

#### **O-74. IMPROVEMENTS IN SURVIVAL IN PATIENTS RECEIVING PRIMARY CHEMOTHERAPY WITH DOCETAXEL FOR BREAST CANCER: A RANDOMISED CONTROLLED TRIAL**

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Primary chemotherapy is increasingly used to treat large breast cancers with the aim of downstaging the primary tumour. Anthracycline-based regimens are commonly used with clinical response rates of up to 80% but pathological response rates of only 20%. Recent interest has focused on the use of taxanes, eg docetaxel, in patients who have disease which is resistant to anthracyclines.

The aim of this study was to determine whether primary docetaxel confers a survival benefit in patients with large and locally advanced breast cancers receiving primary chemotherapy.

Patients with large and locally advanced breast cancer (T2 > 4 cm, T3 or T4) received 4 pulses of CVAP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy. Clinical response was then assessed. Those with a partial (PR) or complete clinical response (CR) were randomised to receive either 4 further pulses of CVAP or 4 pulses of docetaxel. All patients, whose tumours failed to respond, received 4 further pulses of docetaxel.

167 patients have been enrolled into the study; 102 were suitable for randomisation. Median follow-up was 38 months (24–56 months). In patients randomised to receive further CVAP, 3 year survival was 84%, while in those randomised to receive docetaxel, 3 year survival was 97%, ( $p = 0.02$ ; Log rank test). In patients randomised to receive further CVAP, 3 year disease free interval was 77%, while in those randomised to receive docetaxel, 3 year disease free interval was 90% ( $p = 0.03$ ; Log rank test).

Primary treatment with docetaxel resulted in significantly increased rates of survival and disease free interval compared to continued anthracycline based treatment.

#### **O-75. LOCAL RECURRENCE FOLLOWING NEOADJUVANT CHEMOTHERAPY IN PATIENTS WITH LARGE AND LOCALLY ADVANCED BREAST CANCER**

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Patients with large breast cancers are commonly treated with neoadjuvant chemotherapy. This approach has been shown to result in a reduction in mastectomy rates and increase in the number of patients suitable for breast conserving surgery by approximately 10%. However, a concern has been the risk of local recurrence in those who have breast conservation surgery and also in those undergoing mastectomy. This study examined local recurrence (LR) in patients with breast cancer treated with neoadjuvant chemotherapy and surgery.

A total of 173 patients received neoadjuvant chemotherapy

(4–6 cycles of cyclophosphamide, vincristine, doxorubicin and prednisolone). Clinical and radiological responses were assessed after chemotherapy, and treatment was followed by surgery: mastectomy (73%) or lumpectomy (27%) and axillary node sample. Radiotherapy was given to the breast, chest wall and axilla (if positive nodes).

At a median follow-up of 62 months, LR was seen in 10 cases (6%) of patients - 1 of 44 (2.3%) had breast conserving surgery, 6 of 115 (5.2%) patients had undergone mastectomy, and 3 of 6 patients who underwent mastectomy with latissimus dorsi flap reconstruction ( $p < 0.01$ ). T or N stage did not predict LR. Clinical response predicted LR ( $p < 0.01$ ), with patients with stasis or progression more likely to develop recurrence. Patients with histologically positive nodes were more likely to develop LR ( $p < 0.01$ ). Tumour grade did not influence development of LR. Pathological response to chemotherapy did not predict LR, although no recurrences were seen in patients with a complete response to chemotherapy.

Extent of clinical response to neoadjuvant chemotherapy and pathological nodal status may be useful in identifying patients at risk of developing LR following neoadjuvant chemotherapy.

#### **O-76. SURGICAL MANAGEMENT OF THE AXILLA FOLLOWING PRIMARY CHEMOTHERAPY FOR T3 M0 BREAST CANCER**

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The surgical management of patients following primary chemotherapy (PCT) is uncertain. Our aim was to assess the nodal status of patients following chemotherapy (6 cycles of AC).

All 135 patients receiving PCT for T3M0 tumours between October 1994 and September 2000 were included in the study. Response to PCT was assessed by UICC criteria; Complete response (CR), Partial response (PR), No change (NC) and Progressive disease (PD). The unit policy was to proceed to surgery to the breast except where a pathological CR could be proven. All patients had axillary surgery unless contraindicated and all patients also received radiotherapy to the breast or chest wall.

Overall clinical response to PCT is shown in Table 1. Following PCT 78 (58%) patients had a simple mastectomy and 35 (26%) breast conservation. 22 (16%) patients had a proven pathological CR on multiple core biopsies and had axillary clearance only. The analysis of axillary nodal status by response is shown below.

Table 1.

Clinical response	CR	PR	NC	PD
Total	43 (32%)	20 (15%)	65 (48%)	7 (5%)
Node negative	30 (70%)	10 (50%)	24 (37%)	5 (71%)

Although there was a trend towards non-involved nodes with increasing clinical response this was not statistically significant (Fisher exact  $p = 0.097$ ).

