5200 POSTER

Symptoms and Quality of Life in Women Awaiting Breast Cancer Surgery

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Breast cancer is globally the most common malignancy in women and is one of the most common causes of mortality and morbidity. Most women diagnosed with breast cancer will have surgery as a first line treatment. However, symptoms in women with breast cancer prior to any treatment have seldom been investigated. The presence of pre-surgery symptoms may be significant as symptoms can contribute to increased distress and impaired quality of life.
The purpose of this paper is to examine the pretreatment symptoms that women awaiting breast cancer surgery in Ireland are experiencing and the impact of these symptoms on their quality of life. The design of this study is prospective longitudinal. The sample comprised of women newly diagnosed with breast cancer. Symptoms were assessed using the Hospital Anxiety and Depression Scale, Insomnia Severity Index, Functional Assessment of Cancer Therapy-Fatigue and Brief Pain Inventory. The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30(3) was used to assess quality of life. Data was inputted and analysed using PASW (V. 17).
Results indicated that overall participants (n = 94) experienced a range of symptoms prior to surgery, with pain and anxiety being more prevalent symptoms than either fatigue, sleep disturbances or depression. There were no significant correlations found between age, BMI and the symptoms experienced. While participants scored well on the global quality of life scale, quality of life was significantly impacted on by factors such physical, emotional, social functioning and fatigue.
In view of the impact of pre-surgical symptoms on quality of life and post surgery outcomes, there is a definite need to consider that while symptoms may be limited, when present, they could be significant. These women are just at the beginning of a long road through treatment. Early symptoms must be assessed and addressed promptly and effectively in order to improve quality of life and reduce adverse outcomes post surgery.

5201 POSTER

The EXpand Study − Effect of Zoledronic Acid on Prevention of Bone Loss, During Extended Adjuvant Therapy With Letrozole in Postmenopausal Women With Primary Hormone Receptor Positive Breast Cancer Compared to Letrozole Alone

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Background: The treatment of postmenopausal women with breast cancer (BC) with an aromatase inhibitor (AI) suppresses estrogen synthesis, leading to acceleration of bone loss. Bisphosphonates are effective inhibitors of bone resorption and have demonstrated their therapeutic efficacy in malignant bone conditions and prevent bone loss associated with cancer treatment in the adjuvant setting. The aim of this study was to assess the effect of ZOL on the prevention of aromatase inhibitor bone loss (AIBL), administered in combination with Letrozole (LET) in postmenopausal women (PMW) with primary hormone receptor positive (HR+) breast cancer compared to LET monotherapy.
Material and Methods: This prospective, randomized, open-label, two arm phase III trial is the first study to investigate the effect of ZOL administered in combination with LET on the prevention of AIBL as extended adjuvant therapy of PMW with primary HR + breast cancer, pre-treated with 4−6 years of adjuvant Tamoxifen (TAM) after surgery, compared to LET alone. Patients were treated with LET 2.5 mg daily with or without ZOL 4 mg IV q 6 months for 36 months. The primary objective was to assess the BMD change measured by DXA at the lumbar spine (LS) at 36 months. Secondary efficacy parameters and tolerability were also evaluated.
Results: It was planned to randomize 460 pts. The study had to be stopped prematurely due to changes in adjuvant treatment as AIs became the goldstandard. From the 83 pts enrolled, 45 pts completed the entire 36 months of the trial. A significant change in BMD (g/cm^2 CaHA) at month 36 of −0.11 (LS-Mean) in the LET arm (21 pts) compared to −0.02 (LS-Mean) in the ZOL + LET arm (20 pts) was seen (p = 0.0026). This translates into a BMD percent change of −11.47% in the LET arm and −2.57% in the ZOL + LET arm (p = 0.0033). Most frequently reported AEs were bone pain (7.4%), arthralgia (6.8%) and hot flushes (5.6%) in the LET arm and arthralgia (5.5%), bone pain (5.5%) and pain in extremity (4%) in the ZOL + LET arm.
Conclusions: In this prospective, randomized multicenter trial we were able to show that the combination of ZOL with LET as extended adjuvant therapy of PMW, pre-treated with TAM, results in a significantly reduced loss of BMD after 36 months of treatment when compared to the treatment with LET alone. Combination treatment with ZOL and LET was safe and well tolerated.

