

Early drain removal improves quality of life and clinical outcomes in patients with breast cancer – Results from a randomised controlled trial

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ABSTRACT

Purpose: The use of suction drains after breast cancer surgery (BCS) is common practice. However, the optimal time to remove drains is not clear yet and limited research has been conducted so far to assess the impact of their use on patient comfort. The goal of this study was to investigate the effect of early drain removal after BCS on quality of life (QoL) and clinical outcome.

Method: A randomised controlled trial was conducted in 99 patients scheduled for BCS including placement of suction drains. Patients were randomised into either group 1: drains removed output-based, i.e., flow less than 30 ml/day or group 2: drains removed at hospital discharge, i.e., 4–5 days after surgery. A questionnaire on QoL was completed by the patients both pre- and postoperatively.

Results: Early drain removal was associated with a significant improvement in QoL. Additionally, total duration of home care nursing was considerably lower in the early-removal group (19 versus 1 day on average). No differences were observed in wound healing or the rate of wound infections, the latter being slightly lower in the early-removal group (13% versus 6%). Total volumes of fluid drained and/or aspirated were significantly lower in the early-removal group (median 1745 ml versus 752 ml), but more aspirations were needed (median 1 versus 3). The new policy of early drain removal was preferred by 94% of the patients in the early removal group.

Conclusions: Early removal of suction drains improves QoL and has no negative effect on clinical outcomes after BCS.

1. Introduction

Placement of suction drains after mastectomy or axillary lymph node dissection (ALND) has become common practice in breast cancer surgery (BCS) to prevent seroma formation, ever since their first introduction in 1947 (Murphey, 1947). Nevertheless, placement of suction drainage has some distinct disadvantages: skin bacteria can cause infection by retrograde entry through the drain, or the drain itself can cause patient discomfort and a need for daily home nursing (Andeweg et al., 2011). Likewise, drain removal policies across breast cancer (BC) centres vary widely. Only limited prospective research has been performed to date on the impact of wound drains on postoperative quality of life (QoL) in all its dimensions for patients with BC.

Multiple studies have investigated the safety of early drain removal

based on several clinical endpoints (Table 1). No significant difference in the incidence of seroma formation was found by Ackroyd and Reed, 1997 in a study with patients who received BCS with axillary clearance. These patients were randomised into two groups: axillary drains were removed after five days in the first group, while a volume-based criterion of less than 30 ml/day was used for removal in the second group. Similarly, Okada et al. (2015) did not find a significant difference in the incidence of seroma formation between the study and control group. Nonetheless, the number of outpatient visits for seroma was significantly higher in the study group without significant difference in the number of aspirations. These results were obtained in a Japanese cohort where drain removal upon volume less than 50 ml/day or at the latest five days postoperative was compared with conventional drain removal. Unfortunately, conventional drain removal was not specified,

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Table 1
Literature overview ranked by year.

Author	Year	Type of study	Country	Power calculation	Sample size	Surgery	Axillary dissection	Control group		Study group		QoL
								Drain policy	N	Drain policy	N	
Ackroyd	1997	Pro	UK	Yes	120	Mastectomy BCT	Level I-III	< 30 ml/day	61	5 days	59	Yes
Gupta	2001	Pro	India	No	121	Mastectomy	ALND	8 days	57	5 days	64	No
Dalberg	2004	Multicentre Pro	Sweden	Yes	198	Mastectomy	Level I-II	< 40 ml/day	99	1 day	99	Yes
Okada	2013	Retro	Japan	No	214	Mastectomy BCT	Level I-II	< 50 ml/day or 5 days	76	Conv.	138	No
Taylor	2013	Pro	UK	No	596	Mastectomy BCT	ALND	< 50 ml/day or 7 days	263	No Drain	335	No

Pro = prospective, Retro = retrospective, BCT = breast conservative therapy, ALND = axillary lymph node dissection, SLNB = sentinel lymph node biopsy, N = number of patients, Conv = conventional and QoL = Quality of life.

