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POSTER

Excision of primary tumour improves survival in metastatic breast cancer patients

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Background: Metastatic breast cancer (MBC) is an incurable disease, and thus removal of the primary tumour (PT) is not recommended in the routine management. However, several retrospective studies support a benefit of the local control of the PT on survival in patients with MBC. The aim of our study was to assess the impact of local surgery on progression free (PFS) and overall survival (OS) in patients (pts) with MBC at diagnosis.

Material and Methods: A retrospective study was performed between February 1982 and September 2005 in the Hospital Clínico in Valencia. 255 pts diagnosed with MBC at diagnosis were recruited, of whom 132 underwent an attempt of excision of the PT and 123 pts did not received local therapy. Univariate and multivariate analysis of surgery and other prognostic variables was performed in order to avoid potential confounding bias.

Results: Median age was 60 years (25–88). 22.7% were premenopausal and 74.9% postmenopausal. Performance status (PS) was 0 (60%), 1 (18.8%), 2 (15.7%) and 3 (5.4%). Comorbidity was assessed with the Charlson scale, scores in the global series were 0 (75.6%), 1 (16.5%), 2 (7.1%), 3 (0.8%).

Histological diagnosis was ductal carcinoma (78%), lobular carcinoma (11.8%), carcinoma non-specified (8.6%) and other (1.6%). 10 pts had an inflammatory breast cancer. Estrogen receptors were +ve in 37.3%, -ve in 29.8% and unknown in 32.9%. Progesterone receptors were +ve in 32.2%, -ve 34.5% and unknown in 33%. Number of metastatic sites were 1 (54.1%), 2 (26.7%) and 3 or more (19.3%).

Surgery of PT was performed in 132 pts, with a radical mastectomy and axillary lymphadenectomy in 108 pts (83%), mastectomy without lymphadenectomy in 12 pts (4.7%) and tumorectomy in 12 (4.7%).

Operated patients were significantly younger, with lower PS score, and less number of metastatic sites. No differences in Charlson scores were found between operated and not operated pts.

Surgery and number of metastasis were identified as prognosis factors for PFS ($p=0.007$ and $p=0.047$ respectively) and for OS ($p<0.001$ and $p=0.027$ respectively). Significant benefit of surgery was maintained in the multivariate analysis with other potential influenced variables as age, PS and Charlson score.

Conclusions: Surgical removal of PT and number of metastatic sites are independent prognostic factors for PFS and OS in pts with MBC at diagnosis. Local control remains as an important target in the routine management of MBC.

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POSTER

Electrochemotherapy as palliative treatment for chest wall recurrence of breast cancer – initial results

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Background: By applying short electric pulses to cells, the cell membranes can become permeabilised (electroporation). This can be used to augment the effect of chemotherapy, by providing direct access to the cell cytosol (electrochemotherapy). For the drug bleomycin, the enhancement of effect is several hundred folds, enabling once-only treatment. This method has proven highly effective in palliative treatment of cutaneous tumors less than 3 cm in diameter but has not yet been investigated for larger tumour areas. The primary aim of this study is to evaluate the efficacy and safety of electrochemotherapy as a palliative treatment for chest wall recurrence of breast cancer where other modalities have failed.

Material and Methods: This is an investigator initiated phase II clinical trial. 28 patients are to be recruited based on Simon's optimal two-stage design for phase II clinical trials. www.clinicaltrials.gov identifier NCT00744653.

Inclusion criteria includes: Chest wall recurrence of breast cancer; lesions totalling over 3 cm in diameter; symptomatic relief is needed; WHO performance status 0–2; written, informed consent.

Treatment Plan: Patients will be treated in general anaesthesia and a standard dose of bleomycin will be given intravenously. Electric pulses will be administered using a square wave electroporator (IGEA, Carpi, Italy). Re-treatment can be administered three times in case there are areas which have not been sufficiently dealt with in the first treatment round.

Response assessment using RECIST criteria is done by measurement of lesion extension, digital photography and PET/CT-scans. Safety will be reported both in terms of evaluation of adverse events and in terms of patient satisfaction deemed by Derriford Appearance Scale.

Results: So far 5 patients have been treated in the protocol. Considerable reduction of tumour mass was seen in all five cases and symptomatic relief was achieved especially for two of the three patients who had ulcerating tumours. No serious adverse events have been observed.

Conclusion: Electrochemotherapy seems promising as a palliative treatment for chest wall recurrence of breast cancer.

There has to date not been any report of cancer histologies that are resistant to electrochemotherapy, therefore, the results from this trial on local recurrence of breast cancer are likely to lead to information useful for the treatment of larger tumours from other types of cancer as well.

This is an ongoing study and updated results of the first cohort will be presented.

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POSTER

The significance of tumour free surgical excision margins in breast-conserving therapy

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Background: In the last decades, randomized trials have established breast-conserving surgery and radiation as an equal alternative treatment strategy compared to mastectomy in the treatment of breast cancer. In breast-conserving surgery the surgical margin is considered a strong predictor for local recurrence.

The aim of this study was to evaluate the results of re-excisions after breast-conserving surgery and to assess local recurrence rates in patients with an irradical or close tumour margin.

Materials: 411 female breast cancer patients (median age was 55 years (range: 29–83)) treated with breast-conserving therapy (BCT) at the Jeroen Bosch Hospital in the period 2000–2006 were included. Records of 55 patients with an irradical ($n=48$) or close ($n=7$) tumour margin, who underwent a second or third operation to obtain free margins, were retrospectively analyzed and compared to a control-group of 356 patients, in whom free margins were obtained at the first operation.

Results: In 55 of 411 patients (13%) a second operation to obtain free tumour margins was performed. Nineteen patients underwent a re-excision; 36 women were treated with either a mastectomy or a modified radical mastectomy (MRM). A second irradical re-excision was performed in 2 of 19 patients; they were subsequently treated with a mastectomy. Only in 38% ($n=21$, 18/48; 3/7) of the reexcision-specimens, residual tumour tissue was found. The median follow-up ($n=411$) to assess local recurrence was 52 months. During follow-up, 3 (2/48; 1/7) of 55 patients (5.5%) developed a local recurrence. In the control-group, 8 of 356 (2.2%) showed a local recurrence later on. The difference in local recurrence rate between the study group ($n=55$) and the control group ($n=356$) was not significant ($p=0.171$).

Conclusion: In just one third of the patients treated with re-excision/ablation for an irradical or close resection margin, re-excision specimens show residual tumour. Local recurrence rate in the irradical/close margin group was not significant higher than in the control group, in which free surgical margins were obtained at the first operation.

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POSTER

The needs among Greek breast cancer patients during and after treatment

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The aim of this study was to generate new knowledge about breast cancer patients' experience of the treatment in the health care sector and about the needs of breast cancer patients during and after treatment.

Patients and Methods: A sample of patients in contact with Greek hospitals for treatment or control for a cancer were sent an extensive questionnaire with of number of questions concerning patient satisfaction, rehabilitation and other needs, late effects and physical status. The number of participants were 350. The age of responders varied between 20 and 90 years, mean 61 years.

Results: The study showed a number of points for improvement in the communication and support of breast cancer patient during and after treatment. 30% wanted better support and information at the time of diagnosis, and the most so among educated and younger patients. During treatment, 19% of patients felt no psychological support, and 28% felt some support, while 37% felt good psychological support. Only about 49% of patients felt they were seen as an individual during treatment.

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

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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

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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

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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 ≥ 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 ≥ 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 ≥ 10 tablets/day. Most women would, however, opt for oral rather than i.v. cancer therapy; 1/3rd 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

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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 ≤ 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 α 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