



# Efficacy and safety of two post-operative drains: results of a prospectively randomized clinical study in breast cancer patients after breast conserving surgery

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## Abstract

**Objective** To compare the efficacy and safety of two post-operative drains in breast cancer patients after breast conserving surgery.

**Methods** This was a prospectively randomized comparative study of two drains investigated in breast cancer patients after breast conserving therapy. The Redon drain ends in a tip with 28 double perforations while the Quadrain drain features 4 flexible flaps of about 0.15 m length. The drains cost 0.28 € and 3.54 €, respectively. Primary target parameter was the duration of the drains staying in the surgical site. Secondary target parameters were pain post-surgery, seroma volume, final cosmetic result and surgical site infections.

**Results** A total of 88 patients were randomized, 47 and 41 received the Redon drain and the Quadrain drain, respectively. The mean duration of the drains staying in the surgical site was not different between the Redon and the Quadrain drain, 42.6 h ( $\pm$  25.8 h) and 50.1 h ( $\pm$  28.5 h), respectively ( $p=0.1959$ ). The post-operative pain score, seroma size, cosmetic result and surgical site infections were not different for both systems.

**Conclusion** The Redon drain and the new Quadrain drain were not significantly different with respect to duration in the surgical site, post-operative pain, seroma volume and cosmetic result.

**Keywords** Redon drain · Quadrain drain · Breast conserving therapy · Post-operative seroma

## Introduction

Breast conserving therapy is currently the standard treatment strategy for the majority of breast cancer patients in Germany and in many other countries. Indications are a biopsy-proven diagnosis of ductal carcinoma in situ or invasive breast cancer clinically assessed as resectable with clear margins and with an acceptable cosmetic result [1, 2]

One of the most common complications in breast conserving surgery is seroma formation [3]. To prevent this drains are routinely inserted into the wound after breast surgery [4]. Most systems operate with a suction flask but

feature different tips for collecting fluid. One, the Quadrain drain, with four flexible tips, also known as a ‘slit drain’, was initially tested in this center. It was shown to deliver higher volumes of seroma liquid (although with suction flask), was less frequently obstructed and extraction was less painful [5].

The aim of this study was to compare the Quadrain drain with the established Redon drain. Key parameters were duration of the drains staying in the surgical wound, seroma volume, final cosmetic result and incidence of surgical site infections.

## Material and methods

### Study population

A total of 89 patients were prospectively recruited and 88 were randomized between December 2017 and August

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2018. All patients (>18 years) were either diagnosed for histologically confirmed breast cancer of any stage or were referred because of highly suspicious X-ray mammography. All patients were treated with breast conserving surgery at the Department of Gynecology, Obstetrics and Reproductive Medicine–University Medical School of Saarland (66421 Homburg/Saar, Germany). The study protocol was approved by the Ethics Committee of the Chamber of Physicians of Saarland. All patients gave their written informed consent.

## Interventions

Two different drains were used: The Redon drain (B. Braun Melsungen AG, Carl-Braun-Straße 1, 34212 Melsungen, Germany) and the Quadrain drain (Pajunk GmbH Medizintechnologie, Karl-Hall-Strasse 1, 78,187 Geisingen, Germany).

The Redon drain, a closed-suction system, consists of a 0.5 m-long tubing with an inner diameter of 10 Charrière (3.3 mm) which ends in a tip with 28 double perforations. It is made of rigid polyvinyl chloride and is connected to a suction flask (Fig. 1a). Total cost per system is 0.28 €.

The Quadrain drain features the same length and inner diameter as the Redon drain but it is made of flexible silicone. It ends in 4 flexible tips of about 0.15 m length which do not show perforations (Fig. 1b). Total cost per system is 3.54 €.

## Target parameters

The primary target parameter was the duration of the drains staying in the surgical site.

Secondary target parameters were pain score at 3 h, 24 h and 48 h post-surgery, volume of seroma at 10–14 days

post-surgery, final cosmetic result and surgical site infections.

## Study procedures

Patients were randomized in a blinded fashion. The sealed envelope with the treatment allocation was opened by the operating surgeon pre-operatively.

The drains were inserted and fixed with one stitch (Mersilene®, Ethicon) immediately prior to closing the wound by using spikes of 10 mm and 12 mm for the Redon drain and Quadrain drain, respectively. Both were connected with a suction flask (Redonvac®). Drains were left in situ until drained fluid was less than 30 ml/24 h.

