

## 5200

## POSTER

**Symptoms and Quality of Life in Women Awaiting Breast Cancer Surgery**

S. Denieff<sup>1</sup>, M. Gooney<sup>1</sup>, S. Cowman<sup>2</sup>. <sup>1</sup>Waterford Institute of Technology, Health Sciences, Waterford, Ireland; <sup>2</sup>Royal College of Surgeons, Faculty of Nursing, Dublin, Ireland

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 as 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**

M. Hellriegel<sup>1</sup>, M. Mueller<sup>2</sup>, T. Reimer<sup>3</sup>, D.T. Baerens<sup>4</sup>, A. von der Assen<sup>5</sup>, J. Hackmann<sup>6</sup>, K. Schmidt<sup>7</sup>, M. Baier-Ebert<sup>8</sup>, T. Spall<sup>9</sup>, G. Emons<sup>1</sup>.

<sup>1</sup>University of Goettingen, Department of Obstetrics & Gynecology, Goettingen, Germany; <sup>2</sup>Medical Practice, Leer, Germany; <sup>3</sup>University of Rostock, Department of Obstetrics & Gynecology, Rostock, Germany; <sup>4</sup>Medical Practice, Ilsede, Germany; <sup>5</sup>Franziskus-Hospital Harderberg, Department of Obstetrics & Gynecology, Hardenberg, Germany; <sup>6</sup>Marien-Hospital Witten, Breast Center, Witten, Germany; <sup>7</sup>Novartis Pharma GmbH Germany, BU Oncology, Nuremberg, Germany; <sup>8</sup>Novartis Pharma GmbH Germany, Biometrics, Nuremberg, Germany; <sup>9</sup>Clin Sol – Clinical Research Solutions GmbH, Clinical Research Management, Wuerzburg, Germany

**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<sup>2</sup> 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**

S. Novikov<sup>1</sup>, S. Kanaev<sup>1</sup>, P. Krivorotko<sup>1</sup>, V. Semiglazov<sup>1</sup>, L. Jukova<sup>1</sup>.

<sup>1</sup>N.Petrov Research Institute of Oncology, Radiation Oncology & Nuclear Medicine, Saint-Petersburg, Russian Federation

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 signs 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**

C.B.M. van den Broek<sup>1</sup>, N.E. Kofschoten<sup>1</sup>, W. van Gijn<sup>1</sup>, E. Bastiaannet<sup>2</sup>, L. Pahlman<sup>3</sup>, H. Harling<sup>4</sup>, A. Wibe<sup>5</sup>, E.H. Edes<sup>6</sup>, C.J.H. van de Velde<sup>1</sup>, The EURECCA consortium, an ECCO initiative, Brussels, Belgium.

<sup>1</sup>Leiden University Medical Center, Surgery, Leiden, The Netherlands;

<sup>2</sup>Leiden University Medical Center, Surgery and Gerontology and Geriatrics, Leiden, The Netherlands; <sup>3</sup>Uppsala University, Surgery Sciences, Uppsala, Sweden; <sup>4</sup>Bispebjerg University Hospital, Surgery, Copenhagen, Denmark; <sup>5</sup>Norwegian University of Science and Technology and Cancer Registry of Norway, Colorectal Cancer Registry, Trondheim and Oslo, Norway; <sup>6</sup>Deventer Hospital, Surgery, Deventer, The Netherlands

**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