

Younger patients were most dissatisfied. 32% of patients reported, that the hospital staff had no or poor interest in the relatives' situation. After treatment, 25% felt they were not well informed about support possibilities outside the hospital. Among patients who said they needed to talk to a psychologist, 65% had not been offered this service. The breast cancer patients experienced a number of symptoms and late effects related to cancer and treatment. Thus 70% of patients had at least one symptom or effect. Most frequent were fatigue (45%) and sexual problems (28%).

**Conclusions:** The results from the study have been widely shared with health care professionals in order to improve psycho-social and other support for breast cancer patients. Also, Hellenic Medical Society for the Study of Psychosomatic Problems has initiated a strategic initiative to support research and development in patient involvement, communication and support of relatives.

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POSTER

#### The role of cryotherapy on fentanyl use in breast cancer patients

V. Xourafas<sup>1</sup>, P. Heras<sup>1</sup>, A. Hatzopoulos<sup>1</sup>, S. Karagiannis<sup>1</sup>. <sup>1</sup>Hellenic Medical Society for the Study of Psychosomatic Problems, Hellenic Medical Society for the Study of Psychosomatic Problems, Athens, Greece

**The aim** of the present study was to evaluate if oral cryotherapy during chemotherapy may delay or alleviate the intensity of oral pain derived from mucositis among patients who receive super intensive chemotherapy for breast cancer and hereby reduce the number of days with s.c. fentanyl.

**Patients and Methods:** 150 patients of 18 years and older, who were scheduled to receive super intensive chemotherapy were included consecutively and randomised to oral cryotherapy or control. A stratified randomisation was used with regard to type of chemotherapy. Pain was assessed verbally in the daily routine care at the ward. The number of days with s.c. fentanyl and other advanced pharmacological pain treatment were collected from the medical and nursing charts.

**Results:** Our study showed that patients who received oral cryotherapy had significantly fewer days with s.c. fentanyl compared to the control group ( $p < 0.001$ ) and the former also reported less oral pain.

**Conclusion:** Oral cryotherapy reduces oral pain and the number of days with s.c. fentanyl for patients treated with super intensive chemotherapy for breast cancer.

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POSTER

#### Symptoms-signs and quality of life in Greek outpatients with breast cancer

M. Mantzioros<sup>1</sup>, P. Heras<sup>1</sup>, A. Hatzopoulos<sup>1</sup>, E. Mihail<sup>1</sup>, K. Kritikos<sup>1</sup>.

<sup>1</sup>Hellenic Medical Society for the Study of Psychosomatic Problems, Athens, Greece

**The aim** of this study was to evaluate the symptoms, signs and their incidence in the quality of life of breast cancer patients.

**Patients and Method:** We list usual symptoms and signs in breast cancer patients and asked them "What are concerning you today?", after we present cards with the information provided, and we ask to hierarchies these problems. Pain was explored in particular, even when it was not referred spontaneously. Registration of diagnostic, therapeutics and sociodemographic characteristics were done.

**Results:** 65 women with breast cancer were evaluated (mean age 55.2 years SD 14.4). 38 different symptoms were referred, 35.5% are free of symptoms, 26.5% have 2, 7% 3, 1% 4 and 0.5% 5. The most distressful were pain (19%) asthenia (11.5%), nausea and vomits (5%), anorexia (5%), anxiety (5.5%), caught (3%), dyspnoea (4%), alopecia (2%). In the global, pain was referred by 24.5%, asthenia 20%, anorexia 7.5%, nausea and vomits 8%, anxiety 5%, diarrhea 4%, dyspnoea 4%. When asked directly about pain, 58.5% reported, that was assessed using a scale from 0 to 10; pain intensity: Median = 2; media = 2.63 (SD 2.83). Correlation of pain and diagnostic, therapeutics and sociodemographic characteristics; will be present.

**Conclusion:** Pain continues to be the more frequent symptom and cause more suffer. We verify that are 24% of patients only referred pain when questioned directly about that, so it is mandatory to evaluated pain in all visits. Asthenia and anorexia are high incidence, even we have small efficacy in alleviate these, we can implement some strategies of coping. It is a small sample of patients, we will continue this study in order to have a better understanding about what influence suffering from breast cancer patients.

