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Clinical trial

Short versus long-term postoperative drainage of the axilla after axillary lymph node dissection. A prospective randomized study

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Summary

Background. Axillary lymph node dissection (ALND) is a standard procedure in the treatment of breast cancer. Current practice following ALND involves several days of drainage of the axilla to reduce the formation of seroma. The aim of this study is to investigate the feasibility of 24 h drainage.

Study design. A prospective randomized trial was performed comparing 24 h drainage to long-term drainage. The primary outcome measure was duration of hospital stay. Formation of seroma and wound related complications were secondary outcome measures.

Results. Fifty patients were randomised to the 24 h drainage group and 50 patients to the long-term drainage group. 24 h drainage was associated with a shorter hospital stay (2.5 versus 4.6 days, $p < 0.001$). Seroma aspiration was required in 76% of the patients after 24 h drainage and in 64% after long-term drainage ($p = 0.19$). The number of wound related complications was higher after long-term drainage (13 versus 9, $p = 0.33$). Infectious complications were seen in 11 patients after long-term drainage versus 6 after 24 h drainage ($p = 0.18$).

Conclusion. These results indicate that 24 h drainage following ALND is feasible and facilitates early hospital discharge. Furthermore, 24 h drainage is not associated with excess wound related complications compared to long-term drainage.

Introduction

Axillary lymph node dissection (ALND) is part of the treatment of breast cancer in breast conserving therapy as well as in mastectomy. Axillary seroma formation is the most frequent complication after ALND. The reported rate of this complication ranges from 18 to 74% [1–6]. Therefore standard practice following ALND involves suction drainage of the axilla.

The current practice is to remove suction drains as soon as fluid drainage is less than 50 ml/day with a maximum of 7 days. Several pro and cons of both short and long-term axillary drainage have been argued. Although the use of a low vacuum drain permits patients to be discharged with the drain in place, many patients only feel confident with this situation after a few days. Thus early drain removal could shorten hospital stay [7,8]. It also might decrease postoperative discomfort [9,10]. In addition, seroma represents a good culture medium for retrograde skin bacteria in the presence of a foreign body, such as a drain [11,12]. This suggests that early drain removal might decrease the incidence of wound infections. However, if the drain is removed prematurely the continued seroma production might necessitate multiple percutaneous aspirations to remove accumulated fluid [13]. This, on the other hand, also could have a negative impact on the infection rate and on wound healing due to increased tension to the wound.

To evaluate whether 24 h drainage is as effective as long-term axillary drainage we performed a prospective randomised study. The current long-term drainage regime was compared to a short-term drainage regime in which the axillary drain was removed 24 h after surgery.

Methods

The trial was conducted during a 24 month period of time between July 2000 and August 2002. All patients with breast carcinoma who underwent ALND were included in this prospective randomised study. The study objective was to evaluate whether 24 h drainage of the axilla after ALND was as effective as the current practice, which consists of axillary drainage during a maximum of 7 days or shorter when production is below 50 ml/24 h. The primary outcome measure was the length of hospital stay, secondary outcome measures were seroma formation demanding aspiration and wound related complications.

Patients underwent either mastectomy or wide local excision in combination with ALND. An ALND alone was performed in patients that previously underwent a wide local excision of the tumor. The sentinel node procedure was not standard practice at the time of this study. Patients that underwent this procedure were excluded.

Drainage of the axilla was done through placement of a low vacuum closed suction drain inferior to the incision. All wounds were closed with a running 4–0 absorbable monocryl intracuticular suture. After skin closure, randomisation by envelope was performed. Patients were allocated to having drains removed after 24 h, or to leaving drains *in situ* until fluid production was less than 50 ml/day with a maximum of 7 drainage days. Clinical factors reviewed included: demographical parameters, operative details such as previous breast operation, type of operation (mastectomy or breast-conserving), duration of operation and perioperative blood loss. Pathological variables included tumor characteristics such as histology and tumor stage (TNM classification), total number of lymph nodes removed and the number of tumor positive lymph nodes.

The low vacuum drain permits early hospital discharge, after proper patient instruction. A patient instruction programme was earlier implemented in our hospital and continued during this study in patients allocated to long-term drainage. Patients were discharged home either after drain removal or with their drain *in situ*, after proper instruction and if the patient felt confident.

