

Patients and Methods: Fifty primary breast cancer patients (T1: 2; T2: 35; T3: 5; T4: 8 cases, median size 32 mm) who underwent standard neoadjuvant chemotherapy following surgery were evaluated with US, EG and MRI before and after chemotherapy. The diagnosis was made by board certified radiologists/doctors. EG (Hitachi EUB-8500, Hitachi Medical Systems, Japan) images were assigned an elasticity score (1 to 5) according to the Tsukuba Elastography Score [1]. Clinical response was categorized as a clinically complete response (cCR, no enhanced lesion by MRI, no mass by US or score 1 or 2 by EG), or residual tumor (score 3 to 5 by EG). The pathological complete response (pCR) was defined as no invasive cancer with or without remaining DCIS.

Results: Breast conserving operation was performed in 37 patients (74%) and mastectomy was performed in 13 patients (26%). Pathological CR was confirmed in 15 patients (30%). The sensitivity and positive predictive value to predict pathological CR was 53.3% and 57.1% by MRI and 73.3% and 68.7% by EG ($p < 0.05$), respectively. The specificity, negative predictive value was 82.8% and 80.5% by MRI and 85.7% and 88.2%, respectively.

Conclusion: The Elastography is a reliable modality and predicted pCR slightly better than MRI. Together with conventional ultrasonography, mammography and MRI, Elastography will improve the surgical management of breast cancer after Neoadjuvant chemotherapy.

References

- [1] Matsumura T, Tamano S, Shinomura R et al. Proceedings of the Third International Conference on the Ultrasonic Measurement and Imaging of Tissue Elasticity. 2004.

Wednesday, 16 April 2008

12:30–14:30

POSTER SESSION

Epidemiology, prevention, follow-up, management and care

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Poster

Nab-paclitaxel or docetaxel; as alternatives to conventional paclitaxel for the treatment of metastatic breast cancer (MBC): cost utility analysis from the perspective of the United Kingdom (UK)

G. Dranitsaris¹, M. Lidgren², J. Lundkvist², R. Coleman³. ¹Health Economics, Outcomes Research, Toronto, Canada; ²I3 Innovus, Outcomes Research, Stockholm, Sweden; ³Weston Park Hospital, Medical Oncology, Sheffield, United Kingdom

Background: Paclitaxel and docetaxel are commonly used for the treatment of MBC. However, one important drawback in their use, particularly with docetaxel, is their potential for dose-limiting toxicity. To improve the side effect profile and efficacy of paclitaxel, an albumin-bound formulation (nab) was developed (Abraxane[®]). Clinical trials have demonstrated that nab-paclitaxel is safer and more clinically active than both docetaxel and paclitaxel. To provide health economic data from the perspective of the UK, a cost utility analysis comparing nab-paclitaxel to docetaxel, both as alternatives to paclitaxel was conducted.

Methods: The clinical data were obtained from a meta analysis of randomized trials comparing either nab-paclitaxel (260 mg/m² q3wk) or docetaxel (100 mg/m² q3wk), to conventional solvent-based paclitaxel (175 mg/m² q3wk). Health care resource use for the delivery of chemotherapy and the management of grade III/IV toxicity was collected from a survey of medical oncologists and from the cancer literature. Using the Time Trade-off technique, treatment preferences and utility estimates were obtained from interviewing 35 female oncology nurses from 25 centres across the .

Results: Nab-paclitaxel had the most favourable safety profile characterized with the lowest incidence of grade III/IV neutropenia, febrile neutropenia, anemia, emesis and stomatitis. This translated to lower overall costs for managing the grade III/IV side effects of nab-paclitaxel relative to both docetaxel and paclitaxel (£137 vs. £819 vs. £344). Using the median number of cycles administered as reported in the randomized trials and the cost impact of grade III/IV toxicity, the overall cost for nab-paclitaxel would be £7,770 compared to £8,151 for docetaxel and £3,494 for paclitaxel respectively. In the preference assessment, 26 of 35 (74.3%) respondents selected nab-paclitaxel as their preferred agent. As an alternative to paclitaxel, the incremental cost per QALY gained was determined to be more favourable with nab-paclitaxel than docetaxel (£15,700 vs. £22,400).

Conclusions: Nab-paclitaxel is safer and less costly than docetaxel in MBC patients. As an alternative to paclitaxel, the National Health Service of

the UK must decide if the £15,700 cost per QALY gained represents good economic value. Compared to other new cancer agents (e.g. cetuximab for metastatic colorectal cancer), this seems to be a reasonable proposition.