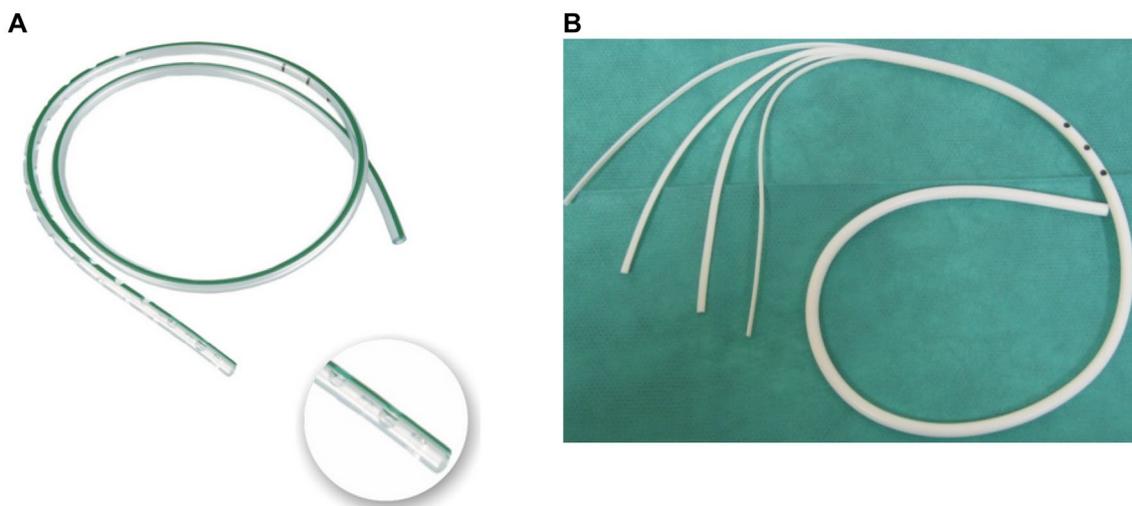
Patients were asked to assess their individual pain score using an 11-point scale of 0–10 3 h, 24 h and 48 h post-operatively.

The final seroma volume was assessed ultrasonographically by a blinded, independent physician 10–14 days after the surgery. The cosmetic result was evaluated at the same time by this physician.

All patients received peri-operatively one dose of low-dose heparin subcutaneously and a single dose of antibiotics (either Ciprofloxacin™ or Clindamycin™ or Cefuroxim™) intravenously.

## Statistics

All patients were analyzed following the intent-to-treat principle. As appropriate for non-inferiority studies, patients were primarily analyzed as treated rather than as randomized. In addition, a sensitivity analysis using the randomized rather than the actual treatment was performed. All target variables were analyzed descriptively by treatment by



**Fig. 1** Drainage systems: Redon drain (a), Quadrain drain (b)

number of observations, mean, and standard deviation for continuous variables and by absolute and relative frequency counts for categorical variables.

The primary objective of this study was to show the non-inferiority of the Redon drain versus the experimental Quadrain drain with respect to the duration of treatment. The non-inferiority margin  $\delta$  was pre-specified as 6 h. The null hypothesis  $H_0$ :  $\text{Duration}_{\text{Redon}} \geq \text{Duration}_{\text{Quadrain}} + \delta$  was tested against its alternative  $H_0$ :  $\text{Duration}_{\text{Redon}} < \text{Duration}_{\text{Quadrain}} + \delta$ .  $\text{Duration}_{\text{Redon}}$  where  $\text{Duration}_{\text{Quadrain}}$  stands for the mean duration of treatments with Redon and Quadrain, respectively. A one-sided, two-sample  $t$  test under the assumption of equal variances was used to test the hypothesis at a one-sided significance level  $\alpha$  of 2.5%.

For all continuous secondary variables the null hypothesis of no difference between both drainage systems was tested using a two-sided, two-sample  $t$  test under the assumption of equal variances. For categorical secondary variables Fisher's exact test was employed. A comparison-wise two-sided significance level  $\alpha$  of 5% was used.

All statistical analyses were performed using SAS version 9.4 software.

