

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 A
30/28	<b>4/22</b>	13/20	6/11	32/39	12/32	38/29	35/32 B
41/43	<b>4/9</b>	5/7	2/2	7/17	56/44	28/38	<b>17/35</b> C
18/21	<b>3/15</b>	2/2	1/1	7/6	<b>28/1</b>	<b>29/5</b>	4/10 D

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

information on the risk of recurrence was 'about right', 50.6% 'too little' and 0.6% 'too much'. 98 (53.8%) remembered being told this risk and 150 (82.4%) gave their own estimates. Patients' estimates and their expectations of the benefits of chemotherapy were compared with their actual risk as determined by the Early Breast Cancer Trialists' Collaborative Group overview.

Age	Nodal status	Est. % risk	Actual risk	Est. % risk	Actual risk
		of rec. without chemo at 5 y (median)	of rec. without chemo at 5 y	of rec. with chemo at 5 y (median)	of rec with chemo at 5 y
<50 y	Node -ve	50	34.1	15	24.7
N = 100	Node +ve	60	58.1	20	42.9
50–69 y	Node -ve	42.5	29.7	12.5	23.4
N = 50	Node +ve	62.5	46.7	20	40

When asked what degree of benefit they felt would make chemotherapy worthwhile, 71.1% of respondents would accept a reduction in the risk of recurrence at 5 y of  $\leq 5\%$ , (range 0.5 to 60%). In conclusion many patients overestimated both the baseline risk of recurrence and the potential benefit of chemotherapy. However, the majority would be prepared to accept similar treatment again for relatively modest benefit.

#### O-80. LIPOSOME-ENCAPSULATED DOXORUBICIN (MYOCET) AND CYCLOPHOSPHAMIDE IS SUPERIOR TO EPIRUBICIN AND CYCLOPHOSPHAMIDE IN FIRST-LINE THERAPY OF METASTATIC BREAST CANCER

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We compared the efficacy and toxicity of liposome-encapsulated doxorubicin (Myocet) and epirubicin (EPI) when used in combination with cyclophosphamide (CPA) in first-line treatment of metastatic breast cancer (Metastatic Breast Cancer). 160 patients with Metastatic Breast Cancer and no prior anthracycline therapy were randomised to receive either Myocet (75 mg/m<sup>2</sup>) or EPI (75 mg/m<sup>2</sup>), in combination with CPA (600 mg/m<sup>2</sup>), every 3 weeks for a maximum of 8 cycles. The primary efficacy endpoints were response rate and time to progression. Responses were assessed by WHO criteria. Cardiac function was monitored by echocardiography. Median age was 54 in both treatment groups. Other prognostic factors were also balanced. Efficacy comparison showed superiority in favour of the MC combination. Overall response rate was 46% versus 39%, median time to disease progression was 7.7 versus 5.6 months ( $p = 0.02$ ); median duration of response was 10 months versus 7.7 months ( $p = 0.005$ , median time to treatment failure was 5.7 months versus 4.4 months ( $p = 0.007$ )). Mucositis was more common in patients who received the MC combination (grade 3: 7% versus 0% with EC). Cardiotoxicity was low in both treatment groups with no clinical. Heart failure reported it is of interest that was no grade 3/4 dermatitis reported with this liposome-encapsulated doxorubicin.

In this randomised prospective study, Myocet was superior to EPI in terms of time to disease progression when combined with CPA, but EPI may have had less acute toxicity in terms of stomatitis/mucositis.

#### O-81. CAPECITABINE NAMED PATIENT PROGRAM FOR PATIENTS WITH ADVANCED BREAST CANCER: THE UK EXPERIENCE

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102 patients with advanced breast cancer received capecitabine in a UK open access program and have been analyzed for response and toxicity. Median age was 53.2 (range 30–95). Patients had received between 0–4 prior chemotherapy regimens for advanced disease. 58% of patients had visceral disease and median number of sites of disease was 1. 60.8% had previously received anthracyclines, 25.5% taxoids and 6.9% infusional 5-FU. A median of 5 cycles were given.

Dose reductions occurred in 32.4% of patients (10.2% of cycles). The mean dose intensity was 95%. There were 3 complete responders, 17 partial responders, and the total objective response rate was 19%. Stable disease was achieved in 46% and progression was seen in 30%. Toxicity is tabulated.

Event	Grade 1 (%)	Grade 2 (%)	Grade 3 (%)	Grade 4 (%)
Neutropenia	2.0	1.0	2.0	1.0
Thrombocytopenia	3.9	2.0	1.0	0.0
Mucositis	1.0	2.9	2.0	0.0
Fatigue	12.7	3.9	2.9	1.0
PPE	15.7	11.8	7.8	0.0
Diarrhea	21.6	5.9	4.9	2.0
Nausea	23.5	5.9	1.0	0.0
Vomiting	11.8	2.9	2.0	0.0

We conclude that capecitabine was well tolerated and active in extensively pretreated patients with advanced breast cancer. Toxicity was manageable at the recommended dose of 1,250 mg/m<sup>2</sup> b.i.d. for 14 days q21 days.

#### O-82. THE ANTI-TUMOUR EFFECTS OF CONJUGATED LINOLEIC ACID IN BREAST CANCER ARE MEDIATED BOTH BY P-53 DEPENDENT AND INDEPENDENT APOPTOTIC PATHWAYS

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**Aims:** The anti-tumour effects of the dietary fatty acid, conjugated linoleic acid (CLA), may be mediated through enhanced apoptosis. However, the effects of CLA on genes involved in apoptosis are unknown and this study examines the effects of