD was positive in 63(86%) at day 14 and (37%) at day 28.
Conclusion: MRD detection at day28 and d14 at the end of induction in patients in CR may have a prognostic significance on clinical outcome and may thus be a useful marker for risk stratification.

P30: INCIDENTAL THYROID MICROCARCINOMAS DURING TOTAL THYROIDECTOMY FOR BENIGN THYROIDAL GOITERS

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Aim: The aim of our study is to assess the frequency of incidentally detected thyroidal microcarcinomas after the performance of total thyroidectomy for presumably benign thyroidal goiters.
Materials and Methods: Our study sample constitutes of 74 specimens of total thyroidectomies, with 56 of them resected due to the presence of multinodular goiters. The specimens were examined by a single experienced histopathology Consultant.
Results: In total, incidental thyroid microcarcinomas were detected in 30/74 of the specimens (40.5%). More specifically, incidental thyroid microcarcinomas occurred in 6 patients with uni-nodular goiter (33.3%) and 24 patients with multi-nodular goiter (42.8%). With respect to their underlying histological type, 27/30 (90%) of them were papillary and 3 (10%) were follicular. Metastatic spread to the local lymph nodes near the isthmus was reported in the only case of multifocal microcarcinoma. Finally, in the group of patients with multi-nodular goiter, the site of the incidental thyroid microcarcinoma was on all occasions situated in the same side of the thyroid gland the nodule was.
Conclusions: The prevalence of incidental thyroid microcarcinomas is steadily increasing over the last decades. The limitations in the pre-operative detection of thyroid microcarcinomas often lead to their discovery as incidental findings during the completion of thyroidectomy. Although of low metastatic potential, patients with multifocal thyroid microcarcinomas need to be investigated further due to possible metastatic spread in the local lymph nodes.

P31: THE ROLE OF ELECTROSURGERY IN THE TREATMENT OF VAGINAL AND CERVICAL INTRAEPITHELIAL NEOPLASIA

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Introduction: The vaginal intraepithelial neoplasia (VAIN) treatment remains controversial. Treatment protocols currently used in clinical practice is radiation, medical therapy and invasive procedures.
Aim of Study: The aim of the present study is to highlight the effectiveness of electrosurgery (LEEP) in patients with intraepithelial neoplasia of the vagina and the cervix.
Materials and Methods: 6 patients with vaginal intraepithelial neoplasia and 10 patients with cervical intraepithelial neoplasia were included. LEEP excision was used with an electrosurgical unit of 80Watt and 3mm healthy surgical margins.
Results: Complete response rate at one year was 85%, the recurrence rate at one year was 25%, while the

response rate at 2 years was 65.5% and the recurrence rate at 2 years was 35.5%.
Conclusions: LEEP excision can be a useful treatment of intraepithelial neoplasia of the vagina and the cervix and provides, in a very short time, an evaluable specimen of the entire lesion.

P32: OUTCOMES OF TRANSPERINEAL TEMPLATE-GUIDED MAPPING PROSTATE BIOPSY AFTER NEGATIVE TRANSRECTAL ULTRASOUND GUIDED BIOPSY

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Introduction: Transperineal template-guided prostate biopsy (TPGB) is widely available in many centers for accurate prostate cancer diagnosis and disease staging (mapping).
Purpose-Methods: We investigate the results of a transperineal route for prostate biopsy guided by a template, in patients with at least one prior negative transrectal biopsy.
From July 2008 through July 2013, 118 patients underwent TPGB of prostate and seminal vesicles, under constant TRUS guidance. 43 men (36.4%) had at least one prior negative transrectal biopsy (one: 29 patients, two: 12 patients, three: 2 patients).
Samples were taken every 5mm throughout the entire prostate gland using a brachytherapy grid. Three cores were taken also from the base of each seminal vesicle. A biopsy disposable device was used (CR Bard, needle: 18G, specimen: 1.8cm). Every sample was carefully labeled according to its location.
Results: Median patient age was 66 years (ratio: 48–86) and median PSA 9.3ng/ml (ratio: 2.7–118). Median prostate volume before procedure was 47cm^3(ratio: 18-137) and after, 56cm^3 (ratio: 20-178). Median number of prostate cores was 36 (ratio: 18-68).
Positive result for adenocarcinoma was found in 47 patients (39.8%). Gleason score was ≤6 in 21 patients (44.7%), 7 in 25 patients (53.2%) and >7 in 1 patient (2.1%).
From the patients that previously have been submitted to at least one negative transrectal prostate biopsy, positive were found 18 (41.9%).
Urinary retention during first 24 hours after the procedure developed in 10 patients (8.5%) and a Foley catheter was inserted for 2 days. The majority of the patients developed hematuria that resolved spontaneously after 1-3 days.
Conclusions: TPGB is well tolerated by patients and can be used safely for the detection and accurate staging of prostate cancer. This technique can be strongly considered if prior transrectal biopsy is negative but suspicion of the disease sustains.

P33: DOUBLE STAPLING TECHNIQUE (DST) FOR LOW ANTERIOR RESECTION OF THE RECTAL CARCINOMA. EXPERIENCE FROM AN ALBANIAN COHORT

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Aim: To demonstrate a new technique used in our clinic and to evaluate the feasibility of the DST in our patients with low rectal cancers and assess its impact on local recurrences and on anastomotic leak.
Methods: Peri-operative and short-term follow-up data were prospectively documented in all 26 patients, undergoing rectal resection for carcinoma using a double stapling technique with a stapled anastomosis at our institution over a 3-year period. The rectum was stapled transversely more than 2 cm below the tumour using the adjustable-angle linear stapler (Roticulator). The first roticulator is kept on the distal rectal stump and rectal lavage was applied by irrigation through the anorectal canal to clear it of debris and intraluminal tumor cells that might jeopardize the short- and long-term health of the anastomosis. With tension applied on the first stapler, a second roticulator is placed distal and adjacent to the first so that no debries and tumor cells are involved in the anastomotic line. The lower rectum is transected between two staplers. Than the circular stapler is applied through the anus and the anastomosis is completed in the usual fashion.
Results: Two patients developed small rectovaginal fistula managed by the conservative treatment and healed 6-8 weeks later. All patients had an operative procedure without events, with an average duration of hospital stay 8.5 days.
Conclusion: This study demonstrates the feasibility of the DST in a country where the incidence of colorectal cancer is increasing and sphincter preservation assumes greater significance. Double-stapling technique is safe for constructing an anastomosis after excision

of the rectum for cancer, in terms of the risk of leakage, the development of an anastomotic stricture, or local recurrence.

P34: EUS- GUIDED FNA BIOPSY IN PATIENTS WITH SUSPECTED PANCREATIC CANCER. THE EXPERIENCE IN DIAGNOSTIC CLINIC IN ALBANIA

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Background: EUS as an important tool for diagnostic of solid pancreatic lesions, has the benefit of being a minimally invasive, well-tolerated procedure, although results are operator-dependent. The addition of FNA (EUS-guided FNA) provides samples for cytopathologic analysis, a major advantage over other imaging techniques.
Objectives: The aim of our study was to evaluate the diagnostic accuracy of endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) biopsy in patients with suspected pancreatic cancer.
Methods: All patients with suspected pancreatic cancer were prospectively evaluated.
A single gastroenterologist performed all EUS-FNAs in a private diagnostic clinic.
Results: Between September of 2012 and July of 2013, a total of 27 patients (mean age 55.7 yr) underwent EUS-FNA procedure for a pancreatic mass were identified by CT scan or MRI. The mean tumor size was 25 x 30 mm. The median number of passes was two (range one to four).
Citology and biopsy examination revealed that 19 lesions were pancreatic adenocarcinoma, 3 lesions were mucinous cystic neoplasm; for 3 patients was concluded negative for malignancy and for 2 patients the result was unsatisfactory sample. Tumor size, tumor location, and number of needle passes did not significantly influence diagnosis, but immediate cytologic evaluation was influential.
Conclusions: EUS-FNA is highly accurate test for the detection of pancreatic adenocarcinoma by using aspiration cytology and biopsy, when other modalities have failed.

P35: INCIDENCE OF UNSUSPECTED GALLBLADDER CANCER DURING AND AFTER LAPAROSCOPIC CHOLECYSTECTOMY

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Introduction: There are many cases reported in literature of unsuspected gallbladder carcinoma (GBC) during and after laparoscopic cholecystectomy (LC). Some of them reported a good prognosis after LC. But the role of laparoscopy is unclear. We conducted this retrospective study of our cases with incidental GBC during and after LC.
Methods: We reviewed 3561 patients who underwent LC from June 1995 to June 2005 In "Mother Tereza" Hospital institution of which, 12 (0.33 %) diagnosed with unsuspected GBC.
Results: These 12 patients consisted of 4 men and 8 women, whose ages ranged from 61 to 82 years, with a median age of 74 years. Threee patients with a pT1a tumor (limited to mucosa) and 1 patients with a pT1b tumor (muscle layer) underwent no further operation. The other 8 patients with a pT2 tumor (subserosa) were converted into open procedure and a more extended procedure with lymph node dissection. All of 8 patients died in a period of 20 months and the cause of death was as below: 2 from bone metastasis, 2 from peritoneal metastasis and 4 from local recurrences. Four patients (3 with pT1 and 1 with pT2) had a good prognosis
Conclusions: Early stage of gallbladder cancer (pT1) have good prognosis if managed with Laparoscopy. More advanced stages we concluded that have a bad prognosis despite treatment with more radical procedure

P36: WHAT IS THE ROLE OF ENLARGED LYMPH NODE RESECTION ALONE IN PATIENTS WITH NONSEMINOMATOUS GERM CELL TUMOR WHO HAD STAGE II OR III DISEASE?

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Introduction: Retroperitoneal lymph node dissection is an important treatment modality in nonseminomatous germ cell tumors of the testis. However, the role of more limited surgical approaches such as resection of enlarged lymph nodes only is still controversial.
Methods: Between January 1991 and December 2010, charts of 94 patients who underwent resection of enlarged retroperitoneal lymph nodes alone were reviewed. Pathologic findings, local recurrence, and adverse effects were noted after this surgical approach.
Results: The median age was 25.5 years. Twenty-one (22.6%) patients had lung metastasis, and 5 (5.4%) patients had non-regional lymph node metastasis at the initial visit. Eighty-seven (91.6%) patients received chemotherapy after inguinal orchiectomy, and the other patients had mass resection only for enlarged lymph nodes without prior chemotherapy. In patients who had chemotherapy before surgery, the median retroperitoneal lymph node size before and after chemotherapy cycles was 55 mm and 32.5 mm, respectively. The pathologic assessment of retroperitoneal masses revealed mature teratoma in 51.6% (n=47) of patients, viable carcinoma in 20.9% (n=19) of patients, and necrosis or fibrosis in 27.5% (n=25) of patients. The median follow-up time was 60.2 months (range, 2.7-334.8 months). During follow-up, 5 (5.4%) patients had radiologic relapse at the retroperitoneal area, and 3 patients developed systemic metastases. Six (6.4%) patients died of their disease, 2 (2.1%) patients were alive with disease, 86 (91.5%) patients were healthy at the last follow-up. Ejaculation status was recorded in 56 patients. Antegrade ejaculation had preserved in 53 (94.6%) of these patients.
Conclusions: Resection of enlarged lymph node metastases alone is a reasonable treatment option for patients with nonseminomatous germ cell tumors.

P37: SURGICAL EXCISION OF CEREBELLAR MEDULLOBLASTOMA: PEDIATRIC CASE REPORT. ADVANCES IN BIOLOGY AND NEW APPROACHES TO TREATMENT

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Introduction: Medulloblastomas are highly malignant embryonic tumours of the cerebellum accounting for 20% of all intracranial tumours of childhood. Although medulloblastoma has been considered a unique disease, several studies demonstrated remarkable intertumor heterogeneity as defined by transcriptional and genetic profiling. Medulloblastoma is commonly recognized to originate from Granule Neuron Precursor Cells or other precursors in the external germinal layer, which fail to differentiate and keep proliferating. Based on identification of molecular phenotypes and clinical characteristics these malignancies constitute four distinct subgroups: Wnt, Shh, Group 3, Group 4.
Purpose: We report a 9-year-old girl who presented to our emergency department with symptoms of persistent headache starting 8 days ago. Head CT scan detected a 4cm-diameter mass, located in the right cerebellar hemisphere. She underwent paramedian suboccipital craniectomy following excision of the lesion. Based on the 3 factors: child's age (>3 years old), no residual tumor and no metastasis, our patient was classified as standard-risk. Surgical treatment was combined with postoperative radiotherapy and currently the third session of adjuvant chemotherapy has been completed (cisplatin, vincristine).
Results: The patient has already survived 8 months post-operatively and remains free of relapse. Current multimodal treatment of medulloblastoma has led to a five year overall survival of about 90% for average-risk patients and of 70% for high-risk ones (3 out of 3 criteria). Despite recent treatment advances, five year

disease-free survival remains low (36%) for patients with dissemination, and approximately 30% of the children will die from their disease.

Conclusion: Our knowledge potentiates change in medulloblastoma classification. Further research is needed, though, to evaluate the different molecular subgroups. We hope that, based on better understanding of key biological pathways, in the near future the introduction of targeted therapies in standard treatment recommendations shall hold promise for improved therapy and better overall outcome of this deadly disease.

P38: RECONSTRUCTION OF SKIN DEFECTS AFTER SURGICAL REMOVAL OF PAROTID MALIGNANT TUMORS

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Background: Though relatively rare, malignant parotid tumors represent 12-22% of all parotid tumors and exhibit a wide histological variability. In early stages, surgical resection followed or not by adjuvant radiotherapy remains the treatment of choice for these tumors. Depending on clinical and pathological findings, surgical procedure includes a variety of options such as partial parotidectomy, superficial parotidectomy, total parotidectomy, and radical parotidectomy with or without neck dissection.

Parotidectomy for malignant neoplasms may result in extensive resection of the surrounding tissues and adjacent anatomical structures including the skin that covers the parotid gland. Skin defects vary in extent, depending on skin invasion by the tumor. Failure to address these defects may lead to functional and aesthetic sequelae, such as prominent skin depression in the preauricular area, facial nerve injury, and mainly facial asymmetry. Local flaps are usually used for reconstruction of small-sized defects. Larger skin defects require regional flaps as well as free tissue transfer.

Purpose: The aim of this study is to demonstrate various reconstructive options in cases with skin defects following ablative surgery of parotid malignant tumors. The results of each reconstructive option as well as the advantages and disadvantages of its use are presented.

Materials and Methods: Sixteen patients with post-ablative skin defects following parotid surgery were reconstructed in Oral and Maxillofacial Surgery Department of Evaggelismos Hospital, Athens. Small-sized defects (n=10) were repaired with various types of local skin flaps, such as Mustarde flap, MacFee flap, as well as free skin grafts. Larger defects (n=6) were reconstructed with pectoralis major myocutaneous flap.

Outcomes: All patients except one were satisfied with reconstructive outcome. One patient died because of serious local infection, while other complications did not occur.

Conclusions: Reconstruction of skin defects following surgical resection of parotid malignant tumors constitutes a challenge for surgeons. Various options are available and should be properly assessed and individualized. Locoregional flaps that are demonstrated in this study provide satisfactory functional and aesthetic results.

