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Comparative Study between Jackson-Pratt Drain and Redivac Drain in Prevention of Seroma Formation after Oncoplastic Breast Surgery

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ABSTRACT

Background: Seroma formation is frequently observed in oncoplastic breast surgeries, seroma development is a common postoperative complication that causes significant patient morbidity.

Objective: This study aimed to compare between the effect of using Jackson-Pratt drain and Redivac drain in patients undergoing oncoplastic surgeries in seroma formation.

Patients and Methods: Eighty female patients with confirmed diagnosed cancer breast Underwent different oncoplastic breast surgery between November 2021 and December 2022 in Medical Research Institute, Alexandria University. All patients subjected to the same preoperative preparations. Patients were randomized to both group A and group B by double blinded randomized controlled method. Group A: (using Jackson-Pratt drain) and Group B: (using conventional Redivac drain).

Seroma was detected by clinical examination at 2, 4, 6, and 8 weeks postoperative.

Results: The mean BMI was 23.0-40.2 (31.0) in group A Vs. 26.0-35.1 (30.0) in group B. The mean time until drains removal was 7-16 (11.5) days in group A Vs. 4-18 (10.8) days in group B. Total drain discharge was in the Jackson drain group (685.33ml) Vs. (915.27ml) in the redivac drain group. Five cases of 40 cases came with seroma in group A with range of amount (190-440) ml and mean amount (278) ml while fifteen cases in group B with range of amount (100-810) and mean amount (482.5) ml in group B. The Number of cases complicated with delayed seroma was 1 case (2.5%) in group A (n=40) while 4 cases (10%) in group B (n=40). Pain score was in group A ranged from 1-4 with mean value 3.2±0.7 and in group B ranged from 2-5 with mean value 4.0±1.0.

Conclusion: Using Jackson-pratt drain is reliable and efficient in reducing seroma formation in different breast surgery techniques especially reconstructive breast surgeries and is very successful to minimize pain associated the drain in comparison to conventional redivac drain.

Key Words: *Breast cancer – Oncoplastic – Seroma.*

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Ethical Committee: The research was conducted after the approval of ethical review committee of Alexandria University, Medical Research Institute. All patients signed an informed consent for intervention including advantages, disadvantages and risk of possible complications.

INTRODUCTION

The uncomfortable consequence of post-operative seroma affects breast surgeons as well as the patient. There are wide variations in the reported incidence of seroma development, which ranges from 3% to more than 90% **[1]**. A seroma is a collection of blood plasma and/or lymph fluid in the breast, axilla, or dead space beneath skin flaps. It is now more frequently viewed as a surgical side effect than a problem **[2]**. Seroma pathogenesis is not entirely known. Seroma development typically results in repeated aspirations of the collection, infection at the surgical site, and frequent visits to outpatient clinics. Moreover, patients may experience severe discomfort, improper wound healing, and skin flap necrosis as a result of it **[3]**.

There are numerous papers that discuss the risk factors and causes of seroma formation, including the type of breast surgery, axillary clearing, age, usage of pressure garments, postoperative arm activity, and preoperative chemotherapy, duration of wound drainage and type of surgical drain used during surgery **[1-4]**.

In recent years, there has been an increase in the number of publications focusing on preventing seroma formation, all of which claim to have one thing in common, closing the dead space following breast surgery procedures **[5-7]**. One of the methods for closing the dead space that has been described is negative closed suction drainage **[2,8,9]**.

Surgical drains have been used in breast surgery for a number of years to evacuate fluids, reducing the buildup of serous fluid, and enhancing wound healing **[13-15]**. Halsted **[16]** popularised the radical mastectomy for breast cancer in the early 1890s, but it wasn't until the middle of the 20th century that closed suction negative-pressure drainage became commonplace **[10]**.

Moreover, the use of a drainage system might even be associated with complications such as blockage of the drain by clotted blood **[11]**. And drain removal problems (such as drain retention or painful removal). Drains are often associated with discomfort and pain **[12,13]**. Length of hospital stay can be increased by the use of drains **[14]** consequently increasing costs. Furthermore, drain sites can leave scars. A drain may also constitute a potential source of infection, acting as a foreign body **[15,16]**. Some of these complications are related to conventional redivac drain which is a negative suction thin plastic (PVC) tube widely used in most UK hospitals, That's why The Jackson-Pratt drain was the next advancement in drain design, forging a fresh path through these difficulties **[17]**.

