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A controlled trial of short-term versus standard axillary drainage after axillary clearance and iridium implant treatment of early breast cancer

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A controlled trial has been conducted to determine the safety of early drain removal after axillary clearance as part of conservation treatment in early breast cancer. A total of 84 patients was entered into the study of whom 41 had the drain removed after 5 days, irrespective of the volume of fluid draining, and 43 had drains removed when fluid was less than 20 ml per day.

Of the standard drainage group, 28% required percutaneous aspiration of lymph because of subsequent accumulation, compared with 49% of the short-term drainage group. Early drain removal was not associated with any increase in wound complications nor in cosmetic outcome, but did enable earlier discharge of patients from hospital.

There is now an accumulation of evidence from controlled clinical trials that patients with breast cancers up to 4 cm in diameter can safely be treated by breast conservation *(1–3)*. The technique which has evolved at Guy's Hospital Clinical Oncology Unit is a combined approach comprising tumourectomy, axillary clearance, iridium implant and external radiotherapy to the breast *(4)*. The axillary clearance is an important part of the procedure, serving as treatment for the involved axilla and also accurately staging the disease, thereby determining the need for adjuvant systemic therapy.

Because of the combination of axillary surgery and interstitial irradiation, there is postoperative accumulation of intra-axillary lymph which is normally removed by a vacuum drainage system. The Unit policy has been to leave the drain in place until the drainage on two successive days is less than 20 ml per 24 h. This usually takes between 10 and 14 days, which necessitates a long stay in hospital for patients feeling relatively well who do not require expert nursing other than vacuum drainage care.

On occasions, the axillary drains have become dislodged before the customary time of removal. In such cases the expected axillary collection of lymph has not always been observed, possibly because of the tamponading effect of fluid collection within the axilla, together with external pressure from the adducted shoulder. It was therefore reasoned that prolonged drainage may be unnecessary. It would certainly be of considerable benefit both to the patient and to hospital resources if the length of stay could be reduced. Accordingly, after a pilot study had shown no major problems arising from early drain removal, a randomised trial was conducted. In the study, patients were either managed in the standard way, or alternatively the axillary drain was removed after 5 days, irrespective of the previously measured lymph drainage.

Methods

Patients

The 84 patients entered into the trial had histologically confirmed infiltrating carcinoma with primary operable lesions not exceeding 4 cm in diameter. All had negative

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preoperative staging investigations which included full blood count, biochemical screen, chest radiograph and bone scan. In addition, bilateral mammography was performed to exclude multifocal disease and contralateral malignancy.

Procedure

The technique of tumourectomy, axillary clearance and iridium implant has been described previously (*4*). This was a one-stage procedure when the original histological diagnosis was made by outpatient needle biopsy (*5*), or as a two-stage procedure when an excision biopsy had been used to make the original histological diagnosis. The ^{192}Ir wires were inserted 36–48 h postoperatively to give a tumour dose of 20 Gy, which usually took 48 h.

Drain removal

Patients were randomly allocated to have their drain removed 5 days postoperatively or to have the standard drainage regimen whereby the drain remained *in situ* until daily drainage was less than 20 ml over two consecutive days. All patients remained in hospital for a minimum of 9 days when sutures were removed, and provided that the drains had been removed, the patient was discharged.

Endpoints

The daily and total drainage was measured for each patient, together with the need for subsequent percutaneous aspiration of fluid accumulating after drain removal. The incidence of wound infection and side-effects was monitored in all cases.

Results

A total of 84 patients was entered into the study, of whom 43 were treated by standard drainage and 41 by 5-day drainage. A comparison of the clinical and pathological characteristics of the patients in the two groups is given in Table I. This indicates that both groups were similar with regard to age, menopausal status, stage, tumour type, weight of axillary clearance specimen, completeness of excision and axillary nodal status.