P39: RECONSTRUCTION BY LATISSIMUS DORSI FLAP ALLOWS EXTENSIVE RESECTIONS OF BREAST CANCER AND GOOD COSMESIS

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Background: Conservative treatment of breast cancer consists in partial mastectomy, axillary staging and radiation therapy of the breast. It became, since 1980, a gold standard for the management of early breast cancer. With the progress of screening methods and the increased diagnosis of early breast cancer, women are asking for this conservative treatment, even in more advanced cases and after neoadjuvant chemo or hormonotherapy. Oncoplastic surgery was proposed to resolve this problem and to facilitate the conservative mastectomy. Techniques of oncoplastic surgery include the latissimus dorsi flap (LDF). Oncoplastic surgery has been practiced in Lebanon since early 2000, but has never been seriously evaluated in the therapeutic armamentarium of breast cancer.

Objective: This is a retrospective study aiming to collect a series of LDF performed in Lebanon, and to evaluate the role of this oncoplastic technique in the conservative treatment of breast cancer. The technique, the indications and the long-run results of LDF should be reviewed.

Material and Method: 60 cases of LDF were collected, through the clinical and operative files of all breast cancer cases treated by one academic surgical oncologist. The patients have been treated conservatively, between 2001 and 2013, for breast tumors whose resection had a high risk of causing deformities or

needed a classical total mastectomy. All the patients gave their written consent for this procedure that was supposed to allow a wider resection and to yield a good cosmesis.

Results: LDF was used in the treatment of 60 breast tumors, infiltrating ductal carcinoma in 77% of cases and infiltrating lobular in 12%, occurring in women 52.6 year old in average. The resected breast specimen had an average volume of 298 cm^3. The clinical status of tumor was T0= 13%, T1= 13%, T2= 43%, T3= 23% and T4= 3%. The lymph nodes were clinically free in 87% of cases. Surgery was preceded by neoadjuvant chemotherapy in 40% of tumors, thus explaining the small remaining pathological size of the tumor that was 1.94 ± 1.1 cm. LDF served to reconstruct the external half of the breast in 33 cases, the internal half in 23 cases and the central area in 4 cases. It was associated to axillary dissection in 57% of tumors and to sentinel node biopsy in 43%, and was followed by radiation therapy in 90% of cases with a usual dose of 60 Gy. Partial or total necrosis of LDF happened in 3 cases only, chronic ischemia in 2 cases and breast deformity in 5 cases. Cancer recurred only in 3 cases (6%).

Conclusion: LDF is a resistant flap that can be used in the resection of large tumors that are located in any of the four quadrants of the breast, mainly after neoadjuvant treatment. It is of particular interest in unilateral breast surgery when other oncoplastic techniques, mainly reductive, are not applicable because they should apply on both sides. Deformity of the breast and cancer recurrence after LDF are rare events.

P40: THE PADDING TECHNIQUE VERSUS THE CLASSIC SUCTION DRAIN USED IN COMPLETE AXILLARY LYMPH NODE DISSECTION

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Introduction: Breast cancer constitutes 37% of all female cancers. In conservative breast surgery with complete axillary node dissection a drain is placed into the axilla to prevent seroma. Drains failed to prevent formation of seromas, so padding technique for closing post-operative space after complete axillary lymphadenectomy without use of a drain was described.

Purpose: This prospective study was carried on 30 female patients. Group (A): composed of 15 patients with padding of the axilla without the use of a drain, while Group (B): composed of 15 with a single drain.

Results: There was no significant difference between the two groups in clinical_characteristics. The use of axillary drain did not prevent seroma formation and was associated with a significant increase in postoperative pain, discomfort, limitation of shoulder motility, wound infection and delayed recovery; affecting the quality of life and normal activities. The padding technique however, allowed a speedy recovery, timely start of postoperative therapy and improved markedly the patient well being and return to normal daily activities. Obese patients with a BMI higher than 35 developed postoperative seroma which was mainly a subcutenous collection rather than true axillary space seroma.

Conclusion: Axillary padding is a feasible and safe technique. It needs accurate and proper patient selection to avoid postoperative complication especially subcutenous seroma.

P41: THE ROLE OF POSTMASTECTOMY IRRADIATION IN T1-2N1 BREAST CANCER PATIENTS

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Purpose: The aim of this retrospective study is to evaluate the role of radiotherapy in locoregional control and survival after mastectomy in T1-2 N1 breast cancer patients.

Methods and Materials: Survival and local recurrence rates of T1-2 N1 (n=145) breast cancer patients who underwent mastectomy with or without adjuvant radiotherapy between 1998 and 2005 were analyzed retrospectively. Kaplan-Meier log -rank test was used to determine local recurrence rates (LRR). Risk factors for survival and local recurrence were evaluated by using the Cox regression test.

Results: Median follows up was 89 months. Median age was 52 (range 29-84). Sixty two (%42) of the patients were premenopausal, while 83 (% 58) were postmenopausal. 89 (% 61) of the patients underwent radiotherapy. Chest wall and axillary region irradiated 50 Gy in 5 weeks. All of the patients received adjuvant systemic therapies including chemotherapy, hormonal therapy or both.
In follow up period 6 (%4) of patients experienced locoregional recurrence; 3 (%3) were in radiotherapy applied, 3 (%5) in radiotherapy unapplied patients. Five and 10 year survival rates for radiotherapy received patients were % 94 and % 87, and for unrecieved patients % 80 and %73 respectively. There was no significant difference in locoregioal recurrence and survival rates between these two groups of patients. In univariate analysis tumor size and number of positive lymph nodes were found statistically significant factors associated with survival rate; on the other hand, premenopausal status and tumor size were found statistically significant factors associated with locoregional recurrence rate ($p<0.05$).
Conclusion: Although statistically significant survival and locoregional control rates were not shown with radiotherapy in our patients, the improvement of survival was obtained. Because of that, radiotherapy should be recommended to T1-2 N1 patients after mastectomy until this controversial role of radiotherapy for this stage is clarified.

P42: HYPOFRACTIONATED RADIOTHERAPY AFTER MASTECTOMY :ANALYSIS OF ACUTE TOXICITY

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Aim: Evaluation of acute skin toxicity in patients with mastectomy undergoing in radiation therapy with hypofractionated schedule (HFRT)and the conventional schedule(CRT).
Material and Methods: 19 patients with mastectomy received with HFRT in the chest wall and supraclavicular region a total dose of 42.5 Gy in 16 fractions and 17 patients with mastectomy received with CRT in the chest wall and supraclavicular region a total dose of 50 Gy in 25 fractions.The age group was 39 to 78 years and all the patients were undergoing to chemotherapy (neoadjuvant or adjuvant).Acute skin toxicity were assessed by the RTOG toxicity criteria.
Results: All the patients undergoing to a CT-simulation and a 3-D conformal treatment planning was used.Photons (6MV) tangentials beams were used for chest wall. Grade I acute skin toxicity was observed in 57% of the patients receiving HFRT and in 56% of the patients receiving CRT.Grade II acute skin toxicity was observed in 31%% of the patients in the hypofractionated schedule and in 28 % of patients undergoing in standard radiotherapy schedule.Grade I II acute skin toxicity was observed in 10% of the patients receiving HFRT and in 8% of the patients receiving CRT.
Conclusions: There was no difference between the two schedules of RT(HFRT and CRT)concerning acute toxicity in postmastectomy patients.Results of late toxicity will be presented after a longer follow-up.

P43: EARLY AND SAVE TUMOR RESPONSE USING IMAGE GUIDED CONCOMITANT BOOST RADIOTHERAPY TECHNIQUE

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Introduction/Purpose: Local control of disease is often one of the main objectives in patients with advanced unresectable head and neck, lung, cervical and brain tumors. The introduction of image guided radiotherapy offers the opportunity to safely apply a supplementary dose to the macroscopic disease. This accelerated radiotherapy course, known as concomitant boost, has the advantage of increasing the total dose delivered and tumor response without increasing the number of fractions.
Materials and Methods: From May 2009 to May 2013, 127 patients were treated with concomitant boost technique. The distribution of primary tumors was 73 patients with lung cancer, 35 patients with head and neck cancer,11 patients with brain tumours and 6 patients with cervical cancer. patients received chemotherapy during radiation therapy. Patients were treated using the conformal or VMAT technique. Planning target volume (PTV) was treated daily with 1.8 Gy for 5 to 6 weeks to a total dose of 45-54 Gy, while the dose to the Gross Tumor Volume (GTV) was boosted up to 55-65 Gy depending on the anatomic region. Organs at risk were irradiated to safe limits. In 74% of the patients we readapted the treatment plan due to local tumor regression using image guidance data (CBCT).
Results: All patients completed the treatment plan with no major toxicity. Follow up was scheduled at the end of the treatment, three and nine months after. All

patients achieved local tumor control, 78 patients with complete tumor response, 39 patients with partial response and 10 with stable disease.
Conclusions: Concomitant boost in combination Image Guided Radiotherapy is a feasible, safe and effective treatment for patients with unresectable carcinomas. Results are encouraging and promising regarding early locoregional disease control.

P44: HYPOFRACTIONATED RADIOTHERAPY IN NSCLC. PRELEMINARY RESULTS

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Introduction: The study of hypofractionated external beam radiotherapy in NSCLC as a curative scheme in stage IIIA-IVA disease.
Purpose: 10 patients (9 men and 1 woman) with median age of 66 years old (range 80-59) received 3-dimentional conformal external beam radiotherapy in linear accelerator and energy of 6MV. All the patients treated daily, from Monday to Friday with 275 cGy/fr, 20 fractions, 4 weeks, total dose of 55 Gy. The histology report showed adenocarcinoma in 3 cases and squamous carcinoma in the other 7 cases. Before radiotherapy, all the patients received chemotherapy. One of them was operated. Half of the patients had 2-field radiotherapy plan and the others 3-field plan. All the patients received prophylactic medication for radiation esophagitis.
Many factors were taking into account before deciding about this radiotherapy scheme (age, performance status, extent of the disease, DVH of treatment plan).
Results: The patients completed their treatment without any acute side effect, grade III-IV. After one year of follow up, there was no local relapse, inside irradiated area. One patient died one month after the completion of treatment and 3 patients had distant metastases.
Conclusions: This hypofractionated scheme is quite effective and radiobiologically equivalent with the standard one (33-35 fractions, 2 Gy/fr) especially when the irradiated area is not extended. Sometimes, it is a cost-effective solution in order to face a waiting list in a busy radiotherapy department.
It is quite interesting to study the late effects of radiation in these patients. So much more time of follow up is necessary.

P45: RADIATIONRECALL MYOSITIS IN A PATIENT WITH NON-SMALL CELL LUNG CANCER TREATED WITH GEMCITABINE

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Introduction: Radiation recall phenomenon is an inflammatory reaction appearing to previously irradiated areas. Antimetabolites, such as gemcitabine, are among those anticancer agents reported to trigger this phenomenon when administered after radiation therapy. Cutaneous involvement is almost always present in this relatively rare event.
Purpose: To present a case of gemcitabine-induced radiation myositis in the absence of skin involvement.
Results: A 56 year-old man presented with a , poorly differentiated, non- small cell cancer of the right upper lung lobe stage IIIB ($cT_3N_2M_x$). The patient was referred for definite chemoradiotherapy. He received the first chemotherapy cycle with the combination of Cisplatin 75mg/m^2 ($D_{1)}$ and Gemcitabine on 1000mg/m^2 ($D_{1, 8}$) and then he received concomitant chemoradiotherapy with 33 daily fractions to a total dose of 66Gy concurrently with weekly Cisplatin (40mg/m^2). Finally, he was planned to receive 5 additional cycles of Cisplatin - Gemcitabine. During the fourth cycle of his post-radiation chemotherapy the patient complained about a pain of his right shoulder that became constant and severe within a week, aggravating by shoulder motion. During physical examination a very painful nodule was palpated in the subscapularis muscle. Notably, no skin reaction was present. MRI of the shoulder revealed a fusiform swelling of subscapularis muscle, within the radiotherapy portal. He was offered a diagnostic biopsy and histology revealed inflammatory cells within the muscle.
The diagnosis of myositis as a radiation recall phe-

nomenon was first in line. Treatment consisted of steroid IM to the involved muscle and PO therapy with an immediate response and relief of pain.
Conclusion: Although radiation myositis is a relatively rare event, radiation recall phenomenon should be kept in mind whenever a patient presents with pain within a previous irradiation field during exposure to certain chemotherapeutic regimens.

P46: THE EFFECTS OF PROTECTIVE AGENTS AGAINST CISPLATIN AND RADIOTHERAPY INDUCED CELL DEATH

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Introduction: Cisplatin and radiotherapy are commonly used regimens in the treatment of pediatric malignant tumors such as medulloblastoma. However, they have many dose limiting adverse effects.
Purpose: The effects of Acetyl-L-carnitine and N-acetyl cysteine on apoptotic cell death mechanisms induced by cisplatin with or without radiotherapy on medulloblastoma cells.
Results: CP decreased the cell viability at 75 uM dose and apoptotic cell death occurred 14.5% and caspase 3 and 8 were increased ($p<0.05$). RT decreased the cell viability and apoptotic cell death occurred 13.3% and caspase 3 and 8 were increased ($p<0.05$). CP-RT treatment decreased the cell viability when compared to both CP and RT and apoptotic cell death and caspase 3 levels were not affected much ($p<0.05$). Caspase 8 levels were increased in CP-RT group when compared to both RT and CP ($p<0.05$). ALC decreased the apoptotic cell death of CP-RT treatment and caspase 3 and 8 levels were affected as same manner ($p<0.05$). NAC reduced the apoptotic cell death and it was effective on caspase 8 levels ($p<0.05$).
Conclusion: ALC and NAC decreased the apoptotic cell death of cells with CP and RT treatment and extrinsic apoptotic pathway affected in medulloblastoma cells. To better understand the effects of ALC and NAC on the apoptotic cell death mechanism caused by CP and RT, intrinsic pathway also must be examine.

Key Words: *Medulloblastoma, cisplatin, radiotherapy, apoptosis, extrinsic pathway*

P47: THE ROLE OF HYPOFRACTIONATED RADIOTHERAPY FOR LOCALLY ADVANCED HEAD AND NECK CANCER PATIENTS UNFIT FOR RADICAL TREATMENT. REPORT OF TWO CASES AND REVIEW OF THE LITERATURE

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Introduction: The standard therapy for locally advanced head and neck cancer is long-course concomitant radiochemotherapy. However, this approach is not suitable for patients with poor performance status or significant comorbidity.
Purpose: To present the results of hypofractionated radiotherapy of locally advanced spuamous cell carcinoma of the base of the tongue in two patients unfit for radical treatment.
Results: Both patients presenting with progressive difficulties in swallowing and articulation and were referred to our department for radiochemotherapy. The short-course radiotherapy was the best choice for both patients since the first denied the long treatment course and the other had a bad performance status. There are literature reports on the use of different radiation therapy schedules for palliation of patients that are not candidates for the standard long-course radiotherapy. Sixteen fractions of 3.125Gy give a total response rate of 73% and local control of 62% and 32% at one and three years, respectively. The HyPo trial (30Gy/5fr/2weeks and 6Gy boost) reported an improvement in quality of life in 62% of patients. Both patients were referred for dental assessment and percutaneous gastric tube placement and had a planning CT scan of the head and neck. They were treated with 3D conformal radiotherapy receiving 30Gy in 10 fractions in the primary tumor, neck and supraclavicular fossa and 15Gy as a boost in the gross tumor volume in combination with weekly cisplatin. Reported toxicity was grade II mucositis. At the end of radiation therapy both patients had significant clinical improvement with substantial decrease of gross tumor volume and pain, increase of tongue mobility and improvement of articulation.