The follow-up was standardised. The first month after discharge all patients were seen at the outpatient clinic every week. Patients in the long-term drainage group who left the hospital with the drain in place were seen when the drain production was less than 50 ml/day or at the 7th day of drainage. When no wound complications were seen, patients were seen next 3 months after discharge. When a wound complication occurred patients were seen when needed. During follow-up in the outpatient clinic complications including seroma, infection and wound necrosis were registered. Seroma formation was defined as a clinically apparent fluid collection in the axilla that required aspiration because of excessive wound tension or patient discomfort. Aspirations were performed with a needle connected to an intervening three-way tap using sterile technique. Neither local anaesthetic nor prophylactic antibiotics were used. For this study we defined infection as every inflammation that urged the attending physician to start antibiotic treatment or when an abscess occurred, requiring drainage. Criteria for wound flap necrosis included demarcation of nonviable tissue along the edges of the flaps.

Statistical analysis was performed to identify differences between the treatment groups. The student *t*-test and the chi-square test were used to compare patient and tumor characteristics, operative parameters, length of hospital stay, the number of seroma aspirations and the incidence of wound complications.

Results

One-hundred consecutive patients with an indication for ALND were included. 50 patients were assigned to the 24 h drainage group and 50 patients to the long-term drainage group. Modified radical mastectomy was performed in 72 patients (72%) and breast conserving treatment in 28 patients (28%). Twelve of these 28 patients only underwent ALND after a previously performed biopsy. The mean age was 58.9 ± 13.9 years. Table 1 shows both groups to be demographically similar. No patient in the study group had diabetes and only one patient in the long-term drainage group used prednisone (5 mg/day). Furthermore there was no significant difference in operative parameters. There were 78 ductal carcinomas with or without associated ductal carcinoma *in situ*, 14 lobular carcinomas and eight other types of carcinomas (e.g. medullar, carcinoid, occult). The TNM classification of the tumors is also shown in Table 1. Most tumors were categorised in the T1 and T2 groups. On average, the total number of lymph nodes removed per patient was 13 with a range of 6–25. Sixty-one patients (61%) had lymph node metastases with an average of five tumor positive nodes.

The primary outcome measure was length of hospital stay (Table 2). Although all patients in the long-term drainage group were encouraged to leave the hospital with a drain *in situ* after proper instruction, there was a significant difference in length of hospital stay between the two treatment groups. Patients who were assigned to the 24 h drain group were discharged home after 2.5 ± 1.2 days. The hospital stay of patients with a long-term drain was 4.6 ± 1.7 days ($p < 0.001$).

The incidence of postoperative seroma formation requiring aspiration was high; 70% of all patients developed seroma (Table 2). We observed more seroma formation in the short-term drainage group (38 versus 32 patients, $p = 0.19$). However, no significant difference was seen in the number of aspirations ($p = 0.53$) and the mean volumes of aspirations ($p = 0.30$) as shown in Table 3. As shown in Table 4, the formation of seroma, measured by the number of patients that required one or more aspiration, was not associated with type of operation, previous biopsy or with the lymph node status.

Isolated seromas were seen in 51 patients. In the remaining 19 patients (27% of the patients with seroma formation) other wound complications were noted in conjunction with the seroma. The overall incidence of wound infection was 17%. In the long-term drainage group 11 patients (22%) developed an infection versus 6 patients (12%) in the 24-h drainage group ($p = 0.18$). Deep infection, requiring surgical intervention, was seen in three patients in the long-term drainage group. One patient in the 24-h drainage group developed an abscess that required drainage. All other infections were treated with antibiotics. No association was found between the development of seroma and the infection rate. Fourteen out of the 70 patients with seroma developed

Table 1. Patient and operation characteristics in the 24 h drainage group ($n = 50$) and the long-term drainage group ($n = 50$)

		24 h	Long-term
Age (years)*		58.22 ± 14.3	59.6 ± 13.8
Type of operation			
Modified radical mastectomy		34	38
Breast conserving treatment		11	5
ALND alone		5	7
Operative parameters			
Duration of operation (min)*		101 ± 21	95 ± 24
Blood loss (ml)*		197 ± 160	201 ± 134
Previous biopsy		20	23
Pathological parameters			
Tumor size	Tx	3	1
	T1	12	15
	T2	27	18
	T3	6	10
	T4	2	6
Ductal carcinoma		41	37
Lobular carcinoma		7	7
Other		2	6
Lymph nodes	Total excised*	13.3 ± 5.1	13.2 ± 4.9
	N0	21	18
	N1	29	32
	Positive nodes*	4.6 ± 4.3	5.1 ± 5.2

*Values represent mean values ± standard deviation. No significant differences were observed in these parameters, *p*-values as calculated by either the student t-test of the χ^2 test of all mentioned parameters are >0.05.

an infection versus 3 out of the 30 patients in which no seroma was found ($p = 0.22$). The number of aspirations had no influence on the development of infection.