Two of the most often utilized closed suction negative pressure drainage tools in surgery are the Jackson-Pratt and redivac drains. These drains are utilized throughout the body during numerous surgical operations **[17,18]**.

Jackson-pratt drain:

The JP drain represented the next leap in drain design. JP drain was first mentioned in a 1971 article authored by two neurosurgeons, Drs. Frederick E. Jackson and Richard A. Pratt **[25]**. A flat, rectangular silicone drain with internal ridges was the initial design; it offered regular drainage and prevented collapse when suction was applied. Now the design includes a round channel silicone drain, which is often opaque with A four-channel design made from pure silicone material which is soft helps to improve patient comfort while providing high tensile strength, Internal portals link open and closed channels to enable fluid to traverse the drain's whole length, change channels, and get around impediments to maximize fluid collection potential by capillary mechanism and also is impregnated with radiopaque barium for X-ray detection, placed in the body cavity and is connected to the reservoir by clear tubing. The reservoir made from silicone walls to provide easy activation of suction and control the power of suction by internal metal coil and internal anti-reflux valve to help prevent backflow of fluid. The reservoir is transparent sidewall with clearly marked graduations for quick and easy identification and measurement exudate **[18]**. The JP drain is still a popular today's option for surgeons of all specializations. A lot of medical professionals will expressly request JP drain by name, As a result, the use of drains in breast surgery is evolutionary **[19]**. Many types of breast surgery include the use of surgical drains, yet we almost ever stop to think about or look into how these vital tools came to be **[20]**.

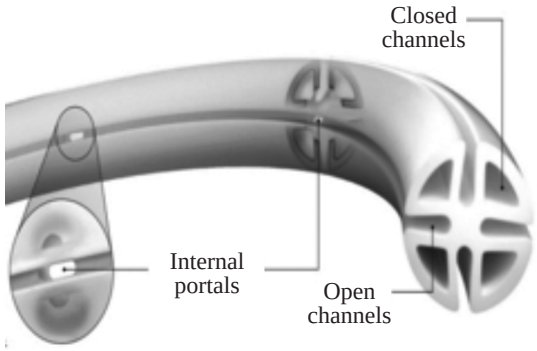

Fig. (1): Showing drain channels with internal portals.

Fig. (2): The reservoir.

By comparing the volume of fluid collected in the drains, the time required for drain removal, seroma formation incidence and drains associated pain, this study aimed to compare between the effect of using Jackson-Pratt drain and Redivac drain in patients undergoing oncoplastic surgeries in seroma formation.

PATIENTS AND METHODS

Before participating in the trial, each patient signed a written informed agreement, and anonymity was ensured.

This was a prospective study conducted at the Medical Research Institute, University of Alexandria's Department of experimental and clinical surgery. This study was univariate analysis of data

that was collected from 80 patients with confirmed diagnosed cancer breast were involved in this study according to guidelines of diagnosis of breast cancer (NCCN), in the period from November 2021 to December 2022. Patients were randomized to both group A and group B by double blinded randomized controlled method.

- Group A: (Using Jackson-Pratt drain) Cardinal Health Medical Co. Ltd.
- Group B: (Using conventional Redivac drain) Ningo Luke Medical devices Co. Ltd.

Four different surgical techniques were performed under general anesthesia on 80 patients with positive axilla classified into 4 groups.

1- Conventional conservative breast surgery (20 cases).
2- Oncoplastic conservative breast surgery (20 cases).
3- Modified radical mastectomy (20 cases).
4- Mastectomy with immediate breast recomstructive surgery by flap (20 cases).

Eighty instances in all were included based on the prior sample size, and they were divided evenly into two groups by chance. Using the closed-envelope method. The first group included 40 cases that underwent breast surgical procedures using Jackson-Pratt drain, and the second one included the remaining 40 cases that underwent the procedure using conventional Redivac drain.

Patient evaluation included detailed history taking, thorough general and local breast examination, in addition to routine preoperative laboratory investigations. Radiological assessment included breast ultrasonography, mammography, core biopsy, and a metastatic workup. An informed written consent was obtained from all of the included participants, following complete explanation of the details and complications of each procedure.

