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Docetaxel, Carboplatin and Trastuzumab (TCH) as Neoadjuvant (neoadj) Therapy in Patients (pts) with HER2-positive (HER2+) Operable Breast Cancer (BrCa)

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Background: In randomised trials the addition of trastuzumab (H) to neoadj chemotherapy (CTx) produced higher rates of pathological complete responses (pCR) compared to CTx alone in operable HER2+ BrCa. In the adjuvant setting the BCIRG006 trial showed that the non-anthracycline (A) containing regimen TCH was equivalent to an A+H containing regimen with substantially less cardiac toxicity. In preparation for a randomised trial comparing neoadj TCH to TC+/- lapatinib (L) +/- H we analyzed the efficacy of TCH in producing pCR in pts not treated in clinical trials.

Methods: We retrospectively reviewed all pts with operable HER2+ BrCa who received neoadj TCH at our Institutions. The TCH regimen consisted of T 75 mg/m², C AUC5 or 6 and H 8 mg/kg loading dose followed by 6 mg/kg maintenance dose administered every 3 weeks by 6 cycles. 12 months of H were planned for all pts. pCR was defined as no evidence of invasive carcinoma in either breast and axillary lymph nodes (LNs). Post-Sx Rx [radiotherapy (RT) and medical Rx] were given as per institutional practice.

Results: We identified 42 pts treated from June 2006 to September 2011. Median age was 50 years (range 35-81). All pts but one had invasive ductal histology. All tumours were HER2+ by immunohistochemistry and/or fluorescent in-situ hybridisation. Other pts characteristics were: G3/G2/uk 29 (69%)/11 (26%)/2 (5%), oestrogen receptor (ER) pos 22 (52%), ER and progesterone receptor (PgR) neg 17 (40%), ER uk 3 (8%). Axillary LNs status following fine-needle aspiration at baseline was: pos 31 (74%), neg 6 (14%), uk 5 (12%). Thirty-six pts (86%) received 6 cycles of TCH, 6 pts received <6 cycles of TCH due to: treatment toxicity (3), lack of efficacy (1), other reasons (2). TCH toxicity was in line with data from previous trials. All pts but one (98%) had a clinical response to neoadj TCH and underwent Sx [(breast-conserving: 15 (36%), mastectomy: 26 (62%)], 1 pt did not undergo Sx due to poor response and had RT. The pCR rate was 43% (18 pts) in the entire population. In the ER and PgR neg population pCR rate was 59%. At median follow up of 26 months (range 3-56) 36(86%) pts are disease-free, 5(12%) pts relapsed after Sx (non-pCR: 4, pCR:1).

Conclusions: In this series of unselected operable HER2+ BrCa the non-A containing TCH regimen produced a high pCR rate, especially in the ER and PgR neg subgroup. Accrual to the ICORG TCH v TCHL v TCL trial, a study with mandatory tissue collection for biomarker analysis, is ongoing.

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A Comparison of Adjuvant Online and PREDICT in Estimating 10 Year Survival Benefit for Adjuvant Chemotherapy in a Clinical Setting

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Background: Adjuvant! is widely used to inform decision making about whether to offer adjuvant therapy in breast cancer by estimating the survival benefit afforded by hormone therapy and chemotherapy.

In 2010, a UK-based online prognostication model called PREDICT was launched, which takes into account the method of presentation (screen-detected or symptomatic) and HER-2 status.

The aim of this study was to determine if the use of PREDICT would alter our unit's recommendations for chemotherapy, which are currently based on Adjuvant!

Materials and Methods: The data for 150 consecutive women undergoing surgery for primary breast cancer were input into both models. Patients were excluded if they had received neoadjuvant hormone therapy of endocrine therapy.

The predicted 10 year survival benefit of adjuvant chemotherapy (above that derived from hormone therapy) was determined.

The results were categorised into <3% benefit - no chemotherapy, 3-5% benefit - discuss the option of chemotherapy and ≥5% - recommend chemotherapy.

Results: The median age was 62 years (range 34-92) and 64 (43%) presented symptomatically. The number of patients in each group is shown in Table 1.

In 28 patients (19%) there were discordant results between the two models. In 17 of these 28, PREDICT upgraded the chemotherapy decision, whilst it downgraded it in 11.

The change in predicted survival benefit category was not related to either the method of presentation (p=0.2) or the HER-2 status (p=1) (Fisher's exact test).

Table 1

10 year Survival Benefit	Adjuvant!, n (%)	PREDICT, n (%)
<3%	87 (58)	93 (62)
3-5%	18 (12)	17 (11)
≥5%	45 (30)	40 (27)

Conclusion: Using PREDICT would alter our unit's chemotherapy recommendation in 19% of patients. We plan to use both Adjuvant! and PREDICT in parallel to evaluate them further in the clinical setting.

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Use of Acellular Dermis (Strattice TM) in Problematic Cases of Breast Reconstructive Surgery

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Background: Since 2002 we have analyzed 302 cases of skin and nipple sparing mastectomies. In 107 cases tissue-supporting extraneous materials such as meshes or acellular dermis have been used.

Because of its excellent texture the acellular dermis can in contrast to other tissue-supporting meshes be used as a direct tissue replacement.

Therefore it is insertable in situations of difficult skin envelope, after radiotherapy or after prior surgical intervention, or even when radiotherapy is planned after the immediate reconstructive surgery. With these indications acellular dermis can give an alternative to flap surgery.

Material and Methods: Since 03/11 we have performed 9 operations with sub muscular implant placement and coverage with acellular dermis. 8 patients had received a prior operation in the context of their breast cancer disease, thereof 4 had skin sparing mastectomy and radiotherapy and 5 had received chemotherapy.

Results: The acellular dermis was placed interpectoral. In 5 cases form and size was not changed and inserted horizontally, in 3 cases the acellular dermis was specifically cut and sewed vertical as a inner bra.

Two cases of wound complications with suture dehiscence could be solved operatively without removing the reconstruction and wound closure above the acellular dermis. None of the cases showed signs of postoperative infection. The average duration of drainage was 9 days (7-13).

Conclusions: The application of acellular dermis demands a detailed surgical planning. The maintenance of important individual surgical steps is quite different from other tissue-supporting materials.

The presented patient collective had a high risk for complications (former operation, former radiotherapy), but the cosmetic result was good and a second operation was could be spared.

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Febrile Neutropenia (FN) in Early Breast Cancer Patients Receiving FEC-D - the Effect of Moving to Primary Granulocyte-colony Stimulating Factor (G-CSF) in the Mersey and Cheshire Cancer Network

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Background: In 2008 the Merseyside and Cheshire Cancer Network published its audit data citing a FN rate of 27% with the newly implemented regimen of FEC-D in node positive early breast cancer. As a consequence the network protocol was amended to recommend primary prophylaxis with pegylated G-CSF [1]. 3 years on we have re-audited this patient group to look at how this alteration has affected FN with this regimen.

Methods: The primary audit was undertaken looking at patients records who received FEC-D with adjuvant intent between March 2005 and November 2007. The second audit was undertaken utilising the same methodology between January and December 2010.

Results: The primary audit looked at 123 patients, their median age was 49. There were 33 episodes of FN, giving a rate of 26.8% and resulting in