Thursday, February 26, 1998 9.00–18.00

Public Health / Genetics

P1 Epidemiology and adjuvant therapy in early breast cancer: A prospective randomised study of 300 Indian patients

K.S. Behgal, G.K. Rath, P.K. Julka, V. Raina, N.K. Shukla. *Dept. of Radiotherapy, AIIMS, Ansari Nagar, Delhi, India*

A prospective randomised trial was started in IRCH, AIIMS, New Delhi, India in October, 1993. The trial included only female patients of early breast cancer (T1–3, N0–1, M0) Selection criteria included an exhaustive metastatic work-up. All patients were supplied a 3 monthly supply of tamoxifen free of cost. All patients had surgery (MRM or QUART). Till date 365 patients have been randomised. Premenopausal patients were randomised to 4 groups:-(1) Tamoxifen alone, (2) Tamoxifen+Chemotherapy, (3) Tamoxifen+Ovarian ablation (4) Tamoxifen+Chemotherapy+Ovarian ablation. The postmenopausal patients were randomised to 2 groups only:- (1) Tamoxifen alone, (2) Tamoxifen+Chemotherapy. Radiotherapy was given as and when indicated. (ie, breast conservation, T3 disease, >4 nodes positive, >50% nodes positive, an inadequate axillary clearance or margin positivity. Chemotherapy was administered to the respective randomised patients (CMFx6 or CAFx6) Following treatment patients were called every 3 months. Average no. of nodes resected was 10.4 in our centre.

Results: Of all 365 patients, the age range was 23–75 yrs. (median 45 yrs.) The commonest age incidence was 40–50 yrs. Distribution of pre- and post-menopausal was identical. The upper outer quadrant was the commonest site of presentation. Nipple discharge was seen in 4.2%, parily did not appear to have an influence on risk of disease. 14.7% had a positive family history. 75% patients were of urban background. Survival analysis was done comparing treatment groups, age, menopausal status, node positivity, no. of nodes positive. Maximum follow-up was 48 months and minimum was taken as 6 months for meaningful analysis. Thus 275 patients were analysed. The period of follow-up, and the sample size are inadequate, however, statistically significant results were seen considering age menopausal status, node positivity and no. of nodes +ve. Node positivity, increasing no. of nodes +ve was associated with a poor prognosis ($p = 0.0011$).

P2 Cost of adjuvant chemotherapy (CT) with CMF and tamoxifen in breast cancer (BC)

R.A. Abdyldaev, T.A. Abdyldaev. *Kyrgyz Institute of Oncology & Radiology, Bishkek, Kyrgyzstan*

Annually, 150–160 BC patients receive adjuvant CT with CMF (cyclophosphamide, 600 mg/m2; methotrexate, 30 mg/m2; 5-FU, 600 mg/m2 on days 1 and 8) and 70 pts receive long-term adjuvant tamoxifen, 20 mg/day in the Kyrgyz Institute of Oncology and Radiology. The cost of 6 CMF couses for one patient is estimated at $274.01 and that of tamoxifen, 20 mg/cay (2 years)- $185.41 (according to the 1997 prices) (Table).

Drugs CMF	Average (mg) of a course (S = 1.7 m^2)	Cost of one bottle (US$)	Quantity (b) or (tab)	Total cost for 1 patient per annum ($)
Cyclophosphamide	12,240	81 (200 mg)	61 b	110.77
Methotrexate	612	0.52 (5 mg)	122.4 b	64.26
5-Fluorouracil	12,240	2.02 (250 mg)	49 b	98.98
Tamoxifen (2 yrs)	14,600	7.62 (10 mg)	60 tab	185.41
(1 year)	7,300	7.62 (10 mg)	60 tab	92.70

To provide 160 pts with 6 courses of CMF per annum, it is required $43,841.60, in addition to $12,979.70 needed for 70 pts receiving tamoxifen, in total $56,820.30. The cost of the FAC regimen, another widely-used in the CIS drug combination, for one patient is $708.21 per year. The average monthly wages in Kyrgyzstan do not exceed US $45–$50, and the budget deficit does not allow to provide all the pts with the CT drugs in a required quantity. Thus, the BC pts cannot afford receiving adjuvant CT at a full value due to economic reasons.

