3-weekly arm, where two toxic deaths were observed. Overall response rate was 39% and 33% in 3-weekly and weekly arms; hazard ratio (HR) of progression was 1.29 (95% CI: 0.84−1.97) and HR of death was 1.38 (95% CI: 0.82−2.30) for patients in the weekly arm.
Conclusions: Although low power due to early termination, this trial does not support the use of weekly docetaxel-based chemotherapy in patients with LABC or MBC.

5048 POSTER

A Q-TWiST analysis of lapatinib plus letrozole compared with letrozole alone as first-line therapy in hormone receptor positive (HR+) metastatic breast cancer (MBC)

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Background: In a phase 3 study of first-line treatment for HR+ MBC, women were randomized to receive either lapatinib plus letrozole (L+Let) or letrozole plus placebo (Let). Combination therapy showed a 14% reduction in risk of disease progression in the ITT population ($p = 0.026$) and a 29% risk reduction in the HER2+ population ($p = 0.019$), with stable QOL in both treatment groups. This analysis applies the quality-adjusted time without symptoms of disease or toxicity of treatment (Q-TWiST) method to compare the trade-off between toxicities and delayed progression.
Methods: The area under overall survival curves for each treatment group was partitioned into 3 health states: toxicity (TOX), time without toxicity or disease progression (TWiST), and the period following disease progression until death or end of follow-up (REL). TOX is time spent with grade 3/4 adverse events (AEs) during progression-free survival (PFS) time. TWiST is the remaining time prior to progression in which no serious AEs were experienced. The utility-weighted sum of the mean health state durations was derived, and treatment comparisons of Q-TWiST were made at varying combinations of utility weights using a threshold utility analysis.
Results: The ITT population included 1286 patients, of which 17% were HER2+ (N = 219). In the primary analysis of the HER2+ population, overall median survival was 140 weeks (data as of 03JUN08). There was no significant difference between groups in mean duration of serious AEs prior to progression (L+Let, 1.95 weeks; Let, 2.14 weeks; $p = 0.90$). The Q-TWiST difference between groups ranged from 8−9.5 weeks favoring combination therapy for all hypothetical utility levels, although none of the comparisons were statistically significant at $p = 0.05$. When counting 2 days of TOX or REL as 1 day of TWiST (i.e. using utility weights of 0.5), the difference in quality-adjusted survival favoring L+Let was 8.8 weeks ($p = 0.09$). For the ITT population, Q-TWiST differences ranged from 0−7.5 weeks.
Conclusion: The significantly longer progression-free survival observed in HER2+, HR+ MBC patients taking the combination of L+Let vs Let was achieved without significant differences in mean duration of serious AEs. Quality-adjusted survival was favored for the combination arm in the overall and HER2+ populations.

5049 POSTER

Impact of psycho emotional therapy in locally advanced breast cancer patients receiving chemotherapy

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Locally advanced breast carcinoma (LABC) is uncommon in developed world however it is still present with a large proportion in developing world. The management of LABC is a challenge not for medical oncologist, surgeon, and radiotherapist but also for psychoncologist. Most of the cases relate to late reporting of breast lump and socioeconomic factors.
This study was performed in HCG Medi-Surge hospital Ahmedabad, Gujarat from 1st July 2007 to 30th June 2008. We divided two groups of LABC who were taking treatment in this hospital in the last one year. One group received psychoncologist helps according to distress level and as well as personal attention from medical oncologist and regular advise from a patient who had completed her treatment and survived while other group is only treated and emotional support was not given.
Result: In group A, we have taken 54 cases compared to group B where we have taken 28 cases. We found that 8 cases out of 28 cases discontinued/lost to follow up their treatment compare to 3 cases out of 54 cases of group A. Most important role was of a patient who finished her treatment and survived.
Treatment of LABC is very long and aggressive. Most of the time patient discontinue or are lost to follow up their treatment especially when they suffer side effects of chemotherapy and poor response. So psycho emotional therapy prior to induction chemotherapy and continued during chemotherapy cycles helps in better patient compliance especially when they have treatment related side effects. Although this fact is well established in developed countries but still needs evaluation in developing countries.

5050 POSTER

Capecitabine provides substantial quality of life gain in patients with pretreated metastatic breast cancer

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Background: In patients with metastatic breast cancer (MBC) for whom anthracycline and taxane use is inappropriate, capecitabine (X) is considered the standard of care. This phase II open-label study (M66103) evaluated the efficacy and safety of X in MBC after pretreatment with paclitaxel or docetaxel, and assessed the effect of X on quality of life (QoL), as measured by the EORTC QLQ-C30 score.
Methods: EORTC QLQ-C30 indexes six multi-item scales of functioning, and measures nine multi-item scales, or single items of symptoms. Items were scaled on a yes or no basis or on 4-point Likert-type scales, while Global Physical Condition and Global QoL were assessed by two 7-point Likert scales. All scores were linearly transformed to a 0 to 100 range. Results were compared with reference data from the EORTC QLQ-C30 Scoring Manual for MBC patients. In total, 136 patients received X (1,250 mg/m^2 b.i.d. for 14 days, q3w). QoL scores were analysed at visit 1 before treatment initiation, at visit 5 after the end of cycle 4 (before cycle 5), and considering all assessments after start of treatment. Missing values at visits after start of treatment were replaced by the method 'last value carried forward' and visit 5 scores were compared to the scores of all assessments after start of treatment.
Results: There was agreement between assessment methods. For all scales of functioning, other than cognitive, patients were in worse general condition, with a lower QoL score than the reference group before therapy. Treatment with X achieved a substantial gain in QoL versus baseline across all scales of functioning, other than cognitive. Patients also reported improved symptom scores for all symptoms, except diarrhoea, a known side effect of X.

	Reference	Pre-X	Post-X (cycle 4)
Scales of functioning	**Higher scores represent better functioning**		
Physical	64.1	62.6	70.4
Role	63.4	42.1	51.7
Emotional	64.8	51.4	65.3
Cognitive	81.1	81.8	85.7
Social	70.1	53.3	70.3
Global Health Status/QoL	50.9	44.9	55.2
Symptom scales	**Higher scores represent more symptoms**		
Multi-item scales			
Fatigue	40.1	52.9	49.1
Nausea and vomiting	12.4	13.9	12.3
Pain	39.0	44.7	37.0
Single items			
Dyspnoea	28.9	43.8	28.0
Insomnia	34.6	42.5	34.0
Appetite loss	28.6	34.2	24.5
Constipation	16.9	17.2	7.3
Diarrhoea	8.1	8.3	18.7
Financial difficulties	16.8	22.9	15.3

Conclusions: These data demonstrate that X provides a substantial gain in specific QoL elements in this patient population. QoL is an important goal of therapy for patients with advanced disease.