Conclusion: Short-course radiotherapy should be kept in mind for patients with locally advanced cancer of the base of the tongue. It can offer tumor decrease and symptom control with acceptable toxicity in patients unsuitable for standard radiochemotherapy approach.

P48: A RARE CASE OF ANAPLASTIC CARCINOMA OF ECTOPIC THYROID TISSUE TREATED WITH PALLIATIVE RADIOTHERAPY

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Introduction: Ectopic thyroid tissue carcinoma is diagnosed in 7% of the adult population. The two lobes of thyroid gland and the thyroglossal duct are the most common sites of its growth and papillary carcinoma is the most common histologic type reported in the literature.
Purpose: To present the rare case of anaplastic carcinoma of ectopic thyroid tissue treated with palliative intend in our department.
Resluts: We present the case of a 70 year old man with a lesion of the right submandibular triangle causing distressing symptoms of dyspnea and pain along with an increase in size the last 6 months. A tumor in close proximity to the salivary gland and few enlarged cervical lymph nodes were documented on the CT and MRI imaging and the lesion was characterized as a mixed salivary gland tumor. After surgical excision the histologic report revealed a malignant tumor with necrosis, fibrosis and immunohistochemical characteristics of an anaplastic carcinoma of ectopic thyroid tissue. The patient was offered chemotherapy but after 3 cycles of CDDP/Paclitaxel there was local tumor progression causing dyspnea and pain.
By the time the patient was referred for radiation therapy he had also metastatic lung disease. Thus, a short course of palliative radiotherapy was deemed suitable for this patient. He was treated with hypofractionated radiation therapy to a total dose of 39Gy in 13 fractions. At the end of radiotherapy course the patient had a remarkable clinical and radiological response with a significant decrease of preexisting dyspnea and acceptable toxicity. There was mucositis grade 2 and dermatitis grade 1. However, one month later the patient was diagnosed with multiple brain metastasis and was offered a short course of whole brain radiotherapy.
Conclusion: Short-course palliative radiotherapy is effective in controlling obstructive symptoms of patients with anaplastic thyroid carcinoma.

P49: A RETROSPECTIVE ANALYSIS OF PREOPERATIVE RADIATION THERAPY FOR RECTAL CANCER: A SINGLE CENTER EXPERIENCE ON LONG TERM RESULTS

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Purpose: To evaluate 196 patients with diagnosis of rectum cancer who were applied preoperative irradiation with or without chemotherapy in our clinic.
Material and Methods: Between years of 2004 and 2012, a total of 196 patients who were treated with preoperative irradiation were analyzed. Histopathological parameters were evaluated. Local recurrence and survival rates were calculated with Kaplan -Meier long- rank test.
Results: Median age was 58 (range 20-86); M/F ratio was 1.7/1. Distribution of 196 patients according to pretreatment tumor stages T2, T3,T4 were 22 (11.2%), 147(75%), 27(13.7) respectively. Tumor stage was found to be significantly affecting survival (p= 0.04), whereas lymph node status wasn't. Sixteen of 196 patients were irradiated 25 Gy/5 fractions, remaining received 45-56 Gy/ 23-28 fractions, and 4 patients received less than 45 Gy. Those patients who were also applied concomitant chemotherapy with either FUFA Mayo regime (126/196) or Tegafur + FA (40/196) didn't show significant difference. Out of all, 18 patients were inoperable (4 of them refused the surgery). Miles was applied to 66 of 178 patients; LAR was applied to 112 patients. Operation types didn't affect survival. Histopathological tumor stages were as following: T0 (complete response):12.9% (23/178); T1-T2: 29.2% (52/178); T3: 51.6% (92 /178); T4: 6% (11/178). Postoperative tumor stage was found to cause statistically significant survival difference (p= 0.02). N stage distribution was N0: 61.7% (110/178); N1:20% (36/178); N2:18% (32/178). N stage was found to be highly significant (p= 0.005). Vascular invasion was not significant statistically, whereas patients with absence of perineural invasion had significantly longer survival (p=0.03).

Local recurrence was observed in 4 patients (2.2%); distant metastasis occurred in 36 patients (20%). Overall 5 year survival rate was calculated as 53.9%.
Conclusion: Preoperative chemo-radiotherapy is standard treatment of choice in selected patients in our clinic. Results were satisfied, comparable to literature.

P50: A COMPARATIVE DOSIMETRIC STUDY OF 3D CONFORMAL RADICAL RADIOTHERAPY FOR BLADDER CANCER PATIENTS VERSUS CONVENTIONAL 2D RADICAL RADIOTHERAPY IN NCI-CAIRO

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Purpose: This study was to compare this multiple-field conformal technique to the 2D conventional technique with respect to target volume coverage and dose to normal tissues.
Materials and methods: We conducted a single institutional prospective comparative dosemetric analysis of 15 patients who recieved radical radiation therapy for bladder cancer presented to radiotherapy department in National Cancer Institute , Cairo in period between November 2011 to July 2011 using 3D conformal radiotherapy technique for each patient, a second 2D conventional radiotherapy treatment plan was done, the two techniques were then compared using dose volume histogram (DVH) analysis.
Results: Comparing different DVHs , it was found that the planning target volume (PTV) was adequately covered in both (3D & 2D) plans while it was demonstrates that this multiple field conformal technique produces superior distribution compared to 2D technique, with considerable sparing of rectum and to lesser extent for the head of both femora.
Conclusions: From the present study, it is recommended to use 3D planning for cases of cancer bladder especially in elderly patients as it produces good coverage of the target volume as well as good sparing of the surrounding critical organs.

Keywords: *Dosimetric study in cancer bladder*

Supportive Care

P51: ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH TONGUE CANCER

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Introduction: There seems to be a discrepancy between the subjective and objective perception regarding quality of life (QOL) of tongue cancer patients.
Purpose: To evaluate the suitability between the subjective perception and the objective impression in regard to the impact of the anti-cancer treatment on the quality of life of patients with mobile tongue cancer (MTC). MTC patients (N=10) that have undergone resection of their tumors (six also given radiotherapy) were interviewed and evaluated using the QOL EORTC standardized questionnaires. The questions assessed both physiological functionality of the oral maxillofacial system and psychological aspects (including body image) and aimed to record patients' experience during the week before the interview and during the week of the interview.
Results: Patients reported no or slight difficulty in chewing (N=6), no or slight difficulty in swallowing (N=8) liquids or meshed food, however half of the patients reported difficulty in swallowing solid food. Dental problems were reported by six patients. All of the irradiated patients suffered from dry mouth. Most of the patients (N=9) did not complain about pain. Half of the patients reported lack of pleasure from eating. Eight patients admitted that they had no problems eating with other familiar or unfamiliar individuals, while the other two patients avoided eating in the presence of other people. Speaking (directly or by phone) was not a problem in the majority of the patients (N=9). Half of the patients were not worried about their body image. Interestingly, half of the patients avoided answering questions related to their personal (intimate) relationships.
Conclusions: The subjective perception of the MT cancer patients confirms the objective impression in regard to their physiological functionality. The questionnaire revealed that more attention should be given to the patients' emotional feelings, body image and psycho-social relationships.

P52: COMPLICATIONS IN TREATMENT OF LUNG CANCER IN ELDERLY PATIENTS

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Introduction: Older patients with lung cancer have worse prognosis. Pre-existing comorbid conditions may severely affect treatment and recovery. Also, hematological and nonhemotological complications affect the outcomes.
Purpose: This study aims to identify the characteristics of lung cancer in older patients
Methods: Three hundred thirteen lung cancer patients included in the study between 2004 and 2012. Several characteristics were described in a questionnaire. SPSS-16 was used.
Results: Among 311 patients, 102 were higher than or equal to 65 years old. Most crowded group consisted of patients between ages of 65 and 69 (n=50, 49 %). Only one patient had age higher than 85 years. 9 female and 93 male patients were examined. In general, performance status was mostly ECOG II. Most of the patients had smoking status. The most common initial symptoms were hemoptysis, cough and dyspnea. Tumor was mostly included in the right lung. Stage IV was the most common stage at the diagnosis. Hematological toxicity was the major concern in this study. Among all of the older patients, most common toxicity associated with therapy was anemia which was followed by neutropenia. Second and third cycles of chemotherapy were two common cycles for anemia. Grade 3 and 4 toxicities were uncommon. Nonhematological toxicities were also seen. Emesis, fatigue and poor appetite were three most seen toxicities
Conclusions: Lung cancer is one of the most important issues in oncology practice. Older patients occupy a very different place among those patients. Aging, comorbid conditions may impair patients' status during chemotherapy and may increase toxicities. More attention should be given about treatment- related toxicities in elderly.

P53: STOMATITIS, GINGIVITIS AND PERIODONTAL ABSCESS IN A PATIENT WITH METASTATIC RENAL CELL CARCINOMA RECEIVING TEMSIROLIMUS AND BEVACIZUMAB: A CUMULATIVE TOXICITY?

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Introduction: Stomatitis, characterized by oral aphthous-like ulcers, has been associated with mTORIs, such as Temsirolimus (Torisel®, Pfizer). Gingival bleeding and osteonecrosis of the jaw has been reported in association with bevacizumab therapy. Both targeted agents have been also related to increased risk of infection. Their potential cumulative oral toxicity, when administered in combination, has not been studied.
Aim: We present the oral toxicity related to the combined administration of temsirolimus and bevacizumab in a patient with metastatic renal cell carcinoma.
Report of case: A patient with metastatic renal cell carcinoma, who received temsirolimus and bevacizumab, developed mTORI-associated stomatitis and unilocular gingival bleeding, focal mucosal necrosis, bleeding and pain. A bacterial infection was suspected as the cause of mucosal necrosis. Gingival bleeding was also related to the administration of bevacizumab, however the additive effect of temsiroimus was also considered. Temsirolimus can depress hypoxia-inducible factor indirectly affecting angiogenesis. Infection could be related to both, temsirolimus and bevacizumab. Antineoplastic therapy was interrupted for one week. Stomatitis was treated with topical corticosteroid solution, while gingivitis responded well to metronidazole. Tentative oral hygiene was also introduced. Swelling, pain, purulent secretion tooth mobility and regional radiolucency compatible with osteonecrosis stage 0, possibly related to bevacizumab administration, developed two months later on the site of previous gingivitis. Remissions and exacerbations of pain, swelling and purulence have been treated with intermittent courses of antibiotics.
Conclusion: A cumulative oral toxicity of temsirolimus and bevacizumab therapy was considered in the present case. Educating patients on the importance of reporting oral adverse events may enhance early recognition and timely management and ensure ad-

herence to treatment. Oral/dental oncology specialists can play a key role in the diagnosis, prevention and management of this toxicity and their expertise should be included when designing oncology trials evaluating agents with known or suspected oral toxicities.

P54: ORAL COMPLICATIONS IN LUNG CANCER PATIENTS: EXPERIENCE OF A DENTAL ONCOLOGY REFERRAL CENTER

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Purpose: To present our 4-year experience (2009-2012) in the treatment of oral complications in lung cancer patients.
Patients and Methods: Forty three patients (21 women, 22 men, mean age 62.6 years) were included in the analysis. Thirty patients received active chemotherapy treatment; 9/30 (30%) received conventional chemotherapy in combination with targeted therapy, 11/30 (36.7%) targeted therapy and 10/30 (33.3%) conventional chemotherapy. Twenty-one patients received i.v. bisphosphonates (zoledronate 76.2%). Eleven patients received bishosphonates combined with bevacizumab; 4 of them had interrupted bevacizumab at the time of referral. Oral clinical and radiographic evaluation was performed and oral hygiene instructions were introduced to all patients.
Results: Thirty three patients were referred by their medical oncologist, 1 was referred by his dentist and 10 were self referred. Twelve patients (27.9%) presented with jaw osteonecrosis (Stage 0: 6, 50%, Stage I: 4, 33.3%, Stage II: 2, 16.7%). Six patients were diagnosed with oral candidiasis, 4 with herpes infection, and 2 with necrotizing ulcerative gingivitis. Nine patients had dental problems, while 5 patients were introduced to the Unit for preventive measures. Jaw osteonecrosis was treated with long term antibiotics, while local ozone oil was applied in 3 patients. Three dental extractions were performed in one patient with osteonecrosis stage 0. Today, 6 patients with osteonecrosis remain in partial remission, 3 are in complete remission, 2 were lost of follow up and 1 worsened. Of the 3 dental extractions, 2 healed and one led to osteonecrosis stage I. Patients with dental problems were further referred to their family dentists.
Conclusion: Osteonecrosis of the jaw, in the present series, was the most common oral complication. The dental oncology expert within in the multidisciplinary team contributed to the diagnosis of oral pathoses and of the osteonecrosis at the early Stage 0.

P55: DENTAL EXTRACTIONS IN ONCOLOGY PATIENTS RECEIVING INTRAVENOUS BISPHOSPHONATES. A CASE SERIES REPORT

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Introduction: Dental extractions are reported as the main risk factor for osteonecrosis (ONJ) in patients receiving i.v. bisphopshonates (BPs).
Purpose: To present the clinical course of 42 dental extractions performed in oncology patients who received intravenous bisphosphonates.
Patients and Methods: Twenty five patients (mean age 61.8 years) receiving i.v. BPs (mean time of administration 36 months) for multiple myeloma (11), breast cancer (13) and lung cancer (1) were included in the study. Patients were informed about the risk of ONJ and gave their consent. Antibiotics were administered for ≥ week before the extraction and until healing. Ozone oil was locally applied in 17 of 25 patients.
Results: Twenty nine extractions were performed in the mandible and 13 in the maxilla. All patients received zoledronic acid; 3 patients also received ibandronate or pamidronate. Twenty four dental

extractions were performed because of pain, purulence, and tooth mobility compatible with ONJ stage 0. Five extractions were adjacent to ONJ stage II. Dental pathology was the cause for 13 extractions. Healing was observed in 35 extractions. ONJ stage I developed after two extractions. The pre-existing ONJ lesion in the 5 cases subsided to stage I. Twenty patients did not received BPs during the extraction and healing period. Mean time of healing was 4.9 weeks in 17 patients with ozone applications versus 15 weeks in the 8 patients without ozone applications, while patient characteristics were similar in the two groups. Mean follow-up was 4.5 months.

Conclusions: High healing rate (35/37, 94.59%) following the dental extractions was observed. This denotes the need for reassessing the dental extraction as the main risk factor for ONJ.

