

social activities, mental health, change in health status perception) showed significant improvement ( $p < 0.05$ ). The cost of the intervention per woman was meanly 40 euros, but costs could be lowered to 20, if non medical personnel should be employed.

This kind of approach is worth of being considered, because of its low costs, safety, and observed results.

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INVITED

### The validity of research/clinical trials of CAM

E. Winer. Dana Farber Cancer Center, Boston, USA

Women with breast cancer use a variety of complimentary and alternative approaches (CAMs), both during active treatment and following the completion of therapy. The percentage of women using CAMs varies from study to study, depending to a large extent on the patient population and the definition of CAM. Women cite a variety of reasons for pursuing CAMs including a desire to improve quality of life, take control over their illness, relieve symptoms, and improve overall survival. Some studies have found that women who use CAMs are more likely to have either physical and/or psychological symptoms compared to non-users.

Unfortunately, there are relatively few studies that have demonstrated unequivocal benefits for many of the commonly used CAMs. Many studies suffer from methodological problems including: inadequate sample size; lack of randomization; failure to blind; and poorly defined interventions and measures of outcome. It is not necessary that all therapies, particularly CAMs, show a survival benefit. However, if any CAM is to be used widely, it should be shown to be safe, particularly if it being used concurrently with other therapy, and that it has some beneficial impact on the user. Recent studies will be highlighted to demonstrate which CAMs have been adequately evaluated to justify common use and which are in need of further investigation.

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INVITED

### Does CAM have a place in breast cancer treatment?

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Most breast cancer patients try one form of complementary and alternative medicine (CAM) or another, often out of desperation. In evaluating CAM, one has to consider foremost its proven effectiveness and its potential risks. It is sensible to differentiate between CAM for prevention, treatment and palliation of cancer.

**Prevention:** Many forms of CAM are promoted for (breast) cancer prevention. The scientific data in support are usually scarce. Some promising (albeit not compelling) evidence exists for the regular use of garlic, green tea, phytoestrogens and panax ginseng. None of these relate specifically to breast cancer.

**Treatment:** An increasing number of CAM treatments are promoted as cancer 'cures', often supported by quasi-scientific data. Essiac, Di Bella therapy, Hoxley formula, mistletoe, laetrile and shark cartilage are just some examples. For none of these therapies is there sufficiently sound evidence to recommend them to breast cancer patients. Several of these alleged cancer 'cures' are associated with significant risks.

**Palliation:** Several forms of CAM are not aimed at prevention or treatment but at increasing the quality of life of cancer patients, often through relaxation and reduction of stress, e.g. reflexology, aromatherapy. Other treatments can ease the adverse effects of orthodox cancer therapies, e.g. acupuncture can reduce nausea and vomiting after chemotherapy. Even though the scientific data are often weak, CAM's role in palliative and supportive care is potentially important.

Friday, 19 March 2004

16:00–17:15

## PROFFERED PAPERS

### Breast conservation

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ORAL

### Gene expression profiling of patients at risk for local recurrence after breast conserving therapy

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**Background:** A limited number of risk factors for developing local recurrence after breast conserving therapy have been identified. The most important risk factors appear to be incomplete resection of the tumor

and young age. The identification of additional risk factors would be very useful in guiding optimal therapy and also improve understanding of the mechanisms underlying local recurrence. We used cDNA microarray analysis to identify gene expression profiles associated with local recurrence after breast conserving therapy.

**Material and Methods:** Gene expression profiles were obtained from 60 patients who were under the age of 51 years at diagnosis of a primary invasive breast carcinoma and underwent breast conserving therapy. Of these 60 patients 26 developed a local recurrence and 34 controls were free of local recurrence at 11 years after therapy. From 10 patients with a local recurrence the RNA of the recurrence was isolated and used for analysis. In total 70 samples were analyzed; 60 primary tumors and 10 recurrences. Gene expression profiling was performed using a glass array containing 18,000 cDNAs. Unsupervised and supervised methods of classification were used to separate the patients in groups corresponding to their disease outcome and to analyze the differences between primary tumors and their recurrences.

**Results:** Hierarchical clustering of patients did not show any grouping reflecting local recurrence status. Supervised analysis revealed a possible classifier consisting of three genes; these data need to be validated. Paired-data analysis showed no set of genes that is consistently different in expression between primary tumors and recurrences. Co-clustering of the primary tumors and their local recurrence in the hierarchical cluster analysis also reflects this.

**Conclusions:** There are no great differences in gene expression patterns between breast carcinomas with and without a local recurrence after breast conserving therapy. The gene expression pattern in primary tumors and local recurrences is very similar. Preliminary results suggest that there may be a classifier for local recurrence after breast conserving therapy.

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ORAL

### Update of the BASO II trial of primary treatment of tumours of excellent prognosis

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This trial examined additional treatments to Wide Local Excision with clear margins, in Grade I, node negative tumours of 2 cm or less with clear margins. Between 1992 and 2000, 1172 patients were randomised to a 2x2 design. The primary outcome measure is local recurrence (LR), defined as tumour in the treated breast. The median follow-up is 54 months. Survival is excellent, only 7 deaths from breast cancer.

LR by randomisation are:

Randomisation	n	LR	LR%PA
Radiotherapy (RT) to intact breast	584	8	0.3
No RT	574	21	0.8
Tamoxifen	200	2	0.2
No Tamoxifen	208	8	0.9
RT plus Tamoxifen	96	0	Nil
No RT, no Tamoxifen	95	6	1.5

Since for those entering only to the RT or the Tamoxifen comparisons, the other therapy could be given electively by centres, the results by treatment received:

Received	n	LR	LR%PA
Neither therapy	174	15	2.0
RT only	191	6	0.72
Tamoxifen only	411	8	0.44
RT plus Tamoxifen	396	2	0.12

It appears that % LR PA is too high from surgery alone but that Tamoxifen is as effective as RT in lowering LR to very acceptable levels. This would have important cost and waiting time implications for RT in the NHS, if borne out by longer follow up.

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ORAL

### Surgical outcomes for clinically occult breast lesions: comparing radioguided occult lesion localisation (ROLL) vs. wire guided lumpectomy (WGL)

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**Introduction:** Widespread screening has resulted in an increased incidence of clinically occult breast lesions. The surgical management