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POSTER

#### Tablet burden in women with metastatic breast cancer: implications for clinical practice

A.J. Dickens<sup>1</sup>, C.J. Twelves<sup>2</sup>. <sup>1</sup>St James's University Hospital, Medical Oncology, Leeds, United Kingdom; <sup>2</sup>Leeds Institute of Molecular Medicine, St James's Institute of Oncology, Leeds, United Kingdom

**Background:** The use of oral anti-cancer drugs is increasing, and it is widely believed patients prefer oral medication. However, with many patients taking oral concomitant medications 'tablet burden' may be an issue.

**Materials and Methods:** One hundred women with MBC were interviewed, mean age 59 (range 35–98); 52% were receiving endocrine therapy, 29% chemotherapy and 8% both. Most (86%) were out-patients identified sequentially in clinic, the remainder were in-patients. We recorded (i) number and nature of tablets, (ii) whether tablets were inconvenient, (iii) self-reported compliance, and (iv) if women would prefer further anti-cancer treatment to be a short i.v. infusion or an additional 6 tablets/day, assuming them to be equally effective.

**Results:** *Tablet burden:* The number of tablets taken/day ranged from 0–31, mean 8.6, median 6; 32% of women took  $\geq 10$  tablets/day and tablet burden was higher in younger women. Analgesics accounted for 40% of tablet burden with endocrine therapy and oral chemotherapy, contributing a further 15%; 28% of tablets were concomitant medicines e.g. statins and anti-hypertensives.

*Compliance:* Most (62%) reported full compliance, 24% omission once/week and 8% more often. Self-reported compliance did not differ between those taking  $< 10$  tablets and  $> 10$  tablets/day.

*Convenience:* Most (68%) reported oral medication as not being inconvenient, 14% reporting inconvenience as 'slight' and 12% as 'very'. Inconvenience was, however, greater in women taking  $\geq 10$  tablets/day.

*Preference:* Half (53%) would prefer additional oral to i.v. therapy, the remainder would prefer i.v. (34%) or had no preference (13%). Preference was not affected by tablet burden. Reasons for preferring oral included difficult i.v. access (31%), convenience (27%) and personal experience (9%); i.v. treatment was preferred due to dislike of tablets (32%), convenience (29%) and not being responsible for remembering to take tablets (18%).

**Conclusions:** Tablet burden is variable, but high in many women with MBC. Although good compliance is claimed, many women find oral medication inconvenient, especially if taking  $\geq 10$  tablets/day. Most women would, however, opt for oral rather than i.v. cancer therapy; 1/3<sup>rd</sup> would prefer i.v. and preference was not affected by tablet burden. Oncologists should critically evaluate the need for concomitant medicines in women with MBC and if possible offer the choice between oral and i.v. anti-cancer therapy.

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POSTER

#### Effects on quality of life (QoL) of docetaxel-based weekly chemotherapy in patients with locally advanced (LABC) or metastatic breast cancer (MBC): results of a single-centre randomized phase 3 trial

F. Nuzzo<sup>1</sup>, F. Di Rella<sup>1</sup>, A. Morabito<sup>2</sup>, A. Gravina<sup>1</sup>, V. Labonia<sup>1</sup>, G. Landi<sup>1</sup>, C. Pacilio<sup>1</sup>, M.C. Piccirillo<sup>2</sup>, M. Di Maio<sup>2</sup>, A. de Matteis<sup>1</sup>. <sup>1</sup>National Cancer Institute, Medical Oncology C, Napoli, Italy; <sup>2</sup>National Cancer Institute, Clinical Trials Unit, Napoli, Italy

**Purpose:** To evaluate whether weekly schedule of docetaxel-based chemotherapy was superior to standard 3-weekly administration in terms of QoL in patients with LABC or MBC.

**Patients and Methods:** Main inclusion criteria were: LABC or MBC, age  $\leq 70$  years, ECOG PS 0–2, no previous chemotherapy for metastatic disease. Patients not previously treated with anthracyclines were randomized to weekly or 3-weekly combination of docetaxel and epirubicin. Patients pretreated with anthracyclines were randomized to weekly or 3-weekly combination of docetaxel and capecitabine. Primary end-point was global QoL change at 6-weeks, measured by items 29–30 of EORTC QLQ-C30. With a two-sided  $\alpha$  0.05 and 80% power for 35% effect size, 130 patients per arm were needed. A Daily Diary Card (DDC) was also used.