In total 5 patients had wound healing problems resulting in skin necrosis, 2 patients in the long-term drainage group and 3 patients in the 24-h drainage group ($p = 0.64$).

Discussion

Surgery remains the principle treatment modality of breast cancer involving ALND in most cases. In 1947 [14] drainage of the axilla has been introduced to reduce the incidence of seroma formation and has since then been widely accepted. Studies with regard to the methods and duration of axillary drainage have been performed earlier. High and low pressure vacuum drains were compared [15–17] and found equally effective in preventing seroma formation and infection rate. The optimal timing of drain removal remains uncertain. Gupta et al. [18] compared 5 versus 8 days axillary drainage and Kopelman et al. [19] compared 3 versus long-term drainage. Both concluded in favour of long-term drainage because less seroma aspirations were necessary. Barwell et al. [20] however concluded that keeping drains *in situ* longer did not protect against seroma formation. Other arguments in favour of short-term drainage are reduction of hospital stay [7,8] and reduced morbidity [9,10].

Hospital stay after surgical procedures has been decreasing and outpatient surgery is growing. Women undergoing surgery for breast cancer are considered especially suitable for this setting because their recovery after surgery is usually rapid. The hospital stay after surgery is predominantly determined by postoperative

Table 2. Outcome measures of the 24 h drainage group ($n = 50$) and the long-term drainage group ($n = 50$)

	24 h	Long-term	*p*-value
Primary outcome measure			
Length of hospital stay (days)*	2.5 ± 1.2	4.6 ± 1.7	<0.001
Secondary outcome measure			
Incidence of seroma formation (*n*)	38 (76%)	32 (64%)	0.19
Infection rate (*n*)	6 (12%)	11 (20%)	0.18

*Values represent mean ± standard deviation.

Table 3. Seroma formation in the 24 h drainage group ($n = 50$) and the long-term drainage group ($n = 50$)

	24 h	Long-term	*p*-value
Patients requiring aspirations (n)	38 (76 %)	32 (64 %)	0.19
Number of aspirations*	2.72 ± 2.52	2.16 ± 2.67	0.28
Number of percutaneous aspirations			
0	12	18	
1–2	14	13	0.53
3–5	17	15	
>5 times	7	4	
Volume per aspiration (ml)*	213 ± 116	186 ± 100	0.30

*Values represent mean ± standard deviation.

Table 4. Number of patients that required one or more aspirations in the 24 h drainage group ($n = 50$), the long-term drainage group ($n = 50$) and in total*

	24 h	Long-term	Total
Type of operation			
BCO	10 (6)	8 (4)	18 (10)
Mastectomy	27 (7)	24 (14)	51 (21)
p-value	0.20	0.83	0.52
Previous Biopsy			
No	24 (6)	20 (7)	44 (13)
Yes	14 (6)	12 (11)	26 (17)
p-value	0.42	0.11	0.07
Lymph node status			
N0	15 (6)	9 (9)	24 (15)
N1	22 (7)	23 (9)	45 (16)
p-value	0.72	0.12	0.19

*Values in ( ) represent the number of patients that did not develop seroma.

wound drainage. Therefore we studied the feasibility of 24-h axillary drainage after ALND. Since we know from previous studies that early discharge contributes to both economical and psychological effects [21], our primary outcome measure was the impact of 24-h drainage on the length of hospital stay. Consistent with other reports [7,8], we observed that early drain removal reduced the length of hospital stay significantly, even in the presence of a patient training program for low-vacuum drain management. Furthermore, we investigated whether 24 h drainage had a negative impact on seroma formation and wound healing. As other authors report [5,6], the formation of seroma remained a dilemma. A high incidence of seroma formation (70%) was found requiring multiple aspirations per patient. However, short-term drainage has no negative influence on the formation of seroma. In contrast to some previous reports [18,19] a similar number of aspirations were required in both the short and the long-term drainage group.

Although ALND is a clean operation, infection rates as high as 19% have been reported [22–24] irrespective of the use of prophylactic antibiotics. Consistent with these reports, we found either a superficial or a deep infection in 17% of all patients. In previous studies no association was found between the duration of drainage and the rate of infection [8,10]. Important in our study is the fact that the number of infectious complications is not higher after short-term drainage, although there were more aspirations in this group of patients.

In conclusion, the results of this prospective randomised study show that 24 h drainage after ALND is feasible and facilitates early hospital discharge. Furthermore, 24 h drainage was not significantly associated with excess wound related complications compared to long-term drainage. In the perspective of the treatment of breast cancer in day-care, 24 h drainage will be an important improvement.

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