P56: JAW OSTEONECROSIS IN A PATIENT WITH CHRONIC MYELOGENOUS LEUKEMIA RECEIVING IMATINIB

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Introduction: Jaw osteonecrosis is an uncommon adverse event related to antiresorptive agents such as bisphosphonates and denosumab. Cases of osteonecrosis have also been related to monotherapy with tyrosine kinase inhibitor agents, such as bevacizumab and sunitinib, with antiangiogenic and, at least local mucosal, immunomodulating effects.

Purpose: We aim to present the case of osteonecrosis in a 71 year old female with chronic myelogenous leukemia receiving imatinib, a potent inhibitor of bcr/abl, PDGF-R and c-kit.

Report of case: Female 71 y.o., receiving imatinib (2008-present) for chronic myelogenous leukemia, complained, in 2010, for pain on the left mandibular molar area following two dental extractions. Between 2005-2006, patient had received chemotherapy and rituximab for non Hodgkin's lymphoma and alendronate and one dose of intravenous zolendronic acid for osteoporosis. Nonhealing extraction, inflammation and purulence lead to the diagnosis of jaw osteonecrosis (2010), which was possibly related to the use of imatinib (2008-present) combined with previous bisphosphonate administration (2005-2006). Conservative management with antibiotics and basic oral care lead to the healing of osteonecrosis one year later (2011). Osteonecrosis recurred on the site of previous lesion one month after a single subcutaneous injection of denosumab (2012), which was administered due to patient's deterioration of osteoporosis. Bone sequestra were surgically removed under antibiotics. Basic oral care and antibiotics continued for two months. The patient today (July 2013) remains asymptomatic and continues the basic oral care and her imatinib therapy. The osteonecrosis lesion has been partially covered with mucosa.

Conclusions: Combined antiresorptive and targeted, with main or secondary antiagiogenic and immunomodulatory action, as in the case of imatinib, may increase the risk of osteonecrosis. With the increasing use of combination therapies, it is important for clinicians to be particularly alert and closely follow the patients.

P57: GREEK CANCER PATIENTS' SATISFACTION WITH THE NURSING CARE WHILE BEEN HOSPITALIZED

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Introduction: The patient satisfaction is one of the most reliability indicators concerning the nursing care and the total quality of care in health care services.

Aim: The aim of the present quantitative descriptive study was to investigate the in-patients satisfaction from the nursing care in an oncology hospital.

Methods: The sample was 298 in-patients with can-

cer. Patients completed the Risser satisfaction questionnaire only if they had been treated more than 2 days in the oncology units. The study was conducted during the period September – December 2010. The questionnaire is consisted of 25 questions divided in 3 subscales, the technical-professional, the educational and the confidence subscale. Patients responded to the questions on 5-point Likert scale. The questionnaire was standardized in the Greek language.

Results: Out of the 298 patients, 133 were male and 165 were female. The mean age was 71.5± 12.5 years. The cancer of digestive system (23,2%), the breast cancer (18,1%) and the prostate cancer (16,4%) was the most frequently diagnosis. The reliability for total scale was good; (Gronbach alpha = 0.78) and for the three subscales was 0.77, 0.79, 0.80. It was found that female was more satisfied in technical –professional group (p=0.475) and the confidence relationship with the nurses (p=0.402). The age, the length of stay and the diagnosis was not found to influence statistically important the patient satisfaction from the nursing care. The mean values of patient's satisfaction from the nursing care were high for the total scale and the 3 subscales. The patients were found to be less satisfied in the confidence subscale (3.9070).

Conclusions: The Greek cancer patients were overall found to be satisfied from the nursing care. This was reflected on the technical-professional, educational and confidence dimension.

P58: SEVERE DESTRUCTION OF THE MANDIBLE ASSOCIATED WITH MULTIPLE MYELOMA

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Background: multiple myeloma is a malignant neoplasm that is characterized by the proliferation of abnormal monoclonal plasma cell. Manifestations of multiple myeloma may include hypercalcemia, bone osteolytic lesions, anemia and renal dysfunction. Osteolytic lesions may develope within any bone including bones at the maxillofacial region.

Case summary: this report demonstrates a case of osteolytic lesions in the maxillofacial region in a 67-year-old woman presented for evaluation of mandibular swelling. Her medical history was remarkable for a multiple myeloma diagnosed 7-years ago that had been treated with autologous hematopoietic stem cell transplantation, chemotherapy and radiotherapy. An examination revealed a bony hard swelling in the left mandible. Paresthesia was present along the left inferior alveolar nerve distribution. Panoramic radiography and computed tomography demonstrated an ill-defined radiolucency area in the left mandibular molar and premolar regions. In addition, "punched – out" osteolytic lesions were noted in the right zygoma, condyle. The clinical and radiographic features were compatible with multiple myeloma. The lesion at the left mandible progressed within few months and caused pathologic fracture, trismus and severe pain.

Conclusions: multiple myeloma should be included in the differential diagnosis of osteolytic lesions in the maxillofacial region in adult patients.

P59: IATROGENIC KAPOSI SARCOMA OF THE ORAL CAVITY

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Background: Kaposi sarcoma (KS) is a vascular neoplasm that appears, in its classic form, on the lower extremities of elderly men, in regions around the Mediterranean Sea. Oral cavity involvement is more common in the iatrogenic and epidemic (AIDS-related) forms of KS. Iatrogenic KS is associated with immunosuppressive therapy in patients who have received organ transplants. This form of KS may present as solitary or multifocal muco-cutaneous lesions with, or without visceral involvement.

Case summary: A 56-year-old woman was referred to the Oral Medicine Clinic at the Sheba Medical Center due to gingival swelling. Clinical examination revealed a diffuse erythematous enlargement of the maxillary gingiva, a reddish- blue nodular enlargement of the right hard palate, symmetric vascular lesions on the buccal mucosa and teeth mobility.

The patient underwent allogeneic hematopoietic stem cell transplantation (HSCT) six month previously

due to myelodysplastic syndrome (MDS), and was treated with cyclosporine.
The palatal lesion was excised and examined microscopically. The histological sections revealed an admixture of granulation tissue with vascular proliferation occasionally showing a slit-like appearance. There were also foci of epithelioid endothelial proliferation. The latter were highlighted by CD34 and CD31immunostains. These findings arouse the possibility of drug-induced KS, which was further confirmed by positive immunostain for HHV8.
Cyclosporine was discontinued and replaced by Prograf (Tacrolimus) with partial resolution of the gingival swelling.
Conclusions: KS associated with organ transplantation usually occurs with transmission of Human Herpes Virus-8 (HHV-8) from the allograft to the recipient or, reactivation of latent infection. Cyclosporine therapy in particular, increases the incidence of KS related to organ transplant in HSCT patients.

P60: PREVENTION OF VTE IN SURGICAL ONCOLOGY PATIENTS: A COMPLETE AUDIT CYCLE

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Aim: Cancer is considered to be a state of acquired thrombophilia and therefore cancer patients are regarded as a high risk group for the development of venous thromboembolsim (VTE). The aim of our clinical audit was to evaluate the adherence to the Trust's guidelines for VTE prevention in surgical oncology patients.
Material and Methods: A total of 40 patients were included in our clinical audit. All of the patients were transferred to a surgical ward after initial admission to the Accident and Emergency Department, where during the investigation of their symptoms a gastrointestinal malignancy was detected or they had a known history of active cancer. The first 20 patients were included in the first part of the audit and the remaining 20 were included in the second part of the audit. We recorded the rates of completion of the relevant VTE risk assessment sheet by the medical staff, the prescription of pharmaceutical thromboprophylaxis, as well as the prescription of compression stockings, according to the current Trust's guidelines. The initial results were re-audited after relevant notifications posted on the Surgical Assessment Unit.
Results: During the initial survey, completion of the VTE risk assessment sheet by the medical staff was performed in 25% of patients, while pharmaceutical thromboprophylaxis was accurately prescribed in 80% of the patients. Moreover, compression stockings were accurately prescribed in 75% of the patients. When re-auditing the above mentioned after the release of the relevant notification, completion of the VTE risk assessment sheet was performed in 75% of cases, while pharmaceutical VTE prophylaxis and compression stockings were accurately prescribed in 90% and 100% of patients respectively.
Conclusions: Prevention of venous thromboembolsim in admission of cancer patients, especially in emergency admission settings, is an often overlooked parameter of the patients' care. Medical and nursing staff should be constantly informed and educated concerning VTE prevention measures, in order to achieve the maximum adherence to the optimal clinical practice policies.

P61: MANAGEMENT OF EROSIVE LICHENOID CONTACT STOMATITIS IN A PATIENT PREVIOUSLY DIAGNOSED WITH ORAL LYMPHOMA AND BISPHOSPHONATE-RELATED OSTEONECROSIS OF THE JAW

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Background: Lichenoid contact stomatitis may be caused by hypersensitivity or chronic toxic reaction from almost any dental material, especially amalgam. We present a case describing the management of erosive lichenoid lesion in a medically-complex patient.
Case summary: An 82 year-old-patient with history of primary diffuse large B-cell lymphoma in the lower lip, who has been treated in our department because bisphosphonate-related osteonecrosis of jaw (BRONJ) in the mandible, complained of persistent mouth burning sensation for several weeks, which impaired quality of life and nutrition. Beside the above mentioned conditions, the patient's medical history included diabetes mellitus type 2, hypertension, hyperlipidemia,

and osteoporosis. The patient regularly takes disothiazide, metformin, simvastatin, and vitamins (folic acid, B, and D). The oral examination revealed reticular-atrophic-ulcerative lesions in the right buccal mucosa and right side of the tongue adjacent to the maxillary first molar. The tooth was previously endodontically-treated, and had an extensive coronal amalgam restoration. The BRONJ lesion was stable with no local inflammatory or suppuration. The buccal lesion was biopsied, and histologic findings were consistent with lichenoid reaction. Clinically, the extensive amalgam restoration was suspected as the causative factor. However, extraction of the tooth was avoided because the risk for another BRONJ lesion. Therefore, the amalgam restoration was removed, the remaining tooth crown was amputated, and the root canals openings were sealed with glass ionomer cement. Following the procedure, the buccal and lingual lesions were resolved, with no relapsed during 10-month follow up.

Conclusions: Removal of the amalgam restoration led to complete resolving of the lichenoid contact stomatitis lesions. In case of indication for tooth removal in a patient with risk for BRONJ, crown amputation should be preferred. This case demonstrates the complexity of management of patients in the oral medicine office, who suffer from several conditions, and need a combined oral-dental care.

P62: CENTRAL VENOUS PORTS IN ONCOLOGICAL PATIENTS. THE EXPERIENCE OF A SINGLE ONCOLOGY UNIT

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Introduction: Central venous catheters (CVC) are often used in haematological patients for chemotherapy, blood products and parenteral nutrition infusion. They are a stable safe venous route, long-lasting and easy accessible having been in daily clinical oncology practice. Advantages of continuous infusion of chemotherapy regimen guarding patient's comfort, reducing the risk of local inflammation and overcoming the risk of extravasations of the cytostatic agents, are their usage background.

Methods: 46 patients with subcutaneous central port catheters implanted from Jan 2005 to July 2013 were reviewed and studied. Implantation techniques, duration time of the port and early and late complications were stated.

Results: Indwelling time was rated from 40days; the shortest up to 2800 days. In 98% of insertion cases, the successful position of the port's edge was checked with X-ray test performed post implantation. Early complications were pneumothorax in 2 % and unsuccessful insertion in 3%, while late ones documented in 12% of patients as: bacteraemia (2%), local skin inflammation (3%), venousthrombosis (2%), catheter migration (1%), skin degeneration over the port's surface (1%), leaking (1%), occlusion (2%).

Conclusion: CVCs play a key role in cancer patients therapies. Their placement is a safe procedure in experienced team with low rate of early complications. Late complications are manageable and may be avoided under careful guidelines of their manipulation/usage.

P63: INDIVIDUALIZED CARE IN PATIENTS DIAGNOSED WITH CANCER: THE CYPRIOT PERSPECTIVE

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Introduction: The concept of individualization has received extensive attention in the literature. Associations of individualized care were found with aspects such as work satisfaction and the professional practice environment. However, the concept has not been explored in the specificities of cancer care. This is important as individualized nursing interventions have been found to improve recovery, health-related quality of life and care quality. This paper is a part of large European study.

Purpose: This explorative and correlational study aimed to explore the concept of individualization (Individualized Care Scale- Patient version) in cancer care settings and explore any associations to quality oncology nursing care (OPPQNCS), trust in nurses (Trust in Nurses Scale) and overall quality of life (EuroQol 5D).

Results: The data were collected from 150 patients diagnosed with various types of cancer including breast, prostate, skin and lung cancers. The mean age of the participants was 57.15 (SD 13.49). The majority of the

patients had planned admissions (79.3%) to undertake treatment such as chemotherapy (63.3%), surgery (11.3%) and radiotherapy (8%). The questionnaires demonstrated high reliability with computed Cronbach α as follows: α=0.925 (ICS), α=0.891 (OPPQNCS), α=0.836 (Trust in Nurses Scale). Patients reported average to high levels of individualization during their hospitalization (mean 3,4221 to 3,9271) and the high levels of trust in their nurses were reflected on all items of the scale (mean 4.30 to 4.46). individualization was positively correlated to the provision of quality oncology nursing care and the trust in the nurses providing the care.

Conclusions: Individualization is a complex concept that appears to influence many other aspects such as the perceived quality of oncology nursing and the trust invested in nurses by the patients. These correlations indicate the positive outcomes of providing individualized care and the importance of introducing measures in clinical practice that ultimately promote individualization.

P64: EMBOLIZATION AND RADIOTHERAPY FOR BONE METASTASES FROM RENAL CARCINOMA

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Introduction: Bone metastases are estimated to occur in 1/3 of patients with renal cell carcinoma. The hypervascular nature of these lesions makes embolisation a reasonable treatment option for tumor decrease and symptom control.

Purpose: To present the combination of embolisation and radiation therapy for bone metastases from renal cell carcinoma and discuss treatment tolerance and clinical results.

Results: We present the cases of two men with bone metastasis from renal cell carcinoma. Computed tomography showed a tumor of the femoral bone with soft tissue mass and bone lysis. Both patients were referred for embolization and adjuvant radiotherapy as palliative therapy for pain and decreased mobility.

Before embolization a digital subtraction angiography (DSA) via the right femoral artery was performed and a superselective catheterization of the feeding vessels was carried out. A control angiogram, both pre- and post- embolization, was used to estimate the degree of vessel occlusion. For both patients, the embolization was performed with microcoils and Tris-acryl Gelatin Microspheres.

Four to eight weeks after the embolization, patients received palliative radiation therapy to the lytic lesion and remaining soft tissue mass. Compliance to radiotherapy schedule was excellent and there was no therapy-related toxicity. A decrease in pain was evident shortly after embolization but further pain control was reported at the end of radiotherapy. Long term follow-up is necessary to confirm tumor decrease in size and improved mobility.

Conclusion: Embolization in combination with radiotherapy appears a reasonable and effective treatment for patients with bone metastases from renal cell carcinoma.