**Results:** The study was closed prematurely because of external evidence against the use of weekly docetaxel. From February 2004 to March 2008, 135 patients (42 LABC, 52 MBC not pretreated with anthracyclines, 41 MBC pretreated with anthracyclines) were randomized: 70 to weekly and 69 to 3-weekly arm. Out of 129 patients with baseline QoL, 89 filled the 6-weeks questionnaires. Global QoL was better in the 3-weekly arm ( $p = 0.03$ ). Role functioning and financial scores were worse with weekly treatments ( $p = 0.02$  and  $p < 0.001$ ). Daily QoL profiles were consistent with a negative impact of 3-weekly treatment in the first week and the reverse during subsequent weeks. Neutropenia and stomatitis were worse in the

3-weekly arm, where two toxic deaths were observed. Overall response rate was 39% and 33% in 3-weekly and weekly arms; hazard ratio (HR) of progression was 1.29 (95% CI: 0.84–1.97) and HR of death was 1.38 (95% CI: 0.82–2.30) for patients in the weekly arm.

**Conclusions:** Although low power due to early termination, this trial does not support the use of weekly docetaxel-based chemotherapy in patients with LABC or MBC.

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POSTER

# **A Q-TWiST analysis of lapatinib plus letrozole compared with letrozole alone as first-line therapy in hormone receptor positive (HR+) metastatic breast cancer (MBC)**

B. Sherrill<sup>1</sup>, M. Amonkar<sup>2</sup>, B. Sherif<sup>1</sup>, J. Maltzman<sup>2</sup>, L. O'Rourke<sup>2</sup>, S. Johnston<sup>3</sup>. <sup>1</sup>RTI-Health Solutions, Biometrics, Research Triangle Park, USA; <sup>2</sup>GlaxoSmithKline, Oncology, Collegeville, USA; <sup>3</sup>Royal Marsden NHS Foundation Trust & Institute of Cancer Research, Clinical Research & Development, Collegeville, USA

**Background:** In a phase 3 study of first-line treatment for HR+ MBC, women were randomized to receive either lapatinib plus letrozole (L+Let) or letrozole plus placebo (Let). Combination therapy showed a 14% reduction in risk of disease progression in the ITT population ( $p=0.026$ ) and a 29% risk reduction in the HER2+ population ( $p=0.019$ ), with stable QOL in both treatment groups. This analysis applies the quality-adjusted time without symptoms of disease or toxicity of treatment (Q-TWiST) method to compare the trade-off between toxicities and delayed progression.

**Methods:** The area under overall survival curves for each treatment group was partitioned into 3 health states: toxicity (TOX), time without toxicity or disease progression (TWiST), and the period following disease progression until death or end of follow-up (REL). TOX is time spent with grade 3/4 adverse events (AEs) during progression-free survival (PFS) time. TWiST is the remaining time prior to progression in which no serious AEs were experienced. The utility-weighted sum of the mean health state durations was derived, and treatment comparisons of Q-TWiST were made at varying combinations of utility weights using a threshold utility analysis.

**Results:** The ITT population included 1286 patients, of which 17% were HER2+ ( $N=219$ ). In the primary analysis of the HER2+ population, overall median survival was 140 weeks (data as of 03JUN08). There was no significant difference between groups in mean duration of serious AEs prior to progression (L+Let, 1.95 weeks; Let, 2.14 weeks;  $p=0.90$ ). The Q-TWiST difference between groups ranged from 8–9.5 weeks favoring combination therapy for all hypothetical utility levels, although none of the comparisons were statistically significant at  $p=0.05$ . When counting 2 days of TOX or REL as 1 day of TWiST (i.e. using utility weights of 0.5), the difference in quality-adjusted survival favoring L+Let was 8.8 weeks ( $p=0.09$ ). For the ITT population, Q-TWiST differences ranged from 0–7.5 weeks.

**Conclusion:** The significantly longer progression-free survival observed in HER2+, HR+ MBC patients taking the combination of L+Let vs Let was achieved without significant differences in mean duration of serious AEs. Quality-adjusted survival was favored for the combination arm in the overall and HER2+ populations.

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POSTER

# **Impact of psycho emotional therapy in locally advanced breast cancer patients receiving chemotherapy**

A. Kaushal<sup>1</sup>. <sup>1</sup>HCG Medi-surge Hospital, Medical Oncology, Ahmedabad, India

Locally advanced breast carcinoma (LABC) is uncommon in developed world however it is still present with a large proportion in developing world. The management of LABC is a challenge not for medical oncologist, surgeon, and radiotherapist but also for psychoncologist. Most of the cases relate to late reporting of breast lump and socioeconomic factors.