The observed complications in each group are set out in Table II. Of the standard drainage group 12 (28%) required aspiration of seroma compared with 20 (49%) of the short-term drainage group (χ^2 Yates = 3.04; DF = 1; $P < 0.1$). The mean number of aspirations was 2.75 for the standard group compared with 3.3 for the short-term drainage cases ($t = 0.58$, not significant). Of the standard group 7/12 (58%) needed only one aspiration compared with 6/20 (30%) of the short-term drainage group (χ^2 Yates = 1.46; DF = 1; not significant).

Within the short-term drainage group, the mean volume for the last 2 days before drain removal was 156 ml for those who required subsequent aspiration and 106 ml in those who did not need any further drainage. The range was 30–470 ml (median 130 ml) for the former group and 10–260 ml (median 100 ml) in the latter group. Thus, the absolute drainage before drain removal was not a good indicator of need for subsequent external aspiration.

Two patients in the short-term group and one in the standard group developed cellulitis of the wound which responded to systemic flucloxacillin. The average duration of hospital stay was 11.7 days for the standard group compared with 9.0 days for the short-term group ($t = 4.9$; $P < 0.01$). The short-term cosmetic outcome was good/excellent in all patients with no appreciable differences between the two groups.

Table I. Comparison of clinical and pathological features of patients treated by standard and short-term axillary drainage

	Standard	*Short-term*
Number	43	41
Age	50.5 ± 8.4	46.1 ± 10.4
Premenopausal	24 (56%)	29 (71%)
Tumour size in cm (mean ± S.E.)	2.7 ± 0.8	2.8 ± 1.0
Tumour type		
Ductal I	8 (19%)	4 (10%)
Ductal II	12 (28%)	14 (34%)
Ductal III	15 (35%)	12 (29%)
Lobular	5 (12%)	6 (15%)
Mucoid	1 (2%)	—
Atypical medullary	2 (5%)	1 (2%)
Mixed	—	4 (10%)
Specimen weight in grams (mean ± S.E.)	103.2 ± 43.3	93.0 ± 34.6
Margins clear	19 (44%)	19 (46%)
Axillary nodal metastases	16 (37%)	20 (49%)
Number of positive nodes	6.8 ± 8.9	4.7 ± 8.0

Table II. Complications in patients treated by standard and short-term axillary drainage

	Standard	*Short-term*
Fluid accumulation	12 (28%)	20 (49%)
Mean number of aspirations	2.75	3.3
Cellulitis	1	2
Lymphoedema	0	0
Stay in hospital in days (mean ± S.E.)	11.7 ± 2.9	9.0 ± 2.2

Discussion

The present trend in breast cancer surgery is towards more conservative surgery together with earlier discharge from hospital. The results of the present study suggest

that these two aims can be achieved safely. Early axillary drain removal, and hence earlier discharge from hospital, would not appear to result in an increase in local complications. The expected axillary fluid accumulation is only a problem for one-half of the patients and can easily be dealt with by outpatient aspirations, which can, if necessary, be carried out by the radiotherapist responsible for giving external radiotherapy. An alternative approach would be to discharge the patient from hospital with the suction drains *in situ (5)*. However, in Britain many patients may be reluctant to assume responsibility for their own drain care.

It seems that these patients destined for seroma formation cannot be identified on the basis of histology of the axillary lymph nodes nor in relation to the volume of daily lymph production during the first few postoperative days. The technique of breast conservation surgery and brachytherapy used in this study would appear to be compatible with early drain removal and therefore early discharge from hospital.

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Assessor's comment

At the end of the day the message seems to be that in patients on short-term drainage nearly twice as many will require repeated aspiration of seroma compared with those on the standard drainage regimen and the reduction in bed days is two for short-term as opposed to the standard drainage group.

I have to say that our standard policy is now to remove axillary drains at 1 week, discharge our patients and aspirate axillary seromas as necessary. We reached this protocol conclusion not on the basis of a control trial but really from necessity to reduce bed occupancy, and we were able to reduce our patients' stay by 5 days by somewhat empirically altering our management of the axillary drains.

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