5202 POSTER

Diagnosis of Small (1 cm and Less) Breast Cancer by Combination of Functional and Anatomical Imaging

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Early diagnosis of breast cancer (BC) can significantly improve treatment results. Accuracy of conventional diagnostic methods is not sufficient in this patient group. Taking into account that advantages and limitations of anatomical and functional imaging are different we test the proposal that their combination can be of significant diagnostic value.
Material and Methods: Thirty five women suspicious for BC with lesion diameter less than 1 cm and inconclusive results of clinical and mamographic examinations were included in this study. High frequency digital wide field of view ultrasound (US) was performed by experienced radiologist. Following sings were considered abnormal: irregular morphology, poorly defined edges, inhomogeneous echo structure, posterior acoustic attenuation, hyperechogenicity. Breast scintigraphy (BrSc) was performed in planar and tomography modes 15 min after i/v injection of 740–860 MBq 99mTc-sestaMIBI. Images with focal and scattered patchy uptake were scored as abnormal. All lesions were verified by biopsy and follow-up or by operation.
Results: US examinations diagnosed benign lesions in 27 of 35 evaluated women: 21 true negative, 6 false negative. In remaining 8 cases US signs of BC were true positive. Sensitivity (Sen), Specificity (Sp) and Accuracy (Ac) of US were as follows: 57%, 100% and 82%.
BrSc revealed 12 of 14 cases of BC and refused malignancy in 16 of 21 women's with benign breast lesions. This resulted in Sen 86%, Sp 76% and Ac 80%.
Taking into account high specificity of US, combination of functional and anatomical imaging looks attractive only in respect of increasing diagnostic sensitivity. This was proved by strategy according to which BC was determined by abnormality either on US or on BrSc with corresponding Sen 100%, Sp 76% and Ac 82%.
Conclusion: Combination of functional (BrSc) and anatomic (US) imaging permit early diagnosis of BC in 100% of women with tumours less than 1 cm by the expense of 24% excessive biopsies.

Oral Presentations (Sat, 24 Sep, 11:15−13:30)
Gastrointestinal Malignancies − Colorectal Cancer

6000 ORAL

A EURECCA Initiative − Differences in Treatment and Short-term Outcome of Rectal Cancer

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Background: Colorectal cancer is the second most commonly diagnosed type of cancer as well as the second most common cause of cancer related death in Europe. There are major differences in survival across Europe. By combining national audits, which have achieved excellent results, a European Audit can lead to treatment improvements and decrease the variation in survival across Europe. Supported by these arguments

the European CanCer Organisation (ECCO) initiated a European audit; European Registration of Cancer Care (EURECCA). The aim of the present study is to assess treatment variety and short term outcome of rectal cancer patients in a combined population based dataset from Norway, Sweden, Denmark and the Netherlands.
Methods: Patients diagnosed with rectal cancer in 2008 and/or 2009 and underwent surgical treatment were selected from the Norwegian Colorectal Cancer Registry, the Swedish Colorectal Cancer Registration, the Danish Colorectal Cancer Database and the Dutch Surgical Colorectal Audit (n = 6597), all population-based registration projects. Differences in age, gender, stage at diagnosis and the use of radio(chemo)therapy were compared between the countries using chi square tests. The use of radio(chemo)therapy was also compared according to stage within the countries. We further compared the 30-day mortality between the countries with a logistic regression model build to assess independent predictive factors.
Results: Overall, the Netherlands had a slightly younger population, no differences in gender distribution were found, and in the Norwagian data stage at diagnosis was more often unknown. The use of radio(chemo)therapy was the lowest in Denmark (24.9%), followed by Norway (50.3%), Sweden (60.7%), and the highest in the Netherlands (81.2%). The use of radio(chemo)therapy differed per stage for each country: in Denmark and the Netherlands patients with stage I, II, and III more often received radio(chemo)therapy; while in Norway stage IV and in Sweden for stage II, and III patients received more often radio(chemo)therapy. Results of the 30-day mortality analyses will be presented late breaking at the 2011 European Multidisciplinary Congress in Stockholm.
Conclusion: In western Europe, there are substantial differences between the use of radio(chemo)therapy. The first results of international comparisons in the population-based EURECCA-project may be the first step to find the right balance between under and over treatment.

6001 ORAL

Surgical Care in Low Rectal Cancer Patients Can Be Improved − an Analysis of 4084 Patients From the Dutch Surgical Colorectal Audit (DSCA)

