

the 2 arms was 25.5 (HTX) and 23.5 (HT) months. PFS and TTP favoured the HTX regimen (Table). Overall survival data are immature.

	HTX (n = 112)	HT (n = 110)	Hazard ratio	p value
ORR, %	71	73		0.72
Complete response, %	23	16		
Partial response, %	47	56		
Stable disease, %	25	16		
Progressive disease, %	4	9		
Median DoR, months	15.9	13.4		NC
Median PFS, months	17.9	12.8	0.72	0.04
Median TTP, months	18.6	13.6	0.70	0.03
1-year survival rates, % (95% CI)	91 (86, 96)	85 (79, 92)		
2-year survival rates, % (95% CI)	75 (66, 83)	66 (56, 75)		

NC, not calculated.

Most non-haematological adverse events (AEs) were grade 1 or 2. The most common grade 3/4 AEs were hand-foot syndrome (HTX 17%; HT <1%) and diarrhoea (HTX 11%; HT 4%). There was a lower incidence of grade 3/4 neutropenia in the HTX arm compared with HT (54% vs 77%). 12% of pts experienced mild to moderate cardiac AEs; 2 pts in each arm had left ventricular ejection fraction declines to <40%. Symptomatic congestive heart failure was experienced by 1 pt in each arm. No pt died due to a cardiac event. 4 deaths recorded during the study were considered to be treatment related (HTX 1 pt; HT 3 pts).

Conclusions: Both regimens demonstrated high ORR, with HTX achieving significant improvement in TTP and PFS compared with HT in HER2-positive LABC/MBC. Both treatments were manageable and cardiac safety was consistent with other H-based trials.

Thursday, 17 April 2008

16:00–17:30

CLINICAL SCIENCE SYMPOSIUM

Lifestyle and survival after treatment for breast cancer

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Invited

What breast cancer survivors want to know about lifestyle after breast cancer

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Awareness of cancer survival has increased greatly since the 1990's due largely to increasing numbers and the work of advocates. If prevalence of and survival with cancer worldwide continues to increase and follows predictions made in the USA, the number of recorded cancer survivors worldwide in 2025 will approach 50 million and in 2050 will approach 70 million. With a European prevalence rate of 34% for breast cancer – the most prevalent cancer in women – issues for breast cancer survivors will of necessity gain more attention.

From the point of diagnosis, breast cancer survivors have to deal with a confusing and disturbing array of conflicting studies and advice, reinforced by media hype regarding cancer scares and cures, so key issues for them are what and who to believe and where to find reliable evidence.

Most survivors will want to know the chances of their breast cancer progressing or recurring and what they can do to minimise those chances. Survivors are living longer and therefore long enough to develop new primary cancers or other chronic diseases.

Together with those who are closest to them, survivors want to learn about and act on helpful recommendations in terms of lifestyle based on sound evidence. They need recommendations on lifestyle that will not do them harm, that help limit the progress of breast cancer and help prevent a recurrence of breast cancer or any other cancer, and help prevent other diseases as well as improve the quality of their lives.

Studies and advice have traditionally focussed on significant components of lifestyle such as food, nutrition, and physical activity as applied to cancer risk and prevention and according to the WCRF/AICR report published in 2007, on the available evidence it is not yet possible to make judgements that apply specifically to survivors.

In tandem with the shift from life-threatening to life-changing disease, survivors want to know more about the changes that women are making in their lives following breast cancer. Apart from understanding more about maintaining a healthy immune system, survivors will increasingly want to extend the focus to address psycho-social aspects of lifestyle including working life, relationships, sexuality, the use of complementary therapies

and supports and the complex interactions of stress and fatigue, on lifestyle choices. The challenge for advocates will increasingly be to find ways of getting these issues and appropriate methodologies onto the research agenda.

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Invited

Stress, distress and support groups – are they important?

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Background: The sustained debate about group therapy and survival across the past decade distracted clinicians from the consistent evidence of quality of life benefits in reducing distress and depression when women with breast cancer attend support groups. A series of prospective, randomized, group therapy studies using larger cohort sizes failed to prolong survival in women with both metastatic (Canadian 235; Australian 227 and American 125) and early stage (Australian 303) breast cancer.

Material and Methods: DSM-IV diagnoses for psychiatric disorders and dimensional measures of anxiety, depression and quality of life were obtained in both Australian trials, where survival was the primary outcome; psychosocial well being was appraised secondarily.

Results: Anxiety was effectively relieved by group therapy in early breast cancer. Clinical depression was both actively ameliorated and new cases prevented across the course of the group therapy for advanced breast cancer compared to controls. Survival was not extended by either intervention.

Conclusions: These studies have consistently reduced distress and significantly prevented onset of new cases of depression in advanced breast cancer. The preponderance of systematic evidence supports the relief of distress, with the strongest evidence for anxiety-related outcomes (fear of recurrence) in early stage cancer. New evidence for the prophylactic benefit in preventing depression in advanced cancer argues for group support being offered to all interested subjects. Psycho-oncology needs to promote behaviors leading to health promotion (smoking cessation, obesity reduction and exercise), preventive screening and early detection, the relief of distress and culturally sensitive interventions to encourage adherence to anti-cancer treatments. Issues of medical mistrust and fatalism leading to anti-cancer treatment drop-outs could be addressed through these interventions.

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Invited

Lifestyle interventions in breast cancer – what do we know and what do we need to know?

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There is increasing recognition of the importance of lifestyle factors (e.g. obesity/body size, diet, physical activity) after breast cancer (BC) diagnosis. Over 50 studies have investigated obesity as a prognostic factor – the majority have identified an adverse prognostic effect. One meta-analysis identified a hazard ratio (HR) of 1.91 for distant recurrence and 1.60 for death for obese vs. non-obese women. Observational data have suggested that some dietary practices (e.g. increased intake of saturated fat in postmenopausal women) may increase risk of recurrence. Recent research has also suggested that low levels of physical activity around the time of BC diagnosis may also worsen prognosis.

Two randomized trials of lifestyle interventions have reported disease-free survival outcomes. The Women's Intervention Nutrition Study (WINS) studied the effect of reducing dietary fat intake to 20% of calories. Dietary fat reduction was associated with a relative weight loss of 2.3 kg. Five year relapse-free survival was significantly improved in the intervention arm (HR 0.76, p = 0.034). The effect was greatest in receptor negative (HR 0.58) vs. receptor positive (HR 0.85) BC. The Women's Healthy Eating and Living Study randomized women to a complex dietary intervention that involved fat reduction combined with increased intake of fruit, vegetables and fiber, up to four years post BC diagnosis. There was no effect on 5 year disease-free survival.

Intervention research (both randomized and non-randomized) has demonstrated the feasibility of physical activity after BC diagnosis. Improvements in fitness, quality of life and body composition have been demonstrated. There are no randomized trials of prognostic effects of physical activity. Similarly, the feasibility of weight loss through diet and physical activity has been demonstrated in BC patients. Apart from the WINS Study noted above, there are no randomized data addressing prognostic effects of weight loss.