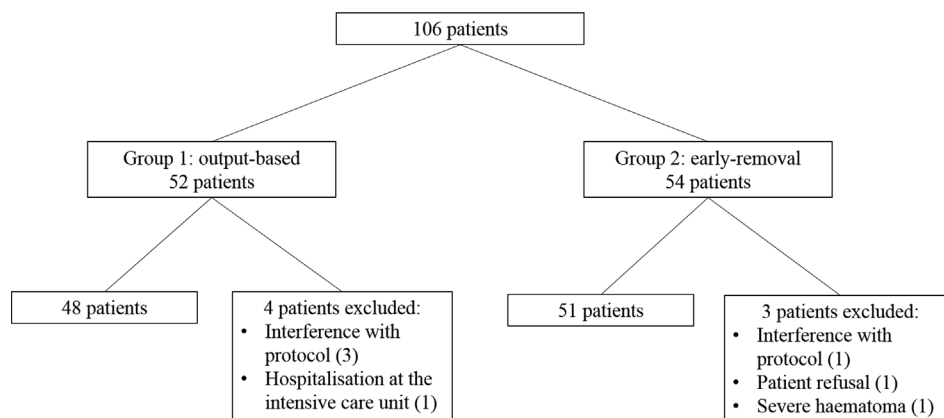


Fig. 1. Trial flow.

drains were removed at the discretion of the patient's physician. Dalberg et al. (2004) reported a higher incidence of seroma, but the total volume of fluid collected after percutaneous aspiration did not differ. These positive effects of drain removal were found in a randomised multi-centre study in five Swedish hospitals. 198 patients with BC who underwent a modified radical mastectomy with clearance of the axilla were randomised into two groups: drains were removed one day after surgery in the first group, while the criterion for the other group was a flow less than 40 ml/day. Gupta et al. (2001) were the first to mention a higher number of aspirations and total volume of aspirations in the early-removal group. They included 121 patients who were randomised to have drains removed either five or eight days post-operatively (64 and 57 patients, respectively). Only one study has been published to date that was closed early. This study was halted after including 24 patients due to higher rates of seroma aspiration, drain reinsertion and physician visit in the early-removal group (Barton et al., 2006).

Infection rate is another important endpoint in many studies since both drains and aspirations can be the cause of infections. Skin bacteria can enter for example retrograde via the drain and cause infection (Andeweg et al., 2011). No higher incidence of infection due to early drain removal has been reported to date. Additional positive effects of early drain removal are reduction in the length of hospital stay (Dalberg et al., 2004; Okada et al., 2015; Taylor et al., 2013) and a lower need of homecare (Andeweg et al., 2011). Ackroyd and Reed, 1997 studied restrictions in shoulder movement and presence of lymphedema, but did not find a significant difference between the standard and early drain removal group.

A systematic review of randomised controlled trials (RCTs) on timing of drain removal was conducted by Kelley et al. (2012). Data of RCTs on axillary dissection for different reasons, were collected from electronic databases such as Medline and Embase. Seven RCTs were retained, including the study by Ackroyd and Reed (1997), Gupta et al. (2001), Dalberg et al. (2004), and Baas-Vrancken Peeters et al. (2005).

The overall quality of the combined dataset was poor. Early drain removal was defined as removal after one to five days postoperatively, late as removal after six to eight days or based on daily output. The authors only mention that a higher total drainage prior to drain removal in the early drain removal group predicted subsequent seroma formation. No significant difference in infection rate was reported between early and late removal. The length of hospital stay was significantly lower in the early-removal group. In conclusion, no optimal timing of drain removal could be determined, a high total volume of drainage prior to drain removal predicted seroma formation but no exact volume was stated (Kelley et al., 2012).

Unlike the impact of early drain removal on clinical variables, the research on the effect of drains on patient comfort and QoL is limited. According to the authors' knowledge, only Ackroyd and Reed, 1997 and Dalberg et al. (2004) have assessed QoL in a quantitative way. The patient questionnaire conducted by Ackroyd and Reed, 1997 revealed that 81% of all patients would prefer early drain removal followed by outpatient seroma aspiration, if necessary. This preference was also evident for those patients who actually developed a seroma and required needle aspiration. No patient claimed that it was inconvenient to return to the hospital. Dalberg et al. (2004) investigated the effect of seroma formation on patient well-being, general health and functional status in a subgroup of 82 patients of which fifty percent developed seroma. No statistically significant differences in QoL were observed. However, the authors did not mention the method of assessment and the full questionnaire was not provided.

Several authors mentioned that drains can cause considerable disadvantages for patients such as a longer duration of nursing care, hindrance in daily activities and social life and reduction in mobility but did not investigate these hypotheses in any further detail (Baas-Vrancken Peeters et al., 2005; Jeffrey et al., 1995; Taylor et al., 2013; Zavotsky et al., 1998). Therefore, the goal of our randomised controlled trial was to compare early drain removal with output-based drain removal in patients who underwent BCS. The primary endpoint was the

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