

tation itself has independent poor prognostic significance. Work in several epithelial malignancies has suggested that advantage for paclitaxel may derive from its activity in patients with p53 mutant (or null) tumours.

ER-pos breast tumours benefit from both tamoxifen and chemotherapy. Whilst a proportion of ER-pos tumours also over-express p53, the data suggest that this has little or no bearing on tamoxifen-resistance and many ER-pos./p53-mutant tumours may remain sensitive to tamoxifen. Paclitaxel and tamoxifen may complement conventional adjuvant chemotherapy in a proportion of ER-neg and ER-pos tumours, respectively. This may explain why paclitaxel has failed to improve disease-free survival in ER-pos patients; p53 mutant tumours are less common in this subgroup and tamoxifen, fed to both arms of the trial, may mask the benefit of paclitaxel in ER-pos patients in the research arm. This effect, most marked in late-relapsing patients, may account for the modest convergence of the survival curves after 52.5-months' median follow-up in CALGB 9344.

#### O-4. THE BASO II TRIAL OF ADJUVANT RADIOTHERAPY, V. NONE AND TAMOXIFEN. V. NONE IN SMALL, NODE NEGATIVE, GRADE I TUMOURS

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BASO II began in Feb 1992, a four arm trial in tumours with excellent prognosis ( $\leq 2$  cm, LN negative, Grade I), age  $< 70$ , treated by wide local excision (WLE) with histologically clear margins.

WLE only	WLE + RT
WLE + Tamoxifen (TAM)	WLE + TAM + RT

Centres could enter to all 4 arms (or) elect for RT or not and enter to the TAM comparison (or) elect for TAM or not and enter the RT comparison.

The trial closed in October 2000 with  $n = 1172$ . This analysis is of local (in breast) recurrences (LR) in the breast. 1122 analysed to follow up date 30 June 2000 (median 35 months, range 1–104). 33 have died: only 7 with or from breast cancer.

##### Randomised comparison

	RT	no RT	TAM	no TAM	RT + TAM	Neither
n	554	549	208	207	96	95
LR	7	20	2	8	0	6
LR% PA	0.4	1.2	0.3	1.3	0	2.1
	$\chi^2$ 5.14		Exact Test		Exact Test	
	p < 0.02		p 0.06		p 0.01	

**Conclusion:** In this excellent prognostic group although the LR rate without RT is satisfactory at 1.2% PA, it reaches 2% PA in cancers given neither RT nor TAM.

#### O-5. RANDOMISED STUDY OF AXILLARY CLEARANCE VERSUS FOUR NODE SAMPLING

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To compare the outcomes of axillary sampling and axillary clearance 855 women with operable women with T<sub>1</sub>–T<sub>3</sub>, N<sub>0</sub> N<sub>1</sub>, M<sub>0</sub> breast cancer were enrolled in 2 consecutive studies of mastectomy (Mx),  $n = 401$  or wide local excision (WLE)  $n = 454$  and were randomised to 4 node sampling (NS) or full level III axillary clearance (NCI). All patients with involved nodes on node sampling had axillary radiotherapy (XRT). Systemic therapy was based on node status and was identical in both randomised groups. Mean follow up was 4429 days for Mx, 2538 days for patients undergoing wide local excision with the median follow up being 3434 days for the combined group. When the mastectomy group and the wide local excision group were analysed separately, there was no significant difference in axillary recurrence within node positive (+ve) or node negative (–ve) groups whether patients had a node sampling or an node clearance. When combined however there were significant differences in axillary recurrence.

Combined Group	Axillary Recurrence				Survival			
	n	5 y	10 y	p value	5 y	10 y	15 y	p value
NCI –ve	260	1.6	1.6	0.017	88.5	77.6	67.5	0.36
NS –ve	283	3.3	6.8		89.9	84.6	70.1	
NCI +ve	164	3.0	6.6	0.086	75.7	62.1	51.1	0.79
NS +ve	148	6.0	9.4		76.4	59.4	51.7	

Patients who were node negative on clearance had a significantly lower rate of axillary recurrence than patients who were node negative on sample. There was no significant influence of axillary treatment on long term survival. These data demonstrate that axillary node sampling is accurate in about 95% of patients. There is a small percentage in which it underestimates axillary node involvement. For the involved axilla, axillary clearance produces a lower (but non-significant) rate of local control compared with axillary radiotherapy.

#### O-6. PROSPECTIVE RANDOMISED STUDY COMPARING RADIO-GUIDED SURGERY (ROLL) TO WIRE-GUIDANCE FOR OCCULT BREAST LESIONS LOCALISATION

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The use of radioisotopes for occult lesion localisation has recently gained considerably interest. Patients undergoing therapeutic or diagnostic procedures for impalpable breast lesions were entered into this study and randomised to either ROLL or wire placement.