## Results

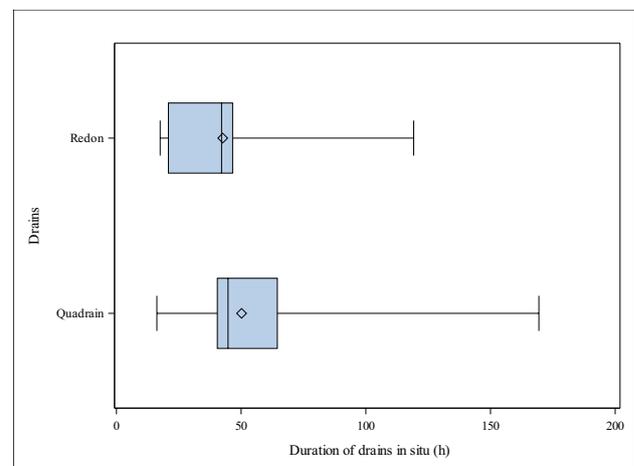
### Study population

A total of 88 patients were randomized. Forty-seven received a Redon drain, 41 a Quadrain drain. Three patients were protocol violators: although randomized to the Quadrain drain group, they received the Redon drain. A sensitivity analysis using the randomized instead of the actual treatment yielded very similar results. Therefore, only the results using the actual treatment are reported below.

The demographic data of the study population are shown on Table 1. Demographic data of study population. Both groups were comparable.

### Primary target parameter

The mean duration of the drain staying in the wound was not different between the Redon and the Quadrain drain 42.6 h ( $\pm 25.8$  h) and 50.1 h ( $\pm 28.5$  h), respectively ( $p = 0.1959$ ) (Fig. 2).



$P = 0.1959$

**Fig. 2** Duration of drains in situ

**Table 1** Demographic data of study population

	Drain		Total
	Radon $N = 47$	Quadrain $N = 41$	$N = 88$ (%)
Age (years)			
< 65	27 (57.4)	19 (46.3)	46 (52.3)
$\geq 65$	20 (42.6)	22 (53.7)	42 (47.7)
Tumor size			
< 2 cm	34 (72.3)	23 (56.1)	57 (64.8)
$\geq 2$ cm	13 (27.7)	18 (43.9)	31 (35.2)
Mean weight of specimen weight (g)	50.8	69.6	
Neoadjuvant chemotherapy	8 (17.0)	8 (19.5)	16 (18.2)
Lymphnode invasion	8 (17.0)	17 (41.5)	25 (28%)
Surgeon			
Senior	24 (51.1)	25 (60.9)	49 (55.7)
Junior	23 (48.9)	16 (39.1)	39 (44.3)

**Table 2** Pain score post-surgery

Hours	Redon	Quadrain	<i>p</i> value
3	2.79 ( $\pm$ 2.1)	2.88 ( $\pm$ 2.1)	0.8411
24	1.87 ( $\pm$ 1.8)	1.78 ( $\pm$ 1.5)	0.8001
48	1.16 ( $\pm$ 1.3)	1.17 ( $\pm$ 1.2)	0.9757

**Table 3** Ratings for cosmetic result by patient and physician

Rating	Very good	Good	Less than good	Total
Patient ( <i>N</i> =78)				
Redon	23	13	5	41
Quadrain	19	14	4	37
Physician ( <i>N</i> =80)				
Redon	30	10	2	42
Quadrain	25	11	2	38

There were no significant differences (with  $p \leq 0.05$ ) between drains for patients as well as physicians

## Secondary target parameters

### Pain

The pain score 3, 24 and 48 h post-surgery decreased over time but was not different for both drains ( $p = 0.8411$ ,  $0.8001$ ,  $0.9757$ , respectively) (Table 2).

### Seroma size

The seroma size 10–14 days post-surgery was not different for both drains, 12.3 ml ( $\pm$ 17.9 ml) for the Redon drain and 13.0 ml ( $\pm$ 18.7 ml) for the Quadrain drain ( $p = 0.856$ ).

### Cosmetic result

A total of 78/80 patients were willing to rate their cosmetic result and allowed the physician do so as well. The majority of ratings were very good or good.

The physicians' ratings were better compared to the patients' ratings ( $p < 0.001$ ). However, patients' and physicians' ratings were not different for the two drains ( $p = 0.8595$ ) (Table 3).