P3 The effect of medical information on womens opinion about breast cancer

G. Tschurtschenthaler, P. Oppitz, J. Hammer, P. Flink, M. Fridrik, G. Michlmayr. *Oberösterreichische Krebshilfe, Linz, Austria*

In October and November 1997 in Oberösterreich (Austria) information campains about breast cancer are arranged by the Oberösterreichische Krebshilfe and the Country of Oberösterreich. To control the effect of the medical information a questionnaire about the change of thinking about early detection of breast cancer including self examination of the breast was designed for the participants.

The first experiences with women answering the questionnaires *before* and *immediately after* the information showed a very high return rate (90%) and documented the benefit of this program.

Consequently an input of at least 300 answered questionnaires is expected and the results will be presented in detail.

P4 Ought the impact of different types of consumer involvement in various research activities (commissioning, trial protocol planning, Cochrane research reviews, etc.) be evaluated?

H. Thornton. *(CAG-CT) "Saionara", 31 Regent Street, Rowhedge, Colchester. CO5 7EA, UK*

"Consumers", like "trialists" or "health professionals" are not a homogenous group: they also vary enormously in terms of their level of knowledge, the skills and expertises they bring, and their attitudes and beliefs.

Dr. Iain Chalmers, Director of the UK Cochrane Centre, at a Consumer Workshop at the 5th Cochrane Colloquium in Amsterdam in October 1997, asked: "Do we need randomised controlled trials to look at the impact of consumer involvement in [Cochrane] reviews? There are different methods of achieving improvements: we need to explore this. E.g. some [consumers] might have expert knowledge, other do not. We need to be clear what one is testing and what the outcome is."

The *Cochrane Collaboration* has always emphasised the importance of consumer input and feedback and affirms in its brochure that this is "essential in order to fulfil its goals."

The *Consumers' Advisory Group for Clinical Trials (CAG-CT)* is a unique working group of profession and patient whose aim is to "initiate, facilitate and produce high quality research that meets the needs of patients, the public and health professionals by advancing education in medical research methodology." Their main activity is to act as a "facilitator for progress" by being used as a resource by those involved in devising randomised controlled trials. Their ethos is one of shared responsibility and collaboration to produce trial protocols which blend scientific expertise with qualitative issues which are of importance to patients. Their concern is to develop methodologies to enable and facilitate this process to achieve "jointly-owned" rather than "imposed" trials, which they have reason to believe will therefore accrue more rapidly.

As Iain Chalmers has said, we need to explore different ways of achieving involvement and to subject such methods to rigorous evaluation to assess their impact. This may accord with *The Lancet* editorial recommendation that "...just as patients' consent must be informed, so must their advocacy." (Vol. 349. p.1635. 1997). By what criteria are such studies to be peer-reviewed?

Why indeed should patients/consumers escape rigorous evaluation of the benefit/harm of their involvement? But, also, why should they be separated out for special scrutiny, any more than any other participant in a truly collaborative, multi-disciplinary research team, where no category should either demand or expect special quarter in a truly iterative process?

P5 Time trends in systemic adjuvant treatment of early-stage node-negative breast cancer in Québec

N. Hébert-Croteau, J. Brisson, J. Latreille, G. Gariépy. *G. Québec, Canada*

To assess compliance with the 1992 St-Gallen Conference recommendations for systemic adjuvant therapy of node-negative breast cancer, we conducted a population-based study among residents of five regions of Québec, Canada. A stratified random sample was selected among all women with node-negative breast cancer newly diagnosed in 1988/89, 1991/92 and 1993/94. Information on the patient, her tumor, the source of care and all treatments received was abstracted from medical charts. Patients were classified as being at minimal, low or high risk of recurrence based on criteria proposed at the St-Gallen conference, and systemic adjuvant treatments received were dichotomized as consistent or not with the conference recommendations. Overall, 1,732 cases of breast carcinoma (1,578 invasive and 154 DCIS) were included in the analysis. The proportion of patients given hormonal or cytotoxic systemic treatment increased from 51.7% to 73.1% from 1988 to 1993. Among women with invasive carcinomas, 23.5% were classified at minimal, 12.9% at moderate and 50.0% at high risk of recurrence. Throughout the study period, virtually all women at minimal risk, including 100% of DCIS, were treated according to the consensus statement. However, the proportion of women so treated increased from 58.8% to 71.4% in the moderate risk group, and from 43.2% to 67.0% in the high risk category. This increase occurred before the publication of the St-Gallen conference. Thereafter, the proportion of moderate and high risk patients treated according to the consensus statement remained stable. Compliance increased with age (69.7%, 78.0% and 78.7% among women under 50 years, 50 to 69, and