P65: EARLY PERCUTANEOUS ENDOSCOPIC GASTROSTOMY PLACEMENT IN PATIENTS TREATED BY COMBINED RADIOTHERAPY- CHEMOTHERAPY IN HEAD AND NECK CANCER

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Purpose: This study evaluates the outcome of early percutaneous endoscopic gastrostomy (PEG) placement in patients treated with concurrent chemoradiotherapy for advanced head neck cancer.

Materials and methods: It is well known that combined chemoradiotherapy increases mucosal toxicity leading to decreased nutritional intake, weight loss and treatment interruption. We retrospectively analyzed the records from a series of consecutive patients with advanced squamous cell head and neck cancer planned for radical treatment with long course or hypofractionated radiation therapy, who underwent PEG placement from January 2010 until May 2012. We determined the effect of early PEG placement on treatment completion without interruption. .

Patients had a planning CT scan using individual immobilization with a thermoplastic device and were treated with 3D conformal radiotherapy to a total dose of 36Gy in thirteen fractions (hypofractionation schedule) or 66Gy in thirty three fractions (long course). They received concomitantly weekly platinum-based chemotherapy.

Results: Fewer interruptions of treatment and a better nutritional status was correlated with early percutaneous endoscopic gastrostomy (PEG).

Conclusions: The results showed that patients with locally advanced head and neck carcinoma undergoing radiotherapy with curative intent and concomitant chemotherapy, had significant clinical benefit from the early placement of PEG. Prophylactic PEG maintains a sufficient nutritional status and reduces the incidence of treatment interruption due to therapy toxicity.

P66: THE CROATIAN EXPERIENCE OF PAIN MANAGEMENT IN LUNG CANCER PATIENTS

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Introduction: Among more than 2800 new lung cancer patients discovered annually in Croatia, most of them are suffering from pain. Lung cancer is the most common malignancy in men, while in women is on the 3rd place. As pain continues to be a prevalent and undertreated symptom experienced by most NSCLC patients worldwide despite analgesics we wanted to find out the situation in Croatia.
Purpose: A prospective study was undertaken to elucidate the frequency, characteristics and managing of chronic malignant pain in lung cancer patients. We reviewed the outcome of lung cancer patients treated by Croatian health care professionals. After collecting data about pain characteristics, transdermal fentanil was used during the three months period in analgesic protocol based on WHO ladder strategy.
Results: Overall 301 patients were enrolled, median age 63 years, most males (74%), metastatic disease (57%) and good PS (58%). Prevalence of moderate and severe pain was > 70 %. Pain intensity was higher in patients with advanced disease (28 vs 13 %), worse PS (46 vs 11 %) and bone metastases (45 vs 23 %). More than 90 % patients was treated with opioid „as needed", 60 % took all analgesics „as needed". As result, more than 95 % patients had inadequate analgesic treatment at the begining of the study.
Conclusions: Controlling pain in lung cancer patients in Croatia is still inadequate, mostly due to incorrect pain therapy administration. All patients can benefit from opioid therapy when correctly applied according to the WHO guidelines, underlying the necessity of better education and need for improvements in pain management.

P67: PRESENTING SYMPTOMS OF PRIMARY NON-HODGKIN LYMPHOMA IN THE ORAL CAVITY AND JAWS: ANALYSIS OF 53 CASES

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Introduction: Non-Hodgkin lymphoma (NHL) is the third most common oral malignancy; yet many cases are diagnosed late due to misleading and indistinctive disease features that may mimic other oral conditions. Our objectives were to review the presenting symptoms of all NHL diagnosed during one decade at our institute, aiming to evaluate reasons for late diagnosis.
Methods: We retrospectively collected all 53 cases of oral/jaw primary-NHL that were diagnosed at the Hadassah-Hebrew University Medical Center from 2002-2011. Patients' demographics and complaints, and clinical, radiological, and morphological findings were analyzed.
Results: Mean patient age at diagnosis was 56.6 ±23.1 years; male-to-female ratio was 32:21. Morphologic diagnoses were diffuse large B-cell (41.5%), follicular (22.6%), marginal zone B-cell (11.3%), and Burkitt (9.4%) lymphomas. All lesions were symptomatic at time of diagnosis; with swelling (81.1%), pain (24.5%), B-symptoms (weight loss, fever, sweats; 13.2%), and neuropathy (13.2%) the most prevalent complaints at presentation. Prior to diagnosis, 13.2% of patients sought dental care for "toothache". However, vast majority of initial clinical-radiological differential diagnosis of the lesions, made by the oral and maxillofacial surgeon prior to biopsy, included malignant (and benign) tumors.
Conclusions: Although majority of lesions were clinically considered malignant, some lesions mimicked benign conditions. Of importance are lesions that masqueraded as toothache, infections, reactive lesions, and osteonecrosis (total of more of one-fifth of lesions), which may not be routinely subjected to his-

tologic evaluation. Facial neuropathy in patient with no history of facial trauma should be carefully evaluated for malignancy. Clinicians should keep in mind that lymphoma has many faces, and it may mimic a wide variety of lesions.

P68 EVALUATION OF NUTRITIONAL STATUS OF CANCER PATIENTS UNDERGOING CHEMOTHERAPY AND THE IMPACT OF NUTRITIONAL SUPPLEMENTATION TO THEIR CLINICAL COURSE: SINGLE CENTER EXPERIENCE

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Introduction: The syndrome of cachexia is frequently observed in patients with cancer. It is characterized by muscle mass loss, with or without fat loss due to energy balance disturbances. Early recognition of the syndrome is an important success factor for any intervention. Disease and treatment have a major impact on nutritional status and it is known that weight loss is an important predictor of mortality.
Purpose: The aim of this prospective study is to assess the nutritional status of cancer patients undergoing chemotherapy and evaluate the impact of nutritional supplementation to their treatment and disease outcome.
Methods and Results: From September 2012 until September 2013 we evaluated 74 serial patients with cancer undergoing chemotherapy (median age 65 years, 48% female, 52% male). Patients with solid tumours were included: lung (36%), gastrointestinal (21%), head and neck (21%), gynecological (11%) and other (11%). We recorded demographics, disease and treatment characteristics and all patients were assessed using the Patient Generated Subjective Global Assessment (PG-SGA) which includes medical history (weight, intake, symptoms, functional capacity, metabolic demand) and physical examination, the Skeletal Muscle Index (SMI) defined by abdomen and pelvis CT scan to identify sarcopenia and finally the Questionnaire of Quality Of Life (EORTC QLQ-30) to evaluate physical and psychological status. All assessments were performed prior to treatment initiation, following two treatment cycles (or two months treatment) and at treatment completion. PG-SGA score of 0-3 was recorded in 20 patients (22%), 4-8 in 24,(24%) while 30 patients (40%) had score 9 or greater. Skeletal Mass Index (SMI) was assessed in 62 patients, from which sarcopenia was identified in 28 (43,5%). The most common symptoms accounting for a high PG-SGA score were: no appetite 14 (40%), pain 12 (32%), constipation 10 (30%), dry mouth 8 (24%) and taste changes 16 (21%). It is of interest that certain patients with high PG-SGA score had normal SMI and the opposite, therefore, we chose to administrate nutritional supplements only to patients with both scores pathological, depending on their calorie needs. Higher PG-SGA scores (≥14 to 22) were recorded for patients with head and neck, gastrointestinal and lung disease. A total of 68% of patients benefited from nutritional supplementation on weight (stabilization or gain) and symptoms (improvement of treatment side effects). Analysis of QoL questionnaires revealed that, nutritional support improves physical (improvement in pain, anorexia and fatigue) and psychological (less worry, less irritable and less depressed) condition.
Conclusions: This study is ongoing, however, from the analysed cohort of 74 patients the tools of SMI and PG-SGA seem very useful in assessing nutritional status and it is evident that nutritional supplementation benefits physical condition, well-being and treatment tolerance of cancer patients undergoing chemotherapy.

Translational Research

P69: A PROSPECTIVE PHARMACOKINETIC STUDY OF DOCETAXEL IN BREAST CANCER PATIENTS IN RELATION TO CYP3A4 ACTIVITY

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Purpose: To study the correlation between pharmacokinetics & pharmacodynamic of docetaxel and CYP3A4 activity in cancer patients.
Introduction: Docetaxel is a taxoid derivative that displays promising activity against metastatic breast cancer. Individuals display significant differences in term of efficacy and adverse effects after exposure to docetaxel. Therefore fourteen Egyptian female Patients with metastatic breast cancer, were treated with single agent docetaxel (100mg/m^2) and blood samples were collected before and after IV infusion for pharmacokinetic study. Hydrocortisone 300mg IV was administered 2 days before docetaxel treatment and Cytochrome 3A4 activity was determined by measuring level of urinary metabolites of 6β-hydroxycortisol (6β-OHF) and cortisol (FC). The level of the drug was determined using HPLC and the correlations were determined.
Results: After cortisol administration, total amount of 24-hour urinary 6β-OHF and FC were19.97±10.43 and 16.84±10.36 mg/24h (mean ±SD) respectively. On the other hand, the 6β-OHF/FC ratio after cortisol administration was 1.86±1.933. The pharmacokinetic parameters of docetaxel were clearance 19.9± 4.5 L/hr, volume of distribution 65.6±28.6 L (mean ±SD) and AUC 7.2 μg/ml.hr (range 5-8.8 μg/ml.hr).
A significant correlation was found between 6β-OHF/FC ratio and neutropenia (p=0.04) in addition correlation between 6β-OHF and C_{max} ($p=0.04$).
Conclusion: The interpatient variability of CYP3A4 activity could be predicted by measuring the 24-hour urinary 63-OHF after cortisol administration. Individualized dosing to optimize drug exposure for each patient could be performed. A farther study of fixed versus individualized dosing of docetaxel is needed.

Key words: *docetaxel pharmacokinetic, CYP3A4 activity, neutropenia, response.*

P70: EVALUATION OF PREOPERATIVE LEVELS OF FIBRINOGEN AND D-DIMERS IN NEOPLASTIC LESIONS OF THE BREAST: PRELIMINARY RESULTS

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Aim: In contrast to the vast majority of intra-abdominal cancers, the present studies in breast cancer have not convincingly proven the existence of compensated disseminated intravascular coagulation during the natural course of the disease. The aim of our pilot study is to evaluate the preoperative values of d-dimers and fibrinogen, markers of active fibrinolytic activity and hypercoagulative status respectively, in patients with breast neoplasias and correlate their values with the underlying histopathology parameters.
Material and Methods: Our pilot study sample constituted of 20 patients with breast tumors, who were surgically treated in our unit; 10 of them (Group A) had breast cancer and the remaining 10 (Group B) fibroadenomas. The exclusion criteria set were the presence of anemia, active inflammation, haematological disorder and recent thromboembolic episode. We evaluated the existence of any differences in the preoperative values of fibrinogen and d-dimers according to the nature of the tumor (benign vs malignant), as well as in the breast cancer group we assessed the existence of any correlation of the laboratory values with the grade of the tumor, the extent of the metastatic spread to the axillary lymph nodes and the positivity of hormonal receptors.
Results: The mean d-dimers value was significantly elevated in the breast cancer group ($p<0.05$), in contrast to the mean fibrinogen value. Focusing in the breast cancer group, there was a positive correlation of d-dimers levels with the tumor grade and the number of infiltrated axillary lymph nodes ($p<0.05$, $p<0.001$ respectively), while no similar findings occurred for the fibrinogen values. Finally, there was a statistically significant elevation of d-dimers values in patients with negative hormonal receptors' status ($p<0.05$), while no similar association was detected concerning the fibrinogen levels.
Conclusions: In contrast to fibrinogen, d-dimers could be a reliable biomarker of breast cancer activity, indicating a firm association between the progression of breast cancer and the establishment of a subclinical, compensated disseminated intravascular coagulation status. Considering, though, the pilot nature of our study, these preliminary results should be validated by further clinical studies.

P71: FSHR EXPRESSION IN COLORECTAL ADENOCARCINOMAS

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Introduction: Receptors for follicle-stimulating hormone (FSHRs) are found only in the gonads and have been localised to the Sertoli cells of the testis and the granulosa cells of the ovary. FSHR has not been studied extensively in cancer. FSHR expression and polymorphisms have been related to ovarian cancer and it has been recently published that FSHR is selectively expressed on the surface of the blood vessels of a wide range of tumors, including a small number of colorectal adenocarcinomas.
Purpose: The aim of this study was to evaluate FSHR mRNA and protein levels in colorectal adenocarcinomas and assess their association with the clinicopathological parameters of the patients.
Results: mRNA expression levels of FSHR between 53 normal and 82 malignant colorectal tissues were similar (median values 1.63 and 1.83, respectively). mRNA levels of FSHR in normal and malignant colorectal tissues were 166 and 64 times lower compared to those in the normal and malignant ovarian tissues respectively. There was no correlation between the FSHR mRNA levels and age, gender, grade, stage, primary site, and disease relapse. FSHR protein was expressed in malignant colorectal tissues, in contrast with normal tissues where it was not expressed ($p<0.001$). Protein levels of FSHR differed among tumors of different primary site in statistically significant manner ($p<0.001$). Moreover, protein levels of FSHR were significantly correlated with overall survival, with patients with low protein levels having survival benefit compared to patients with high protein levels ($p=0.032$).
Conclusions: FSHR exhibited elevated protein levels in colon carcinomas compared to normal tissue samples and was correlated with primary site and overall survival, indicating a possible role for this receptor in colon carcinogenesis and suggesting a potential prognostic biomarker for colorectal adenocarcinoma. The role of FSHR in colorectal cancer warrants further investigation.

P72: IS THERE ANY ASSOCIATION BETWEEN SENTINEL LYMPH NODE POSITIVITY AND HISTOPATHOLOGY PARAMETERS IN BREAST CANCER SURGERY?

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Aim: The aim of our study was to assess the existence of a possible association between the standard breast cancer histopathology parameters and the presence of infiltrated sentinel lymph node(s) during the performance of sentinel lymph node biopsy.
Material and Methods: We performed a retrospective study, including in the study sample a total of 82 patients, who were submitted to either a mastectomy or wide local excision, accompanied by sentinel lymph node biopsy; 41 of them had positive sentinel lymph node(s) and were sequentially submitted to an axillary node clearance (Group 1). The remaining 41 patients had a negative sentinel lymph node biopsy and served as the control group (Group 2). The groups' patients were matched for age, type of operation and ER, HER2 status (ER+, HER2-). The histopathological parameters compared between the groups were the size and grade of the primary tumor, the presence of vascular invasion, the presence of an in situ component and the number of identified sentinel lymph nodes.
Results: The comparative analysis of the obtained data revealed that the mean age of the patients in group A was 61.46 years (SD +/-11.8) vs 61.56 years (SD +/-12.31) in Group B ($p>0.05$, ns). The tumor grade variation between the two subgroups was as following: Group A: 5/42 grade I, 23/42 grade II and 14/42 grade III carcinoma, whereas in Group B 9/42 grade I, 19/42 grade II and 12/42 grade III ($p>0.05$, ns). The mean tumor size for Group A was 26.6mm (SD +/-16.06) vs 22.78mm (SD +/-11.92) for Group B ($p>0.05$, ns). Moreover, presence of an in situ component was detected in 28/41 patients in Group A vs 25/41 in Group ($p>0.05$, ns). Additionally, vascular invasion was present in 28/41 patients in Group A vs 8/41 patients in Group B ($p<0.05$). Finally, the mean number of sentinel lymph nodes was 2.32 (SD +/-1.25) in Group A vs 1.73 (SD +/-0.92) in Group B ($p=0.019$).
Conclusions: Our study results suggested that the presence of vascular invasion and a higher number of sentinel lymph nodes were associated with a greater likelihood of positivity of the sentinel lymph node(s) and therefore the need for the performance of sequential axillary lymph node clearance. However, we

observed that the tumors in the patients with positive sentinel lymph node(s) were of larger size and hosted more frequently an in situ component, although the comparative analysis did not reveal the presence of statistically significant differences for these parameters between the two study groups.