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Background: Oncological outcome for rectal cancer has improved considerably since the introduction of TME surgery. However, in patients with low rectal cancer requiring an abdominoperineal excision (APE) the number of irradical resections and tumour perforations remain high. A surgical audit was performed In order to evaluate the quality of (peri) operative care and to determine areas for improvement.
Patients and Methods: A pooled analysis was performed on 4084 patients that were included in the audit between 2009 and 2010.
Results: In 2010, 92 out of 94 hospitals in The Netherlands participated in the DSCA registration (98%) compared to 89% in 2009. When the data of 2009 is compared to that of the NKR (Dutch cancer registry) it is estimated that 85% of the patients have been entered. The average age at diagnosis was 67 yrs and 83% of the patients were ASA I or II. Preoperative staging with MRI as advised in the Dutch Guidelines was made in 89% of all elective patients and 88% was discussed in a multidisciplinary meeting. Of all patients with an indication for neoadjuvant treatment 87% did receive (chemo)radiotherapy. The distance of the tumour to the anal verge was <5 cm in 37% and 5−10 cm in 41% in which an APE was performed in 65% and 14% respectively. A large variation is found when the type of surgery (LAR vs. APE) is compared among hospitals. Even though the importance of circumferential resection margins ($\geqslant$1 mm) is widely accepted, these data were missing in 43% of the patients. Positive CRM were found in 12% and occurred more often in APE than LAR (16% vs. 10%). In T4 tumours receiving APE involved margins were found in 25% and 15% in tumours close to the anal verge (<5 cm). Adjuvant chemotherapy was administered to 15% of the patients which is conform the Dutch guideline recommendations.
Conclusion: The high registration rate clearly demonstrates that the Dutch surgical community is dedicated to improve the transparency and the quality of peri-operative care. High standard preoperative care is provided for most patients with low rectal cancer. However, there is a considerable variation among hospitals in the APE rates and pathology reports. The large number of missing CRM is worrying since it serves as a key measure of the quality of rectal surgery. The audit has identified areas for improvement in low rectal cancer patients in The Netherlands. In order to ameliorate surgical care standardized pathology reports and surgical workshops are required to decrease the number of irradical resections during APE.

6002 ORAL

Short Term Outcome After Neoadjuvant High Dose Rate Endorectal Brachytherapy or Short Course External Beam Radiotherapy in Resectable Rectal Cancer

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Background: Total mesorectal excision (TME) together with preoperative radiotherapy has reduced the local recurrence rates after resection for rectal adenocarcinoma. However, preoperative radiotherapy increases the risk of long term and short term postoperative complications. The standard choice is preoperative external beam radiotherapy, but preoperative endorectal brachytherapy has been used as an alternate neoadjuvant treatment. The purpose of this study was to compare immediate postoperative outcome between preoperative external beam radiotherapy and preoperative endorectal brachytherapy.
Material and Methods: 318 patients treated with preoperative endorectal brachytherapy (HDEBRT) at the McGill University Hospital, Canada were matched (age, gender and stage) to patients from the Swedish Rectal Cancer Register treated with; short course preoperative radiotherapy, SCRT, (n = 318) and TME-surgery alone, RT− (n = 318). The brachytherapy group was given 6.5 Gray (Gy) daily endoluminal over 4 days followed by TME-surgery after 4−8 weeks. The SCRT-group was given 5 Gy daily over 5 days and TME- surgery the next week. Patients were followed until 30 days post operatively. Complications were divided into surgical, cardiovascular and infectious.
Results: A total of 954 patients were included in the analysis. The SCRT group had a lower number of cardiovascular complications than both HDEBRT (10 vs 25, p = 0.0136) and RT− (10 vs 23, p = 0.0273). The HDEBRT patients had fewer minor surgical complications than patients in the SCRT-group (53 vs 91, p = 0.0042). No difference could be seen between the three groups regarding major surgical complications or infectious complications. The HDEBRT group had a lower frequency of R2 resections than both Swedish groups and the proportion R0-resections were higher in the HDEBRT group than in RT− (p = 0.0250).
Conclusions: Preoperative irradiation given as brachytherapy yields less surgical complications than SCRT and a higher number of patients with R0-resections. There are differences in registration between Sweden and Canada, especially regarding complications. A longer interval between radiotherapy and surgery is beneficial for tumour regression and this could be reflected in the number of radical resections.

6003 ORAL

Role of KRas Status in Patients With Metastatic Colorectal Cancer Receiving First-line Chemotherapy Plus Bevacizumab − a TTD Spanish Group Cooperative Study

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Background: Data suggest that Kirsten-ras (KRAS) mutational status has no predictive role in patients with metastatic colorectal cancer (mCRC) treated with bevacizumab and chemotherapy [Ince et al. 2005]. The prognostic role of KRAS status is less clear. To investigate this further, an exploratory, retrospective analysis of the MACRO randomized phase III study [Tabernero et al. ASCO 2010, abstract 3501] was performed to investigate the relationship between KRAS status and clinical outcome in patients with mCRC who received first-line treatment with chemotherapy plus bevacizumab (Bev) followed maintenance therapy with Bev ± chemotherapy.
Methods: Patients with mCRC received capecitabine/oxaliplatin (XELOX) plus Bev for 6 cycles followed by maintenance therapy with XELOX plus Bev or single-agent Bev. Tumour samples from consenting patients were collected at baseline and analyzed for KRAS status. The relationship between KRAS status and overall response rate (ORR), progression-free survival (PFS) and overall survival (OS) was analyzed: (i) in all evaluable patients; and (ii) by maintenance regimen.
Results: The intent-to-treat population included 480 patients. KRAS status was analyzed in 331 patients; 180 (54.4%) had KRAS wild-type (WT) and 151 (45.6%) had KRAS mutant (MT) tumours. In the XELOX-Bev