### Surgical site infections

A total of 9 surgical site infections were recorded, 4 and 5 for the Redon- and Quadrain drain, respectively ( $p = 0.569$ ). In one case a re-operation was performed, while the others were conservatively treated.

## Discussion

### What did we do?

This prospectively randomized study compared two post-operative drains in breast cancer patients after breast conserving therapy. No significant differences in efficacy or safety were found.

### Why is this topic important?

Post-operative surgical site infections in breast surgery can cause harm for patients and unnecessary costs for the society. Thus, avoidance of this adverse event is key for all stakeholders. Drains can reduce seroma formation and associated infections [6], although there are also studies out putting the effect of drains into question [7].

### Our results

#### Duration

The mean duration of the drains staying in situ was 42.6 h (1.78 day) and 50.1 h (2.08 days) for the Redon and the Quadrain drain, respectively ( $p = 0.1959$ ). Patients left the hospital at the day of drain removal with the exception of those who still had an additional axillary drain. This time period is comparable with the results by Jain et al. who reported post-operative hospitalizations of 2.9 days with drain and 1.9 days with no drain. It is interesting to note that Jain et al. [8] and Okada et al. [9] removed the drains once the drainage volume was  $< 50$  ml/24 h, while in this study the upper limit of drainage volume was  $< 30$  ml/24 h.

#### Pain

The pain score 24 and 48 h post-surgery was approximately 1.8 and 1.2, for both drains. These scores were lower than those published by Jain et al. Their pain scores with drains were 4.5 (24 h) and 2.2 (48 h). Even pain scores of patients without a drain were higher, 3.2 (24 h) and 1.4 (48 h) than what was documented in this study [8]. However, it is acknowledged that pain scores are highly subjective and comparisons between different studies and patient cohorts are difficult.

#### Seroma

The seroma size 10–14 days post-surgery was not different for both drains. About 12–13 ml of seroma were finally detected sonographically, a volume clinically irrelevant. No punctures were necessary. This result confirms

other researchers' findings of insertion of a drain after breast cancer surgery reduces complications caused by seroma formation, especially in cases of axillary dissection [10–13].

### Cosmetic result

In this study patients and physicians were asked to rate the post-operative cosmetic result. The majority of ratings were very good or good, but the physicians' ratings were significantly better, possibly due to patients' unrealistic expectations of the cosmetic result after oncoplastic surgery.

In addition, there was no difference between the cosmetic results with respect to the drains. This was unexpected as it was assumed that the suction force of the Redon drain could cause tissue damage and dents of the skin while the Quadrain drain features flexible flaps which would be more tissue friendly.

### Infections

A similar low number, 4 and 5 surgical site infections (~ 10%) were recorded for both drains, despite peri-operative administration of antibiotics. This is similar to previously reported studies [14] which recorded post-operative infections after breast surgeries of 0.8–26% [15–18]. Post-operative drains help to keep the wound surfaces together which results in reduced seroma/hematoma formation. However, drains could also facilitate a retrograde infection [19–21] which has been reported to start 2 days post surgery [19, 22]. In contrast, other researchers did not report any increase in infection rates after longer duration of drains in situ [4, 8, 21].

However, there are other factors promoting surgical site infections: ASA Score (American Society of Anesthesiologists), wound class, body mass index and re-operated patient [23], none of which were assessed in this study. To keep the number of surgical site infections low, we suggest besides the administration of a single dose of an antibiotic, daily thorough wound management and strict adherence to aseptic practices with all patients [23].

### Limitations

Analysis of the results of this study has several limitations: (1) this study focused on breast conserving therapies, but not on mastectomies and axilla dissections; (2) the sample size was relatively small; (3) only two of many drainage systems on the market were evaluated; (4) no control group without a drain was included.

### Conclusion/what does this mean for mankind?

In conclusion, the Redon- and the Quadrain drains did not differ with respect to either efficacy or safety. Therefore, the less costly alternative could be chosen.

**Author contributions** GS: project development, manuscript writing. MZ: data collection. CG: data analysis. LG: manuscript editing. RS: manuscript editing. CM: manuscript editing. IJ-B: manuscript editing. JE: manuscript editing und reviewing. E-FS: manuscript editing und reviewing.

### Compliance with ethical standards

**Conflict of interest** None of the authors declared any conflict of interest.

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