P73: CIRCULATING TUMOR CELLS IN COLORECTAL CANCER: A COMPREHENSIVE REVIEW OF THE LITERATURE

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Introduction: Circulating tumor cells in colorectal cancer represent an entity not clearly defined. Issues of characterization of these cells as well as a possible prognostic and predictive value of their detection in colorectal cancer patients' blood are under intense investigation.
Purpose: A literature review was undertaken in Pubmed-indexed journals using key words "colorectal cancer AND circulating tumor cells". References from relevant articles were also manually searched and abstracts of interest were extracted.
Results: Circulating tumor cell positivity in colorectal cancer patients that persisted or was enhanced during treatment was a marker of poor prognosis both for overall survival and progression free survival. This was a finding both in the operable and the widespread/metastatic disease. A wide range of markers and techniques is used to characterize and isolate these cells with some of the surface cytokeratins being the most commonly along with Reverse Transcription PCR detection. The introduction of proteomics bares the promise of new markers for detection of circulating tumor cells along with the profiling of these cells and the further understanding of their biology. Moreover, circulating tumor cells were shown to be candidates for KRAs mutational analysis with high concordance to the primary tumor and its corresponding liver metastases, thus providing an easily accessible tissue reserve for analysis.
Conclusions: Circulating tumor cells represent a powerful tool of both prognostic and predictive value for colorectal cancer patients across all stages of disease. Validation and standardization of techniques for isolation and characterization of these cells has the potential to provide accurate information for disease biology.

P74: CLINICAL SIGNIFICANCE OF SERUM HEPATOCYTE GROWTH FACTOR (HGF) LEVELS IN HEPATOCELLULAR CARCINOMA

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Purpose: Hepatocellular carcinoma (HCC) is the commonest primary malignant cancer of the liver in the world. The question of which molecular markers will prove to be the most useful for selecting treatment for individual patients with HCC and which will be validated remains unanswered. This study was conducted to investigate the serum levels of hepatocyte growth factor (HGF) in HCC patients and the relationship with tumor progression and known prognostic parameters.
Material and Methods: Fifty-four patients with HCC were investigated. The HGF assay was employed the quantitative sandwich enzyme immunoassay technique (ELISA). Age and sex matched 20 healthy controls were included in the analysis.
Results: The median age of the patients was 60 years (range 36-77 years); where males consistituted of majority of the group (88.8%). All of patients had cirrhotic history. Fourty-six percent (n=25) of patients had Child-Pugh Score A, 30% (n=16) had Score B or C. All of the patients were treated with local therapies and none of them received sorafenib. The baseline serum HGF levels were significantly higher in patients with HCC than in the control group ($p < 0.001$). Male patients had higher serum HGF levels compared with female patients ($p=0.01$). Serum HGF levels was significantly higher in the patients with elevated serum ALT levels than others with normal serum ALT levels ($p=0.05$). Poor performance status ($p<0.001$), viral etiology of cirrhosis ($p=0.03$), large tumor size ($p=0.01$), lower serum hemoglobin levels ($p=0.03$), and not be treated for HCC ($p=0.001$) related to worse survival. However, serum HGF had not significantly adverse effect on survival ($p=0.58$)
Conclusions: Despite serum HGF levels was found diagnostic value, serum HGF levels had no prognostic value in patients with HCC.

P75: CLINICAL SIGNIFICANCE OF SERUM EPITHELIAL CELL ADHESION MOLECULE (EPCAM) AND VASCULAR CELL ADHESION MOLECULE-1 (VCAM-1) LEVELS IN EPITHELIAL OVARIAN CANCER

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Purpose: Cellular adhesion molecules might be good markers in some types of malignant tumors, useful information in diagnosis and prognosis. The objective of this study was to evaluate of serum levels of **e**pithelial cell adhesion molecule (EPCAM) and vascular cell adhesion molecule-1 (VCAM-1) and in regard to diagnostic, predictive and prognostic value in epithelial ovarian cancer (EOC) patients.
Material and methods: Fifty EOC patients were enrolled into this study. Serum EPCAM and VCAM-1 levels were determined by the solid-phase sandwich ELISA method. Age and sex matched 30 healthy controls were included in the analysis.
Results: Median age of patients was 56.5 years old, range 22 to 83 years. Majority of the patients had advanced disease (stage III-IV) (90%). The baseline serum EPCAM levels were significantly higher than in the control group (p=0.03). However, there was no significant difference in the serum VCAM-1level between EOC patients and controls (p=0.24). Patients with metastatic disease had higher serum VCAM-1 level compared with non-metastatic patients (p=0.03). Moreover, no other clinical variables including response to chemotherapy were found to be correlated with both serum assays (p>0.05). No correlation was found between serum EPCAM and VCAM-1levels in EOC patients (r_S =0.105, p=0.362). Patients with no response to chemotherapy and with platinum-resistant in relapsed disease had worse outcome in both of progression-free (PFS) and overall survival (OS) analyses. However, neither serum EPCAM level and nor serum VCAM-1 level was significantly adverse effect on either PFS or OS.
Conclusions: The baseline serum levels of EPCAM and VCAM-1were significantly higher in EOC patients and metastatic EOC patients, respectively. However, these assays had no predictive and prognostic value in this patient group.

P76: WHOLE EXOME ANALYSIS IN PATIENTS WITH FAMILIAL BREAST CANCER

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Hereditary breast cancer accounts for 5-10% of all breast cancers and is caused by genetic alterations in the BRCA1&2 genes. Another 20-25% of all breast cancers is characterized as familial, in BRCA free patients with family history of hereditary breast and ovarian cancer associated cancers. The intense quest for an expected BRCA3 gene in the past has proven unsuccessful. Recent research points out mutations in other low or moderate penetrance genes collectively increasing the risk of developing and inheriting breast cancer. Whole exome analysis, the sequencing of the exons of all genes, provides a highly attractive strategy for the investigation of familial breast cancer, offering the potential to apply an agnostic rather than a candidate gene approach.
The purpose of this study is to analyze genetic alterations in the familial breast cancer candidate genes of moderate (ATM, CDH1, CHEK2, STK11, TP53, PPM1D) and low penetrance (PTEN, NF1, NBN, BARD1, BRIP1, PALB2, RAD50, RAD51, FGFR2, LSP1, MAP3K1, TGFB1, TOX3, MSH2, MSH6, PMS1, MLH1, HMMR, NQO2, PMS2, XRCC3).
We have performed whole exome analysis with next generation sequencing in 12 familial breast cancer patients. All patients were BRCA1&2 negative for pathogenic mutations and large genomic rearrangements. Exomes of adult, noncancerous patients were used as controls. The mean risk calculated over 66 SNPs in the candidate genes was larger in the experimental versus the control group (1.74 vs 1.195). In one patient, the identification of genetic alterations in the STK11 gene led to the diagnosis of the Peutz-Jeghers syndrome, confirmed later by clinical estimation.
Whole exome analysis provides unique and clinically relevant information in the investigation of familial and hereditary breast cancer. It provides yet another option in the clinical setting as next generation sequencing displays comparable sensitivity and accuracy to conventional Sanger sequencing and affordable cost.

P77: MICRORNA AND CANCER OF THE TONGUE

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Introduction: MicroRNAs (miRNAs) are a group of endogenous, non-coding, 18–24 nucleotide length single-strand RNAs that regulate gene expression at the post-transcriptional level through mRNA degradation or translational repression. They are involved in regulating diverse cellular biological processes such as cell cycle, differentiation and apoptosis leading to malignancies, including oral squamous cell carcinoma (OSCC). Altered microRNA expression has been associated with both cancer progression and metastasis. There are only few mentions about the miRNAs that are expressed in the squamous cell carcinoma of the tongue.
Purpose: The aim of our study is to evaluate whether miRNA expression analysis could be used as a diagnostic tool to discover the primary site of malignancy, within the tongue.
Material and methods: We have collected twelve samples from the tumor and its healthy adjacent tissue of the tongue. We will use miRNA real-time PCR array system to identify miRNA expression profiles of squamous cell carcinoma of the tongue.
Results and conclusions: According to other recent studies small number of dysregulated miRNAs have been implicated either as oncogenes or tumor suppressors, affecting the initiation and progression of OSCC through the regulation of proliferation, apoptosis, metastasis and chemoresistance. Also, these missexpressed miRNAs have been shown to have potential as novel diagnostic, prognostic and therapeutic tools, which are expected to advance the clinical management of OSCC in the near future.

P78: DIAGNOSTIC AND PROGNOSTIC VALUE OF SERUM TISSUE POLYPEPTIDE ANTIGEN IN ADVANCED LUNG CANCER

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Background: lung cancer is one of the most lethal malignancies however No serum marker is routinely recommended till now.
Patients and methods: This is a prospective case control study including two groups of patients: Group I: Patients with advanced lung cancer .Group II: patients with benign lung disease as control. Serum Tissue Polypeptide Antigen (TPA) levels were measured at baseline by ELISA technique before first line chemotherapy. The TPA cutoff taken was 1800 pg. /ml. Primary end point was comparison of high TPA in cases and controls. Secondary endpoint was correlation between high TPA and disease progression (PD), Progression free survival (PFS) and overall survival (OS) in advanced lung cancer patients.
Results:30 patients with advanced lung cancer (16 non-small and 14 small cell lung cancer) and 15 patients with benign lung disease were included and followed up during the period from October 2008 to October 2011 with median follow up of one and half year. High TPA was found in 50% of lung cancer cases compared to 26% in controls, (p= 0.014).High TPA was found in 64% of cases showing PD versus 36% normal TPA (P=0.08).1 year PFS in high TPA was 32% versus 39% in normal TPA, (p=0.2).1 year OS in high TPA was 46% versus 73% in normal TPA, (p=0.6).
Conclusion: Serum TPA is a potential marker for advanced lung cancer.
***Key words**: TPA- lung cancer*

P79: EVALUATION OF VASCULAR ENDOTHELIAL GROWTH FACTOR AS A PROGNOSTIC MARKER IN INOPERABLE HEPATOCELLULAR CARCINOMA

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Background: Hepatocellular carcinoma (HCC) ranks as the seventh most common malignancy in males and the ninth most common in females.HCV infection is a major risk factor for hepatocellular carcinoma. Egypt has the highest prevalence of HCV worldwide and has rising rates of HCC

Methods: This was a prospective study evaluating the prognostic value of vascular endothelial growth factor (VEGF) in 75 inoperable hepatocellular carcinoma patients treated with at least one session of transarterial chemoembolization (TACE). VEGF was measured before and after intervention.
Results: Partial response was achieved in 22 patients (29%) while, 36 patients (48%) had stable disease. Time to disease progression was 6.2 month. Pretreatment serum VEGF level was of prognostic value.
Conclusion: pretreatment VEGF could be used as a prognostic marker for inoperable HCC treated with TACE.

P80: INTRACELLULAR SIGNALLING VIA THE AKT AXIS AND DOWNSTREAM EFFECTORS IS ACTIVE AND PROGNOSTICALLY SIGNIFICANT IN CANCER OF UNKNOWN PRIMARY (CUP): A STUDY OF 100 CUP CASES

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Background: Hypothesising that cancer of unknown primary (CUP) may harbour unique characteristics, we present a translational study of the immunohistochemical expression and clinical correlation of key PTEN/AKT pathway molecules.
Patients and Methods: We collected 100 paraffin-embedded CUP tissue blocks. We studied using tissue microarrays the expression of PTEN, phospho-AKT, Cyclin D1, p21, phospho-RPS6. From the percentage of staining tumour cells and the literature, we selected cut-offs to classify the expression of each biomolecule. We correlated IHC expression with clinical data.
Results: PTEN, pAKT, and pRPS6 showed frequent expression. At univariate analysis, high IHC expression of pAKT and pRPS6 displayed statistically significant association with worse survival. Prognosis was worse upon concurrent high IHC expression of pMAPK and pAKT {median overall survival = 8 months [95% confidence interval (CI) 5.3-10.7] versus 17 months [95% CI 13.1-20.9]}. In multivariate analysis, high p21 was associated with better survival (risk ratio [RR] = 0.34 [95% CI 0.16-0.73], P = 0.005). High expression of pAKT (RR = 2.39 [95% CI 1.23-4.66], P = 0.01) or pRPS6 (RR = 2.76 [95% CI 1.31-5.84], P = 0.008) was associated with worse survival.
Conclusions: p21 expression conferred favourable prognosis, while high pAKT or pRPS6 expression predicted worse prognosis. Concurrent MAPK and pAKT expression had a marked adverse impact on survival.

P81: PROGNOSTIC SIGNIFICANCE OF ESR1 GENE AMPLIFICATION, MRNA/PROTEIN EXPRESSION AND FUNCTIONAL PROFILES IN HIGH-RISK EARLY BREAST CANCER: A TRANSLATIONAL STUDY OF THE HELLENIC COOPERATIVE ONCOLOGY GROUP (HECOG)

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Background: Discrepant data have been published on the incidence and prognostic significance of ESR1 gene amplification in early breast cancer.
Patients and Methods: Formalin-fixed paraffin-embedded tumor blocks were collected from women with early breast cancer participating in two HeCOG adjuvant trials. Messenger RNA was studied by quantitative PCR, ER protein expression was centrally assessed using immunohistochemistry (IHC) and ESR1 gene copy number by dual fluorescent in situ hybridization probes.
Results: In a total of 1010 women with resected node-positive early breast adenocarcinoma, the tumoral ESR1/CEP6 gene ratio was suggestive of deletion in 159 (15.7%), gene gain in 551 (54.6%) and amplification in 42 cases (4.2%), with only 30 tumors (3%) harboring five or more ESR1 copies. Gene copy number ratio showed a significant, though weak correlation to mRNA and protein expression (Spearman's Rho ,0.23, p = 0.01). ESR1 clusters were observed in 9.5% (57 gain, 38 amplification) of cases. In contrast to mRNA and protein expression, which were favorable prognosticators, gene copy number changes did not obtain prognostic significance. When ESR1/CEP6 gene ratio was combined with function (as defined by ER protein and mRNA expression) in a molecular classifier, the Gene Functional profile, it was functional status that impacted on prognosis. In univariate analysis, patients with functional tumors (positive ER protein expression and gene ratio normal or gain/amplification) fared better than those with non-functional tumors with ESR1 gain (HR for relapse or death 0.49–0.64, p = 0.003). Significant interactions were observed between gene gain/amplification and paclitaxel therapy (trend for DFS benefit from paclitaxel only in patients with ESR1 gain/amplification, p = 0.066) and Gene Functional profile with HER2 amplification (Gene Functional profile prognostic only in HER2-normal cases, p = 0.029).
Conclusions: ESR1 gene deletion and amplification do not constitute per se prognostic markers, instead they can be classified to distinct prognostic groups according to their protein-mediated functional status.