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Poster

Breast care nurse led follow-up is associated with high levels of patient satisfaction

J. McIntosh¹, A. Silk², A.M. Sammon¹, C.A. Fowler¹, F. Thornton¹, C.J. Fide¹. ¹Gloucester Royal Hospital, Breast Care Department, Gloucester, United Kingdom; ²Gloucester Royal Hospital, Public and Patient Involvement, Gloucester, United Kingdom

Background: Following a diagnosis of breast cancer, women commonly enter a physician led follow-up care programme. Published patient perceptions of such follow-up models have included patients feeling hurried, clinic appointments lacking reassurance or continuity and patients feeling uncomfortable about expressing emotional concerns to a doctor. The role of the breast care nurse (BCN) in patient follow-up is starting to be evaluated, and where examined the majority of patients reported a preference to receive their follow-up from a BCN. There is, however, a paucity of published data on patient satisfaction with this method of follow-up.

Materials and methods: Local ethical committee approval was granted for this study. A peer-reviewed, validated questionnaire was given to women receiving BCN led follow-up after diagnosis and treatment for breast cancer. This comprised 47 statements relating to the BCN led follow-up programme, with response alternatives arranged as a five-point scale ranging from "strongly disagree" to "strongly agree". Questionnaires were distributed to patients attending follow-up clinics in plain, sealed envelopes which also contained a pre-paid and addressed envelope for return. Patients were asked to complete their questionnaires at home following the appointment. Responses from the first 10 questionnaires returned were examined as a pilot study to ensure that the questionnaires had been presented in an intelligible format.

Results: A questionnaire return rate of 92% was achieved (55/60), with most questionnaires fully completed. Respondents had a mean age range of 55–64 (35%). 100% (53/53) of respondents agreed or strongly agreed that they knew who to contact if they had a problem between appointments, and 98% (52/53) felt able to contact the BCN in this situation. 96% (53/53) strongly agreed or agreed that they were given a chance to say what was on their mind and that their views were being fully considered, and 100% (53/53) of respondents agreed or strongly agreed that they felt able to express themselves and ask the BCN questions. Overall, 100% (52/52) agreed or strongly agreed that they were satisfied with their care and 92% (47/51) agreed or strongly agreed that they had had thorough follow-up care (data collection ongoing).

Conclusions: High levels of patient satisfaction with BCN led follow-up are expressed in this study, and these results may identify an important future role for BCN's within the multidisciplinary breast care team.

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Poster

Prognosis and survival of patients with T1a breast carcinoma: a single center retrospective study

V. Massard¹, G. MacGrogan², M. Deblet³, C. Tunon de Lara¹, L. Mauriac³. ¹Institut Bergonié, Surgical Oncology, Bordeaux, France; ²Institut Bergonié, Breast Pathology, Bordeaux, France; ³Institut Bergonié, Medical Oncology, Bordeaux, France

Background: Management of patients with breast cancer ≤ 5 mm remains controversial. No clear-cut treatment guidelines are currently available for this increasing population. The aim of this study was to better characterize these tumors and to find prognostic factors.

Methods: We retrospectively studied 247 patients treated at the Bergonié Institute (France) between 1980 and 2006. All patients with breast tumors measuring >0.1 cm and ≤ 5 mm (pathological size, pT1a) were included in this study. Patients having bilateral or anterior contralateral invasive breast cancer were excluded. Axillary lymph node dissection was done in 139 patients. Survival curves were evaluated by Kaplan–Meier method and univariate analysis by the logrank test.

Results: Median follow-up was 90.9 months. Overall survival was 96% at 5 years and 94% at 10 years. Distant disease free survival was 98% at 5 years and 94% at 10 years. Distant disease free survival was 98% at 5 years and 97% at 10 years for pT1aN0 versus 68% at 5 years and 57% at 10 years for pT1aN+. In univariate analysis, axillary nodal status, mitotic index, lymphovascular invasion and estrogen receptor status (positive or negative) were significant prognostic factors. ($p = 7.3 \times 10^{-9}$; $p = 0.01$; $p = 0.05$ and $p = 0.05$).

Conclusions: pT1a breast tumors have an excellent prognosis. Axillary nodal status seems to be the strongest prognostic factor. Randomized

studies are needed to better codify the therapeutic sequence in order to spare patients from unnecessary secondary effects and iatrogenic complications.