This study was performed in HCG Medi-Surge hospital Ahmedabad, Gujarat from 1<sup>st</sup> July 2007 to 30<sup>th</sup> June 2008. We divided two groups of LABC who were taking treatment in this hospital in the last one year. One group received psychoncologist helps according to distress level and as well as personal attention from medical oncologist and regular advise from a patient who had completed her treatment and survived while other group is only treated and emotional support was not given.

**Result:** In group A, we have taken 54 cases compared to group B where we have taken 28 cases. We found that 8 cases out of 28 cases discontinued/lost to follow up their treatment compare to 3 cases out of 54 cases of group A. Most important role was of a patient who finished her treatment and survived.

Treatment of LABC is very long and aggressive. Most of the time patient discontinue or are lost to follow up their treatment especially when they suffer side effects of chemotherapy and poor response. So

psycho emotional therapy prior to induction chemotherapy and continued during chemotherapy cycles helps in better patient compliance especially when they have treatment related side effects. Although this fact is well established in developed countries but still needs evaluation in developing countries.

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POSTER

# **Capecitabine provides substantial quality of life gain in patients with pretreated metastatic breast cancer**

H. Lueck<sup>1</sup>, M. Kaufmann<sup>2</sup>, P. Reichardt<sup>3</sup>. <sup>1</sup>Medizinische Hochschule Hannover, Gynäkologisch-Onkologische Praxis, Hannover, Germany; <sup>2</sup>University Hospital Frankfurt, Department of Obstetrics and Gynecology, Frankfurt, Germany; <sup>3</sup>Helios Klinikum Bad Saarow, Klinik für Innere Medizin III, Bad Saarow, Germany

**Background:** In patients with metastatic breast cancer (MBC) for whom anthracycline and taxane use is inappropriate, capecitabine (X) is considered the standard of care. This phase II open-label study (M66103) evaluated the efficacy and safety of X in MBC after pretreatment with paclitaxel or docetaxel, and assessed the effect of X on quality of life (QoL), as measured by the EORTC QLQ-C30 score.

**Methods:** EORTC QLQ-C30 indexes six multi-item scales of functioning, and measures nine multi-item scales, or single items of symptoms. Items were scaled on a yes or no basis or on 4-point Likert-type scales, while Global Physical Condition and Global QoL were assessed by two 7-point Likert scales. All scores were linearly transformed to a 0 to 100 range. Results were compared with reference data from the EORTC QLQ-C30 Scoring Manual for MBC patients. In total, 136 patients received X (1,250 mg/m<sup>2</sup> b.i.d. for 14 days, q3w). QoL scores were analysed at visit 1 before treatment initiation, at visit 5 after the end of cycle 4 (before cycle 5), and considering all assessments after start of treatment. Missing values at visits after start of treatment were replaced by the method 'last value carried forward' and visit 5 scores were compared to the scores of all assessments after start of treatment.

**Results:** There was agreement between assessment methods. For all scales of functioning, other than cognitive, patients were in worse general condition, with a lower QoL score than the reference group before therapy. Treatment with X achieved a substantial gain in QoL versus baseline across all scales of functioning, other than cognitive. Patients also reported improved symptom scores for all symptoms, except diarrhoea, a known side effect of X.

	Reference	Pre-X	Post-X (cycle 4)
<b>Scales of functioning</b>			
<b>Higher scores represent better functioning</b>			
Physical	64.1	62.6	70.4
Role	63.4	42.1	51.7
Emotional	64.8	51.4	65.3
Cognitive	81.1	81.8	85.7
Social	70.1	53.3	70.3
Global Health Status/QoL	50.9	44.9	55.2
<b>Symptom scales</b>			
<b>Higher scores represent more symptoms</b>			
<i>Multi-item scales</i>			
Fatigue	40.1	52.9	49.1
Nausea and vomiting	12.4	13.9	12.3
Pain	39.0	44.7	37.0
<i>Single items</i>			
Dyspnoea	28.9	43.8	28.0
Insomnia	34.6	42.5	34.0
Appetite loss	28.6	34.2	24.5
Constipation	16.9	17.2	7.3
Diarrhoea	8.1	8.3	18.7
Financial difficulties	16.8	22.9	15.3

**Conclusions:** These data demonstrate that X provides a substantial gain in specific QoL elements in this patient population. QoL is an important goal of therapy for patients with advanced disease.