P82: INSULIN-LIKE GROWTH FACTOR 1 RECEPTOR ((IGF1R) EXPRESSION AND SURVIVAL IN OPERABLE SQUAMOUS-CELL LARYNGEAL CANCER

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Introduction: Prognosis of patients with operable laryngeal cancer is highly variable and therefore potent prognostic biomarkers are warranted. The Insulin-like Growth Factor Receptor (IGFR) signaling pathway plays a critical role in laryngeal carcinogenesis.
Patients and Methods: We identified all patients with localised TNM stage I-III laryngeal cancer managed with potentially curative surgery between 1985 and 2008. Immunohistochemical (IHC) expression of IGF1R-alpha, IGF1R-beta and IGF2R was evaluated using the immunoreactive score (IRS) and mRNA levels of important effectors of the IGFR pathway were assessed, including IGF1R, IGF-binding protein 3 (IGFBP3), suppressor of cytokine signaling 2 (SOCS2) and members of the MAP-kinase (MA2K1, MAPK9) and phosphatidyl-inositol-3 kinase (PIK3CA, PIK3R1) families. Cox-regression models were applied to assess the predictive value of biomarkers on disease-free survival (DFS) and overall survival (OS).
Results: Among 289 eligible patients, 95.2% were current or ex smokers, 75.4% were alcohol consumers, 15.6% had node-positive disease and 32.2% had received post-operative irradiation. After a median follow-up of 74.5 months, median DFS was 94.5 months and median OS was 106.3 months. Using the median IRS as the pre-defined cut-off, patients whose tumors had increased IGF1R-alpha cytoplasm or membrane expression experienced marginally shorter DFS and significantly shorter OS compared to those whose tumors had low IGF1R-alpha expression (91.1 vs 106.2 months, p=0.0538 and 100.3 vs 118.6 months, p=0.0157, respectively). Increased mRNA levels of MAPK9 were associated with prolonged DFS (p=0.0655) and OS (p=0.0344). In multivariate analysis, IGF1R-alpha overexpression was associated with a 46.6% increase in the probability for relapse (p=0.0374). Independent predictors for poor OS included node-positive disease (HR=2.569, p<0.0001), subglotic/transglotic location (HR=1.756, p=0.0438) and IGF1R-alpha IHC overexpression (HR=1.475, p=0.05).
Conclusion: IGF1R-alpha IHC overexpression may serve as an independent predictor of relapse and survival in operable laryngeal cancer. Prospective evaluation of IGF1R-alpha prognostic utility is warranted.

P83: PREDICTIVE AND PROGNOSTIC SIGNIFICANCE OF VEGF-A SPLICE VARIANT MRNA EXPRESSION IN BEVACIZUMAB-TREATED PATIENTS WITH METASTATIC BREAST CANCER

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Introduction: VEGF-A exon 8 distal splice site variants are anti-angiogenic. Their prognostic utility in advanced breast cancer and predictive significance for bevacizumab (Bev) benefit have not been studied.
Patients and Method:. 75 patients with metastatic breast cancer treated with weekly docetaxel (HE11/06) and 100 treated with weekly paclitaxel and bevacizumab (HE11/07) were included in this retrospective study. Formalin-fixed tumors were macrodissected and RT-qPCR was applied for relative quantification of VEGF-A165, 189, 206 isoforms spliced at exon 8 proximal site (VEGF-Axxxa) and at

exon 8 distal splice site (VEGF-Axxxb). Their effect on progression-free survival (PFS) and overall survival (OS) was examined.
Results: For high VEGF-Axxxa, the Hazard Ratio (HR) for progression was 1.22 (p=0.44) in non-Bev treated patients and 0.62 (p=0.14) in Bev-treated patients, while the HR for death was 1.45 (p=0.20) and 0.43 (p=0.01) respectively. The interaction of VEGF-Axxxa with bevacizumab administration was significant (p=0.0059) for OS. High tissue VEGF-Axxxb was not prognostic in non-Bev treated patients but was predictive for Bev benefit in the HE11/07 cohort (HR for progression 0.54, p=0.02 and HR for death 0.46, p=0.01). The ratio of tissue VEGF-A xxxa/xxxb was not prognostic neither predictive. No significant correlation of the study molecular parameters with objective response to bevacizumab was found. Exploratory analyses done only in Bev-treated patients suggested that abundance of VEGFR1 mRNA in peripheral blood and low VEGFR2 mRNA in tissue correlated with poor outcome. In multivariate analysis, high tissue mRNA of anti-angiogenic VEGF-Axxxb retained independent prognostic significance for superior PFS, while high tissue mRNA of angiogenic VEGF-Axxxa in the presence of bevacizumab therapy predicted for favorable OS.
Conclusions: Tissue mRNA expression of angiogenic VEGF-Axxxa isoforms may be an adverse prognostic factor in the absence of bevacizumab and is a favorable predictive factor for bevacizumab benefit. Tissue expression of anti-angiogenic VEGF-Axxxb is predictive for bevacizumab benefit.

P84: IMPLICATIONS OF mRNA AND PROTEIN OVEREXPRESSION OF PROGNOSTIC MARKERS IN EARLY STAGE COLORECTAL CANCER TREATED WITH STANDARD CHEMOTHERAPY

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Introduction: Several studies have recently shown the predictive and prognostic role of biomarkers in colorectal cancer patients. Purpose: We sought to investigate the prognostic role of TYMS, TYMP, PTGS2, TOP1 and DPYD in 98 colorectal cancer patients treated with fluoropyrimidine-based regimens, such as DeGramont and FOLFOX.
Methods: The methodology applied included immunohistochemistry, mRNA and gene microarray analysis. Results: The grand majority of tumors exhibited protein overexpression of COX2 (69 %), Topo-I (75%) and TS (75%) by immunohistochemistry. There was a statistically significant association of TP with stage (p=0.04) and of Topo-I with primary site (colon *vs* rectal) and stage (p=0.019). The mRNA study showed a positive association of TOP1 with stage and lymph node infiltration (p=0.005). A clear statistically significant association of markers with overall survival and disease free survival could not be shown. However a trend for the association of high TYMS mRNA expression and OS (p=0.061) and high PTGS2 mRNA expression and DFS (p=0.063) could be detected in the multivariate analysis. Using supervised hierarchical clustering, based on the expression of the aforementioned five genes, our 30 patients separated into two clusters. One of the clusters was enriched with patients with infiltrated lymph nodes (p<0.05), suggesting that these genes might have an impact on the tumor's ability to metastasize.
Conclusions: These findings indicate a possible prognostic role of TYMS, TYMP, PTGS2, TOP1 and DPYD and warrant further investigation in a larger cohort of colorectal cancer patients.

P85: EVALUATION OF THE PROGNOSTIC/ PREDICTIVE VALUE OF UPA/PAI-1 IN TRASTUZUMAB TREATED METASTATIC BREAST CANCER PATIENTS

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Introduction: The urokinase-type plasminogen activator (uPA) and plasminogen activator inhibitor type 1 (PAI-1) are associated with an aggressive course in breast cancer and are used to determine whether chemotherapy is needed in node-negative patients. Purpose: The aim of the study was to evaluate the possible prognostic/predictive value of uPA/PAI-1 expression in metastatic breast cancer (MBC) patients treated with trastuzumab (T).
Methods: Formalin-fixed paraffin-embedded tumor tissue samples were collected from 227 patients with MBC treated with T. Clinical information was collected retrospectively from the patients´ medical records. Central review of HER2 status by fluorescence in situ hybridization (FISH) and/or immunohistochemistry (IHC) revealed that only 139 (61%) of the patients

were truly HER2-positive. uPA, PAI-1, ER, PgR and Ki67 were evaluated by IHC, according to previously described scoring systems. The localization of uPA and PAI-1 staining was determined to be predominately cytoplasmic in tumor cells and stromal cells. Time to progression (TTP) and survival were calculated from the initiation of T. After the initial analysis two separate patient cohorts were analyzed in the context of a validation study.

Results: Median TTP was 15 months for the HER2-positive and 10 months for the HER2-negative patients (p=0.22). Median survival was 50.6 months for the HER2-positive and 37 months for the HER2-negative patients (p=0.006). Tumor cell uPA protein expression was strongly associated with tumor cell PAI-1 (p=0.001) and Ki67 (p=0.002) expression. Positive stromal cell PAI-1 protein expression was associated with decreased risk for death in HER2-negative patients treated with T (HR=0.38, 95% CI 0.20-0.72, p=0.003). This interaction remained significant in the multivariate analysis of the first cohort but not in the validation analysis.

Conclusions: Our study indicates that a number of patients with MBC not overexpressing HER2 and expressing PAI-1 in the stroma may gain significant survival benefit by trastuzumab therapy. Although our validation studies did not confirm this effect we believe that this is mainly due to the use of TMAs, the small number of patients analyzed retrospectively and the presence of crosstalk between uPA and HER2. Further studies are warranted to explore more in depth our findings.

Publications

1. B-hCG (HUMAN CHORIONIC GONADOTHROPIN) AS A TUMOR MARKER FOR MESOTHELIOMA

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Introduction and purpose: Mesotheliomas are aggressive tumors arising from mesothelium. Tumor markers are biochemical substances produced by tumor cells or due to the effect of malignant process. Tumor markers can be used for screening, to diagnose, determining the prognosis of cancer. β-hCG is a marker of germ cell tumors and trophoblastic disease. 49 years-old man was admitted to hospital with abdominal dullness. Physical examination reveals ascites, and abdominal masses. Imaging showed ascites, peritoneal thickening. Peritoneal biopsy showed biphasic; epitheloid-sarcomatoid mesothelioma which was inoperable. We studied his serum tumor markers. The tumor markers were normal except hisβ-hCG(441mIU/mL). His testicular exam, chest tomography was normal. We gave him chemotherapy. After the first chemotherapy his PS was 2, disease progressed. Before the second chemotherapy time β-hCG was 3944mIU/mL. We wonder if his paraffin embedded tissue samples were stained with β-hCG, and/or (hPL). β-hCG was positive in the cytoplasm of sarcomatoid component.

Results: We thought that if the mesothelioma cells can be differentiate to trophoblasts or if they secrete β-hCG/β-hCG like glycoproteins. In a study showed that mesothelial cells are pluripotent, they've the capacity to differentiate into different cells. In another report of two pleural mesothelioma cases, with high serum β-hCG, who have bizarre giant cells mimicking trophoblasts, immunostained for α-β-hCG, hPL. They called 'choricarcinomatous portion', they thought that it's a gonadotropin-producing malignant mesothelioma. At immunostaining of our case, sarcomatoid portion has been positive for β-hCG, and hPL which aren't mimicking trophoblasts.

Conclusion: Rising serum β-hCG levels with disease progression can be predictive of treatment response, can be a prognostic marker for mesothelioma if it is high at the beggining. β-hCG may be the marker for treatment prediction, and disease prognosis of mesothelioma patients.

2. METASTASES TO THE JAWBONE MIMICKING DENTAL PAIN - A CASE REPORT

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Cancer is a complex disease in which many basic processes, such as cell division, apoptosis, and cell migration, are dysregulated. It is the process of metastasis that results in morbidity and eventual mortality. Metastatic tumors to the oral region are uncommon and may occur in the oral soft tissues or in the jawbones. Because of its rarity, the diagnosis is challenging and should be considered in the differential diagnosis of inflammatory and reactive lesions which are common in this area.

We are presenting a case of a 67 years old female patient with breast cancer and known metastases to the brain and lungs. The patient has complained of pain on the left mandible lasting for a couple of months. Her dentist related the pain to a dental abscess originated from her lower left molars. A root canal treatment was performed on the first and second left lower molars, with only short term relief of the pain. Further investigation of the pain characteristics at our clinic, revealed a burning sensation on the left lower lip and chin. Panoramic and periapical radiographs demonstrated an irregular resorbtion of the distal root of the left first mandibular molar. The cortical borders of the mandibular canal at the molar area were undetectable. Computed tomography revealed an expansile lytic destructive lesion in the body of the left mandible eroding both the buccal and lingual cortical plates and intensive FDG uptake was noted on PET-CT.

The radiological and clinical features of neuropathic pain were highly suggestive of malignancy (primary or metastatic).

3. METASTATIC RENAL CELL CARCINOMA AT PTERYGOPALATINE FOSSA AND MAXILLARY SINUS. A CASE REPORT

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Purpose: According to literature lung and long bones are the usual metastatic sites from kidney cancer.
The aim of the presentation of this case is to highlight an unusual site of bone metastases from renal cell carcinoma (RCC).
Material and methods: We are presenting the case of a 69 year old woman treated with nephrectomy in 2000 for a RCC. In September 2009 she had a face MRI due to progressing left face numbness and ipsilateral lacrimation. The scan revealed a 26x18,5 x19 mm mass extending from the right maxillary antrum to cavernous sinus for which she had a debulking surgery. The pathology report revealed a clear cell, highly positive for CK8.18, CD10, Vimentin and negative staining for chromogranin metastatic RCC. Postoperative CT scans showed residual disease without lymph node involvement. Patient received adjuvant therapy with Avastin and INF. Tumor reassessment with MR imaging after completion of the 6^{th} and 13^{th} cycle of systemic therapy showed stable disease. After completion of the 18^{th} cycle, she refused further treatment. In January 2011 she started 2^{nd} line chemotherapy with Everolimus (Afinitor) due to progressive disease on MRI. Six months later the patient was referred for radiotherapy for disease progression. She had a planning CT scan and was treated with 3D conformal radiotherapy to a total dose of 30Gy in 10 fractions with an anterior and lateral field. It is a month after radiation therapy and we are expecting the new MRI.
Results: The patient completed the radiation therapy with satisfactory treatment tolerance. Follow up includes MR imaging of the treated area for treatment evaluation.
Conclusion: Radiotherapy is a well tolerated therapeutic approach for an unusual site of metastatic renal cell carcinoma at pterygopalatine fossa and maxillary sinus.

4. NASOPHARYNGEAL LIPOSARCOMA-A RARE CASE

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Purpose: Liposarcoma is a malignant soft tissue tumor common in adults. The trunk and lower extremities are the most likely sites to be affected and tumor development in the head and neck region is extremely low. Liposarcoma of the nasopharynx is exceptionally rare and only a few cases have been described in the literature.
Materials and Methods: A case of a 53 year old male patient with a 5-year history of chronic nasal congestion is presented. A small right–sided lesion was revealed with endoscopy. Magnetic Resonance Imaging findings included a mass at the posterior wall of the nasopharynx, measuring approximately 2x4x2.5cm. The patient declined medical advice for surgical resection. He experienced worsening of symptoms with nasal congestion and right otalgia and seeks for medical attention five years later.
MR imaging and nasopharyngeal endoscopy were performed recently and showed mild enlargement of the lesion (measuring approximately 3x4 cm). Endoscopic biopsy and tumor debulking were performed and histopathology revealed a grade 2 myxoid round cell liposarcoma. The patient was then referred for treatment with adjuvant chemotherapy that consisted of a doxorubicin-based regimen (110mg/m²) every 2 weeks for a total of 6 courses. Following chemotherapy, the patient was treated with 3D conformal radiotherapy.
He received 66Gy, fractionated at 2Gy/day, 5 days a week, for 33 days. Radiotherapy was completed without any side effects.
Results: The patient is alive and disease free, 3 years after radiotherapy.
Conclusions: Although liposarcoma is usually treated with surgery, resection of the nasopharyngeal type with an acceptable tumor free margin is not possible due to the anatomic location. The role of adjuvant chemotherapy is not clearly defined while the role of postoperative radiotherapy, as an adjuvant therapy, is considered significant because it appears to decrease the rate of local recurrence.