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Poster

Breast cancer during pregnancy – a prospective and retrospective European registry (GBG-20/BIG02-03)

S. Loibl¹, A. Ring², G. von Minckwitz³, M. Heinrigs⁴, M. Lenhard⁵, F. Amant⁶, C. Weiss⁷, D. Augustin⁸, V. Nekljudova¹, M. Kaufmann³.
¹GBG Forschungs GmbH, Medical, Neu-Isenburg, Germany; ²Guys Hospital, Dept of Medical Oncology, London, United Kingdom; ³University Hospital, Women Hospital, Frankfurt, Germany; ⁴LMU, Women Hospital, München, Germany; ⁵University Hospital Grosshadern, Women Hospital, München, Germany; ⁶Katholieke Universiteit Leuven, Women Hospital, Leuven, Belgium; ⁷University Hospital, Women Hospital, Köln, Germany; ⁸Klinikum Deggendorf, Mammazentrum, Deggendorf, Germany

Background: In the treatment of the pregnant breast cancer patients, the evidence upon which we base our decisions has been largely limited to case reports, case-control studies and retrospective cohorts. Therefore, the German Breast Group has launched a registry (GBG-29/BIG 02-03) for patients with breast cancer that has been diagnosed during pregnancy.

Material: Every pregnant breast cancer patient is eligible. The primary endpoint is the fetal outcome 4 weeks after delivery. Secondary endpoints are maternal outcome of pregnancy, stage and biological characteristics of breast cancer, breast cancer therapy (treatment, response to chemotherapy, type of surgery), sensitivity and specificity of diagnostic procedures, outcome of the newborn after 5 years, outcome of breast cancer 5 years after diagnosis.

Results: From April 2003-December 2007, 122 patients have been prospectively (n = 39) and retrospectively (n = 83) registered. The median age is 33 years (range 24-43). T1-2: 71.7%; T3-4: 28.3%; N+ 66.6%; ductal invasive 83.8%, lobular 4.8%, inflammatory 4.8%, Grading 3: 69.5%, ER/PR neg 53.5%; Her-2 pos: 41.3%. At the time of diagnosis the median gestational age is 21 weeks; 21.6% of all patients have been diagnosed during the 1st, 43.3% during the 2nd and 35.1% during the 3rd trimester. From the patients who continued pregnancy, 33.3% received surgery only, 43.2% were treated by surgery and chemotherapy, 5.4% were treated only by chemotherapy and 2.7% had no treatment. Cytotoxic regimens used during pregnancy: EC/AC n = 23, CMF n = 11, FEC = 7, taxane = 11. The median time of delivery was 36 weeks (range 30-42), 54 newborns exposed to systemic therapy had alopecia (1), small for gestational age (1), 1 had trisomia 18 and died one week after birth, 1 had necrotic enterocolitis and died 3 weeks after birth. Fetal outcome in babies, who received intrauterine chemotherapy was not different from those who did not.

Conclusion: Pregnant breast cancer patients can probably be treated as close as possible to standard recommendations in specialized multidisciplinary teams. The registry needs to be continued to get better data on long time follow-up.

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Poster

Febrile neutropenia, related hospitalizations and chemotherapy delivery in breast cancer patients younger than 65 years receiving pegfilgrastim primary prophylaxis vs current practice neutropenia management

M. Schwenkglenks¹, G. Von Minckwitz², G. Lyman³, A. Lopez-Pousa⁴, P. Bacon⁵, S. Lawrinson⁶, M. Aapro⁷. ¹University Hospital, European Center of Pharmaceutical Medicine, Basel, Switzerland; ²University of Frankfurt, German Breast Group GBG Forschungs GmbH, Neu-Isenburg, Germany; ³Duke University, University Medical Center, Durham, USA; ⁴Hospital Sant Pau, Oncology, Barcelona, Spain; ⁵Amgen (Europe) GmbH, Medical Affairs Department, Zug, Switzerland; ⁶Amgen Ltd, Biostatistics, Uxbridge, United Kingdom; ⁷Clinique de Genolier, Institute Multidisciplinaire d'Oncologie, Genolier, Switzerland

Background: Elderly patients are recognized as being at substantial risk of febrile neutropenia (FN) during cancer chemotherapy (CT), but younger patients are also at risk, particularly with the trend toward more intense regimens. Furthermore, FN frequently leads to CT dose modification. Delivery of planned dose is essential in younger patients who are likely to be treated with curative intent. In this subgroup analysis from the NeuCuP project, we compare the relative merits of FN prevention with pegfilgrastim primary prophylaxis (PPP) vs current practice neutropenia management (CP) in patients <65 years of age.