Axillary surgery should be indicated for all patients following PCT regardless of clinical response.

#### **O-77. A NOVEL GRADING SYSTEM TO ASSESS PATHOLOGICAL RESPONSE AND PREDICT SURVIVAL IN PATIENTS RECEIVING PRIMARY CHEMOTHERAPY FOR BREAST CANCER**

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Primary chemotherapy is used to treat large and locally advanced breast cancers. A complete pathological response has been shown to be a prognostic indicator, but only 20% have a complete response. The prognostic significance of lesser degrees of pathological response in terms of survival, is unclear. We have developed a novel grading system for assessing different degrees of pathological response to chemotherapy and have examined its prognostic significance.

Patients with large primary breast cancers received 6 pulses of CVAP chemotherapy. Pathological response was assessed in the breast tissue resected after completion of chemotherapy using a novel five point graded scale (1 = no response to 5 = complete response). All patients were followed up for 5 years. Survival and disease free intervals were compared to pathological responses using the log rank test.

176 patients were recruited into this study. The 5-year survival for these patients was 76% and 5-year disease free interval (DFI) 62%.

Grade of Response	5-year survival (%)	5-year DFI (%)
1	65	38
2	60	46
3	78	67
4	82	73
5	100	89
Log rank test	0.022	0.043

This novel method of assessing pathological response can be used to predict survival and disease-free interval in patients receiving primary chemotherapy for breast cancer.

#### **O-78. BREAST CANCER PATIENTS USE OF A TOUCH SCREEN IN THE DAY TREATMENT AREA TO RECORD TOXICITY, HEALTH STATE AND QUALITY OF LIFE – A 12 MONTH EXPERIENCE**

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Between the start and end of 2000, 256 patients with breast cancer had complete treatment records against which to assess their recorded symptoms attributable to disease and the effects of treatment on their lives whilst attending the day treatment area for chemotherapy. They were asked to use a touch screen ques-

tionnaire at each attendance for chemotherapy and individuals used the screen from once to 12 times. The screen questionnaire was derived from standard recording systems to assess toxicity severity and duration (31 questions) with 3 added questions on the patient's assessment of her health state, global quality of life and performance status. In this report only the major features are shown from over 31000 data items thus obtained. The records obtained were from 928 'form' completions, 617 adjuvant or neoadjuvant and 311 metastatic. The data were stored in MS Access allowing ease use of data storage and analysis. The patient data were then matched to the department treatment booking database to link outcomes against disease stage and treatment given. The data are presented as percentage scores for selected items in the 2 groups, metastatic and secondly, adjuvant or neo adjuvant.

fatig	apptit	diarr	vom	naus	health	QL	PS	
11/8	89/64	80/71	91/86	54/38	<b>4/23</b>	<b>5/28</b>	44/23	<b>A</b>
30/28	<b>4/22</b>	13/20	6/11	32/39	12/32	38/29	35/32	<b>B</b>
41/43	<b>4/9</b>	5/7	2/2	7/17	56/44	28/38	<b>17/35</b>	<b>C</b>
18/21	<b>3/15</b>	2/2	1/1	7/6	<b>28/1</b>	<b>29/5</b>	4/10	<b>D</b>

Figures show % incidence metastatic/% incidence adjuvant. A = nil toxicity or best health state; B = mild toxicity/impairment of state; C = moderate toxicity or impairment; D = severe toxicity or impairment

**Bold figures** indicate clinically important differences between groups, either direction

This is a rapid and accurate method to record toxicity, functional health state, formal performance status and quality of life in a self-report, real-time format. It is quick, patient-friendly and is an extremely powerful, inexpensive technique for recording auditable data for non-trial as well as trial patients at all stages of disease for patients on treatment. We have plans to extend its use to the OPD waiting area for patients who may be on oral or hormonal therapy.

#### **O-79. PATIENTS' PERCEPTIONS OF THEIR PROGNOSIS AND THEIR EXPECTATIONS OF THE BENEFIT OF ADJUVANT CHEMOTHERAPY IN EARLY BREAST CANCER**

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Women with early breast cancer, even those with relatively low risk of recurrence, are increasingly offered adjuvant chemotherapy. Patients are now encouraged to participate in the decision whether to have this treatment. To do this effectively they need to be given adequate information. This study explores the knowledge and understanding of a group of women who have completed adjuvant chemotherapy. We sent questionnaires to all 249 surviving patients who received adjuvant chemotherapy between 6/95 and 6/99 at the RLH, all treated by the same Medical Oncologist. All had been told the size, grade and no. of involved nodes and had been advised of likely prognosis.

182 patients replied (73.1%), median age at diagnosis 47.5 (29 to 69). 22.5% were educated beyond O level. 48.8% felt that