5. IS THERE A ROLE FOR RADIOTHERAPY FOR INTRACYSTIC BREAST CANCER? REVIEW OF THE LITERATURE AND CASE REPORT

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Introduction: Intracystic breast carcinoma is a rare breast tumor comprising less than 3% of breast cancers. Although at first intracystic breast carcinoma was thought to be a variant of ductal carcinoma in situ, it's now a common belief that some lesions may be low risk invasive tumors. In all cases, prognosis for intracystic breast carcinoma is excellent. Disease specific survival rates approach 100%, although the presence of a large amount of nuclear atypia influences negatively the prognosis.
Purpose: To present the therapeutic challenge for a woman referred for radiotherapy for an intracystic breast cancer since there are conflicting aspects in the literature and no specific guidelines for the role of adjuvant radiation therapy.
Results: This case concerns a 66 year old woman with a family history of breast cancer, presenting with a palpable and painless mass of the left nipple area. The patient had a breast conserving surgery with excision of the sentinel lymph node and three additional nodes. The histological report confirmed a 1.7cm tumor, c-erb-B2 negative, ER and PR positive, with the characteristics of an intracystic papillary breast carcinoma, gr I-II and negative lymph nodes. The patient was referred for adjuvant radiotherapy. After a histologic revision, microscopic invasive cancer was documented and the patient was offered whole breast radiotherapy with standard fractionation (2Gy/fr). The patient completed the irradiation schedule with minor treatment toxicity. Two years after the completion of radiotherapy there is no local recurrence and cosmesis of the breast is excellent.
Conclusion: Since there are no specific guidelines for the role of radiotherapy for intracystic carcinoma, adjuvant radiotherapy should be an option since it is in line with literature reports and offers local control with minor toxicity.

6. LONG TERM SURVIVAL IN A GASTROINTESTINAL STROMAL TUMOR PATIENT WITH BONE METASTASIS; CASE REPORT

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Introduction: Gastrointestinal stromal tumors are the most common mezenchimal tumors of the gastrointestinal tract. They often metastasize to peritoneum and liver. Bone metastasis are rare. Here we present a patient with vertebral metastasis living without progression for 9 years.
Case Presentation: A 63 years old male patient attended to hospital with back pain. He had a history of pararectal mass excision with a pathologic diagnosis of malign mesenchimal tumor suggesting leiomyosarcoma 3 years earlier. Postoperative pelvic radiation therapy was given. Lumbal vertebra magnetic resonans imaging revealed a metastatic mass involving T11-T12 and L1 vertebras expanding into spinal canal and compressing spinal cord at that level. At bone scintigraphy there was increased activity at T12 vertebra. T12 vertebra anterior decompression and stabilization was done. Pathologic examination made the diagnosis of CD117 positive gastrointestinal stromal tumor. Retrospective pathologic analysis of the stained preparations of the pararectal mass showed morphologically identical tumors but immunohistochemical analysis couldn't be done because of inconvenience of parafin blocks. On thoracoabdominal computed tomography there were no other metastatic lesions. İmatinib 400mg and biphosphonate therapy was started. Postoperative follow up MRI of the spine showed residual metastatic lesions in T11-T12 and L1 vertebras. Even with no radiotherapy to bone metastasis, the patient had stable disease for 9 years with no complaints, still using imatinib.
Conclusion: Bone metastasis of GIST's are rare. There are few reported cases in the literature. Our patient had a pathologically proven c-kit (CD117) positive bone metastasis to spine living for 9 years witout progression on imatinib therapy.

7. SINCRONE LEFT BREAST CANCER AND LEFT OCULAR MELANOMA

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At the Oncology Service was present a 58-year old female patient with a mass on her left breast and blurred vision with decrease of the optical field on left eye. Main problem that she refers was a mass at the left breast and vision problems, started five months before she came to do the clinical visit for the breast. She underwent to all imagine and laboratory examination (ultrasound, mammogram, CT total body, bone CT, tumoral markers etc) among them a head VT with diagnosis of uveal metastasis with retinal detachment of the left bulbus.

Palpation revealed a retroareolar mass with irregular contours of the left breast. ECHO and breast mammography showed a 30 x 30 mm retroareolar left breast mass with irregular contours and a small (1cm) left axillary node. FNA of the breast resulted C5.

The case was treated as left breast cancer with suspect metastasis of the left bulbous occuli (T2N1M1). A left mastectomy with axillary node dissection was carried out. The postoperative period was uneventful. Biopsy showed infiltrating ductal carcinoma grade I-II; 6 axillary nodes were negative. Hormonal receptors were negative.

A month later she underwent again to surgery, enucleation of the left bulbous occuli was realized and biopsy showed melanoma. The patient received chemotherapy and her physical state is good, while going through periodical exams.

Key words: *breast cancer, diagnosis, ocular melanoma.*

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8. PAIN IN BREAST CANCER SURVIVORS

P. Heras, A.Stefanopoulos, K.Grigoriou,
A. Eleftheriadi, T. Sirbilatze, K. Kritikos

Hellenic Medical Association of Psychosomatic Problems

Introduction: Pain after breast cancer treatment is common, may have several causes, this symptom is characterized by an importuned reduced functional and emotional.

Purpose: Describe the pain in women with breast cancer, identify factors of improvement and worsening of pain in the lives of women, identify and locate the pain of women undergoing treatment for breast cancer (TBC).

Methods: Thirty women undergoing TBC, attending a rehabilitation center during the period February to August of 2011, an responding to a form of the disease, treatment and pain. An image was applied to identify the location of the pain

Results: Most women were aged over 50 years. There is an equitable distribution between mastectomy and lumpectomy. The pain began after the breast surgery in 46.7 % of the women, daily frequency, and constantly, interfering with sleep and mood. Movements related to increased pain were reaching, pushing, pulling and supporting.

Conclusions: To know, recognize and deal with the symptom allows therapeutic alternatives for its relief, minimizing the physical and emotional effects that the pain may cause in the relief of these women.

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9. GREEK CENTERS EXPERIENCE IN ONCOLOGIC PATIENTS WITH COMMUNITY ACQUIRED PNEUMONIA

P. Heras, K.Grigoriou, A.Stefanopoulos,
A. Eleftheriadi, T. Sirbilatze, K. Kritikos

Hellenic Medical Association of Psychosomatic Problems

Introduction: Community Acquired Pneumonia (CAP) is an important cause of morbidity amd morbility. Hospital admissions for CAP have markedly increased over the last decade, particularly in elderly patients.

Purpose: With this study, our aim was to compare the severity and outcomes of respiratory infections in patients with previous diagnosis of neoplasms with the ones without, in our hospital.

Methods: We reviewed all cases of 'Pneumonia' in hospitalized patients between January 1st and December 31st of 2012.

Results: A total of 320 patients (80 oncologic) were admitted with CAP in 2012. There were no significant differences regarding age between both groups (68 versus 71 years, p=0,133).

Oncologic patients had a higher mortality rate (14.7% versus 28.8%, p=0.003) and more severe disease (SOFA score)(p=0.021). Among patients with oncologic disease, 40 had active disease in the past year, but we only found a tendency for lower survival when comparing these patients with the ones with disease not considered active (343 versus 193 days, p=0.054). Of our patients, 23 had been treated with chemotherapy on the previous 3 months, in a median of 19 days

before the admission with CAP. Only 11 patients did chemotherapy after the CAP admission, in a median of 32 days.
Conclusions: Despite all the limitations of being a small, retrospective study, with this report we hope to alert for how important it is to better understand respiratory infections in oncologic patients in order to improve treatment and prognosis.

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10. EVALUATION OF SATISFACTION IN BREAST CANCER PATIENTS

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A. Eleftheriadi, T. Sirbilatze, K. Kritikos

Hellenic Medical Association of Psychosomatic Problems

Introduction: Overall care requires evaluation, analysis of best professional practice, constantly improving information.
Purpose: We wanted to optimize written support for breast cancer patients (pts) who require neoadjuvant or adjuvant medical treatment. Then, we evaluated the impact on pts satisfaction.
Methods: After assessing pts satisfaction in comprehensive care with a questionnaire, we created a PCP, validated by pts. After given it, we assessed pts satisfaction with the same questionnaire. Then we compared results before (n=310) and after PCP (n=177).We selected the Excellence Score (ES) by taking into account only 'very satisfied' and excluding 'satisfied' scores and the Dissatisfaction Score (DS) by combining 'not very satisfied' and 'very dissatisfied'.
Results: As regards the explanation of treatment justification, ES rose from 67 to 74 % (p NS). Concerning procedure and adverse effects information, ES rose from 63 to 79 % (p 0,001) and 52 to 62 % (p 0,043). When we focus on information related to disease and treatment, ES of written information rose respectively from 36 to 56 % and 39 to 62 % (p<0,001), DS decreased from 21 to 3% (p 0,001 and 20 to 1 % (p<0,001). ES of oral information of 49 to 48 % increased to 65 and 72 % (p<0,001). The satisfaction about possibility to ask questions and to have response rose respectively from 68 to 99 % (p 0,021) and 61 to 97 % (p 0,017).
Conclusions: This study confirms the importance of good written documentation with positive impact not only on written records but also on the face to face physician-patient relationship.

11. IMPACT OF PARACENTESIS ON HEALTH-RELATED QUALITY-OF LIFE (HRQoL) IN CANCER PATIENS WITH MALIGNANT ASCITES

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Introduction: Malignant ascites (MA) is an accumulation of fluid in the abdominal cavity due to uncontrolled tumor growth on the peritoneal surface. MA leads to a significantly impaired general health status and to poor quality-of-life. Paracentesis is the most common treatment for MA.
Purpose: This study was designed to evaluate the impact of paracentesis on HRQoL in cancer patients with MA.
Methods: A prospective, observational study was conducted. The impact was measured by using EQ-5D before and within 1 day after paracentesis. Results were compared with EQ-5D utility scores of other health conditions reported in the literature.
Results: In total, 29 patients were enrolled between 07/2007-08/2009; 45 paracenteses in 28 patients were available for QoL analysis. Mean EQ-5D scores before (0.48±0.26) and after (0.56±0.30) paracentesis revealed a mean increase of 0.08±0.25 indicating a 17 % improvement. QoL improved after 44.4 % of paracenteses, remained unchanged after 26.7% and even deteriorated after 28.9 %. Literature search for other conditions revealed 0.56 means score for hemodialysis patients (1) and 0.48 mean score for patients with chemotherapy-induced-anemia (2).
Conclusions: In over 50 % of patients undergoing paracentesis for MA, no benefit in terms of HRQoL was detected. Before paracentesis, MA patients reported HRQoL equivalent to patients with chemotherapy-induced-anemia. Even after an improvement with paracentesis, patients' HRQoL improved only to a mean level of hemodialysis patients. Study results confirmed poor HRQoL in patients with MA even after paracentesis.

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12. THE IMPACT OF MESH EROSION IN SURGICAL RESTORATION OF PELVIC ORGANS PROLAPSE

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P. Siderisl, D. Agrapidis, A. Antsaklis

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Introduction: The surgical restoration of uterine pro-

lapse stage 2 and 3 and anterior vaginal wall prolapse is made by mesh. If no attendant uterine prolapse then additional surgery is needed. It can be vaginal hysterectomy or amputation of the cervix (Manchester Repair) combined with anteroposterior colporrhaphy.
Aim of Study: The aim of the present study is to highlight mesh erosion in combination with type of surgery for pelvic organ prolapse.
Materials and Methods: Reviewing the medical files of women operated the years 2012-2013 for uterine prolapse and anterior vaginal wall prolapse.
Results: There were 30 vaginal hysterectomies and 17 Manchester procedures with placed mesh. The mesh material was polypropylene (monofilament wide porous). Women aged 50-65 years and were treated with local estrogen both pre and postoperatively. Women were divided into 2 groups, in group A of vaginal hysterectomy and mesh two erosions (6.8%) occured, while in Group B Manchester procedure and mesh no erosion was noticed.
Conclusions: The combination of Manchester procedure and mesh placement had better results in our study as there was no erosion of the anterior vaginal epithelium. Potential factors are less operative time and less tissue injury of the vaginal epithelium.

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13. OVARIAN ADENOCARCINOMA RELAPSE

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Introduction: Ovarian cancer is the second most common gynecological malignancy and the most common cause of death in women with malignancy of the reproductive system. High relapse rates after surgery and additional therapy are observed in advanced (> 3) rather than limited (1 or 2) stages of the disease (70% and 20-25% respectively).
Aim of Study: Highlighting a case of serous ovarian adenocarcinoma recurrence.
Materials and Methods: Was a 40 year old patient with abdominal pain, moderate fever, nausea with vomiting.
Results: In the history of the patient was reported that she had underwent a bilateral oophorectomy for serous ovarian adenocarcinoma preserving her uterus for future fertility. The clinical examination revealed a mass on the right side of the minor retroperitoneal pelvis and coexisted findings of biochemical relapse. The mass was in contact with the iliac vessels, and the ipsilateral ureter, resulting in ureteral dilatation. The patient underwent exploratory laparotomy and excision of the mass. The intraoperative rapid biopsy showed recurrence of the primary tumor. The excision of the mass was complete but laborious due to solid affinity with the iliac vessels and ureter. Anatomical elements were preserved and additional total hysterectomy with debulking procedure were conducted, after mobilization of superior rectum, technique applied in cases of pelvic exenterosis. All the adhesions of the small intestine were removed until the Treitz ligament. The postoperative recovery was uneventful. The patient was discharged on the sixth postoperative day with instructions of a new MRI of the abdomen and retroperitoneum for further assessment by oncologists.
Conclusions: Recurrent ovarian cancer is common. Despite several therapeutic choices, the decision of the appropriate treatment is individualized. Resection of relapse in combination with adjuvant treatment offers the best therapeutic results.

Index

Index

Index

Index

ΚΑΙ ΤΩΡΑ ΕΓΚΕΚΡΙΜΕΝΟ

Το YERVOY™ (ipilimumab) ενδείκνυται για τη θεραπεία του προχωρημένου (ανεγχείρητου ή μεταστατικού) μελανώματος σε ενηλίκους που έχουν λάβει προηγούμενη θεραπεία.[1]

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1. Περίληψη Χαρακτηριστικών Προϊόντος του YERVOY™. 2. Hodi FS *et al. N Engl J Med.* 2010;363(8):711-723.

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