O-4. Does timing of breast cancer surgery in relation to the menstrual cycle phase affect prognosis? The Yorkshire Breast Cancer Group Intervention, Timing and Survival Study

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The effect of breast cancer surgery timing during the menstrual cycle on prognosis remains controversial. We conducted a multi-centre prospective observational study to establish whether timing of interventions influences prognosis. Here we report 3-year survival results for "primary" patients (regular cycles, no oral contraceptives within last 6 months):

Data were collected regarding timing of interventions (first tumour handling & subsequent surgeries) in relation to patients' last menstrual period (LMP) & first menstrual period after intervention (FMP); hormone profiles (follicle stimulating & luteinizing hormone, progesterone, oestradiol) were also measured. Overall & disease-free survival (OS, DFS) were assessed using Cox's Proportional Hazards model adjusting for intervention type, Nottingham Prognostic Index & adjuvant therapy. Initial analysis incorporated LMP in its continuous form & subsequent exploratory analyses used categorisations of Senie, Badwe & Hrushesky. Hormone profiles with LMP & FMP data were also used to define menstrual phase.

611 patients were recruited from 25 centres between '93 & '00. Median age was 43 (range 19–55) years. At a median follow-up of 58 (range 0–132) months there have been 115 deaths; 56 occurred within 3 years of surgery. Types of first surgery were excision biopsy (18%), lumpectomy (48%) & Mastectomy (33%). 14% of tumours were grade I, 42% grade II, 40% grade III; 51% were node positive. Menstrual cycle according to LMP was not statistically significant at the 5% level for the 412 patients in the "primary" group (OS HR=1.02, 95% CI [0.99,1.04], $p = 0.14$; DFS HR=1.00, 95% CI [0.98,1.02], $p = 0.92$). Exploratory analyses indicated possible increased OS when surgery occurred in the follicular phase of the menstrual cycle.

In this analysis timing of surgery in relation to the menstrual cycle phase had no significant impact on 3-year survival. This may be explained by our lower than expected event rate. Unlike previous studies this cohort has received modern adjuvant treatments, some of which will have caused ovarian suppression.

O-5. Sentinel lymph node biopsy for breast cancer: from investigational procedure to standard practice

Almanac Trialists Group.

Background: Sentinel lymph node biopsy, popularised in melanoma, has revolutionised the management of breast cancer. **Methods:** A multicentre randomised trial has been performed comparing SNB to conventional axillary treatment in clinically node-negative invasive breast cancer patients. The primary outcome measures were arm/axillary morbidity, quality-of-life (QoL) and economic evaluation. Only surgeons achieving a set standard (localization rate of $\geq$90% and false negative rate of $\leq$5%) in 40 consecutive audit patients proceeded to the randomised phase. From November 1999 to October 2003, 1031 patients were randomised to undergo SNB (515) or standard axillary surgery (516). The sentinel lymph node (SN) was identified using a combined technique involving Patent Blue V and 99mTc-albumin colloid injected peritumourally. Patients with SN metastases proceeded to axillary clearance or received axillary radiotherapy (non-randomised). The intention to treat analyses of data to 6 months is presented in this paper.

Results: The failed localisation rate for SNB was 2%. Axillary metastases were similar in both standard and SNB arms (23% vs. 26%). Relative risks for sensory loss and lymphoedema at 6 months were 0.26 and 0.38. Axillary operative time, drain usage, hospital stay and time to resume normal day-to-day activities were substantially reduced in the SNB group. At 1, 3 and 6 months after operation, overall patient-recorded QoL and arm morbidity scores were significantly better in the SNB group. These benefits were not at the cost of raised anxiety in the SNB group.

Conclusions: SNB is associated with reduced arm morbidity and better QoL life compared to standard axillary treatment.

O-6. Combination blue dye sentinel lymph node biopsy and axillary node sampling: the Edinburgh experience

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Axillary lymph node status is an important prognostic factor for breast cancer. The axilla can be staged by axillary dissection, 4-node axillary sampling or sentinel lymph node biopsy (SLNB).

At the Edinburgh Breast Unit, our practice has been to perform axillary node sampling in patients with breast cancers of under 2 cm to stage the axilla. Unlike axillary node sampling, SLNB enables targeted localization of lymph nodes. We therefore combined 4-node axillary sampling with blue dye SLNB. This allows targeted localization of the lymph nodes while overcoming any possibility of involved lymph nodes failing to take up blue dye.

This is a retrospective study of 361 patients who underwent a total of 364 procedures, combining blue dye SLNB and axillary lymph node sampling. A minimum of 4 lymph nodes were removed. The mean number of lymph nodes biopsied was 5.1, with a mean of 2.3 sentinel lymph nodes and 2.9 sample nodes. 53 patients (14.8%) had a positive sentinel lymph node and 11 patients (3.2%) had an involved sample node. Of the 11 patients with a positive node sample, 2 had negative sentinel lymph node and in another 2 patients, the SLN was not found. This gives a minimum false negative rate of 3.8% for SLNB.

This audit indicates that combination blue dye SLNB and 4-node axillary sampling has improved sensitivity over that of blue dye SLNB alone and may be useful as an alternative in hospitals without nuclear medicine capabilities.