Methods: Studies involving breast cancer CT regimens with moderately-high (15-20%)/high (≥20%) risk of FN were identified by literature review. For this integrated analysis, individual patient data were available from

8 clinical trial and 3 observational studies involving these regimens and PPP (pegfilgrastim 6 mg in all cycles) or CP neutropenia management (no granulocyte colony-stimulating factor [G-CSF] or pegfilgrastim/daily G-CSF in any cycle). Descriptive data are reported for the subgroup of patients aged <65 years with respect to FN over all cycles (primary outcome measure) and other related parameters.

Results: 2024/2282 patients were aged <65 years (1149 PPP, 875 CP). Patients' mean age (±SD, years) was 49.0±8.5 for PPP vs 50.1±8.6 for CP, around one quarter had Stage IV disease (27% vs 28%) and about one third had prior CT/radiotherapy (30% vs 37%). The most common CT regimens were docetaxel (Doc), Doc/doxorubicin (A)/cyclophosphamide (C), ADoc and AC → Doc. In cycle 1, 76% of CP patients received no G-CSF, 12% received pegfilgrastim only, and 12% received various G-CSF regimens. FN, FN-related hospitalization and CT delivery parameters for PPP vs CP are shown (Table).

	All cycles n (%) [95% CI]		Cycle 1, n (%) [95% CI]	
	PPP (N = 1149)	CP (N = 875)	PPP (N = 1149)	CP (N = 875)
FN	60(5) [4, 7]	136(16) [13, 18]	34(3) [2, 4]	80(9) [7, 11]
FN-related hospitalization	39(3) [2, 4]	82(9) [7, 11]	29(3) [2, 3]	50(6) [4, 7]
Dose delay >3 days	173(15) [13, 17]	137(16) [13, 18]	N/A	N/A
Dose reduction ≥15%	93(8) [7, 10]	204(23) [21, 26]	N/A	N/A

Conclusions: FN and related hospitalizations were less frequent in younger breast cancer patients who received PPP rather than CP neutropenia management in support of CT with moderately-high/high FN risk. Fewer CT dose reductions occurred in the PPP group. PPP may offer better FN protection and aid delivery of planned CT doses in this patient group.

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Poster

Breast units in Germany – yes or no

M. Dieterich¹, T. Reimer¹, B. Gerber¹. ¹University of Rostock, Department of Obstetrics and Gynecology – Breast Unit, Rostock, Germany

Background: Currently there is an ongoing discussion concerning the necessity of certified Breast Units (CBU) in Germany. The establishment of new BU leads inevitably to a decreased density of Breast Cancer (BC) treating hospitals. On the other hand better treatment options are being hoped for BC patients treated at BU. For that reason we analyzed the treatment of BC in CBU in comparison to not certified hospitals regarding treatment strategies, local recurrence (LR), overall survival (OAS) and the impact of continual education in northern Germany.

Material and Method: A retrospective analysis of 1327 patients diagnosed with BC in the years 1997/98 and 2005/06 was performed. Data has been collected from the Cancer Register Rostock using the "Giesener Tumor Documentation System" (GTDS®). BC patients who received treatment either at a CBU or a not-certified hospital with the following criteria were included: pT1-4, pN0/+, cM0/+. Pearson's chi-square test and survival analysis using Kaplan Meier were performed for statistical analysis.

Results: OAS (p = 0.398) and LR (p = 0.398) did not differ with regard to the treating hospital. Concerning the applied surgical methods (breast conserving therapy, oncoplastic surgery, modified radical mastectomy) a significant difference (p < 0.001) was found between patients being treated at a CBU or a not certified hospital. The rate of breast conserving surgeries was significant higher in CBU and additionally the rate of secondary operations was fewer. The number of BC treating hospitals decreased from 1997/98 to 2005/06 from 7 to 3. Simultaneously the number of patients treated at certified BU increased.

Conclusion: Despite missing advantage for OAS, the treatment of BC patients should be performed at CBU. With increased numbers of patients the surgical treatment was superior in CBU and with more treatment options the patient satisfaction and quality of life was increased.

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Poster

Common polymorphisms and haplotypes in NAD(P)H:Quinone Oxidoreductase-2 (NQO2) make a contribution to breast cancer susceptibility

K. Yu¹, W. Li¹, G. Di¹, Z. Hu¹, Z. Shao¹. ¹Cancer Hospital/Cancer Institute Fudan University, Department of Breast Surgery, Shanghai, China

Background: Clinical evidence supports a role of estrogen in breast carcinogenesis. The estrogen metabolites such as semiquinone and quinone can lead to depurination and mutation of DNA. Although it has been elucidated that NAD(P)H:quinone oxidoreductase-1 (NQO1) can