General anaesthesia was used for every instance. All surgical operations were done by the same surgical team, utilizing the same surgical devices eliminating any difference in dissection and operative time. Following surgery, all patients were taken to the recovery area before being moved to the internal ward, where early ambulation was promoted. The visual analogue scale (VAS) **[28]**, with 0 representing no pain and 10 representing the worst pain ever, was used to measure pain.

Most patients were discharged with drains within the first day after operation. They were informed and well instructed how to evacuate and calculate the amount collected in the drain every 24h. The amount was recorded and the total drain discharge was calculated after drain removal. We removed the drains when it discharged less than 50ml per 24h for two successive days with change the color to clear as well. Postoperative seroma was defined by the presence of subcutaneous fluid collection causing patient discomfort after drain removal within 60 days from surgery.

Our primary outcome was Amount of seroma, postoperative drain discharge volume, Detection of clogged drain causing drain failure and Pain related to the site of the drain whereas the secondary outcomes included Detection of delayed seroma and Number of visits of the clinic.

Eligibility criteria: All patients have breast surgery and axillary clearance surgery; Patients with comorbidities such as bleeding disorders and connective tissue disease were excluded.

Statistical analysis:

The Statistical Package for Social Sciences was used to perform the statistical analysis of the data (IBM, SPSS version 25; SPSS Inc., Chicago, Illinois, USA). The use of descriptive statistics was used (frequency and percentage for categorical variables, range, mean, and SD for quantitative variables). To determine the significance of differences depending on the patients' postoperative satisfaction, the Fisher exact test was used. With *p*-values under 0.05, a difference was deemed statistically significant.

RESULTS

Starting with demographics, the age of the included cases was ranging from 26 to 73 years with the mean age was 47.2 and 48.2 years in the Jackson-pratt drain and redivac groups, respectively. Additionally, BMI had mean values of 31.0 and 30.0kg/m^2 in the same groups, respectively Regarding systemic comorbidities, diabetes mellitus was present in 7 (17.5%) and 6 (15%) of cases. As shown in Table (1).

There was no statistical significant difference between the two studied groups regarding breast size *p*-value 0.981. As shown in Table (2).

Regarding time until drain removal The study shows that there was no statistical significant difference between the two studied groups, Range in Group A Jackson-pratt drain was 7-16 days with (mean 11.5) and 4-18 days and with (mean 10.8) in Group B Redivac drain (*p*-value 0.348). The previous data are summarized in Table (3).

Table (1): Comparison between the two studied groups regarding basic demographic and clinical data.

	Group A Jackson-pratt drain "n=40"	Group B Redivac drain "n=40"	*p*-value
Age:			
Range	26-73	36-67	*t*=0.6416
Mean	47.2	48.2	*p*=0.45 N.S.
S.D.	11.1	8.5	
BMI:			
Range	23.0-40.2	26.0-35.1	*t*=0.177
Mean	31.0	30.1	*p*=0.07 N.S.
S.D.	3.6	2.6	
Smoking:			
Yes	0 (0.0%)	0 (0.0%)	X^2=0.89
No	40 (100.0%)	40 (100.0%)	*p*=0.425
Diabetes:			
Yes	7 (17.5%)	6 (15%)	X^2=0.96
No	33 (82.5%)	34 (85%)	*p*=0.365
Hypertension:			
Yes	5 (12.5%)	6 (15%)	
No	35 (87.5%)	34 (85%)	

p was significant if <0.05.
N.S. = Not significant.

Table (2): Tumor criteria and operative data in the two groups.

	N (%) (n=80)	Jackson N (%) (n=40)	Redivac N (%) (n=40)	*p*-value
Operations type:	–	–	–	1
- Conventional Breast conservative	20 (25%)	10 (25%)	10 (25%)	–
- Reconstructive breast surgery with Flap	20 (25%)	10 (25%)	10 (25%)	–
- Modified radical Mastectomy	20 (25%)	10 (25%)	10 (25%)	–
- Oncoplastic Breast conservative	20 (25%)	10 (25%)	10 (25%)	–
Tumor type:	–	–	–	0.27
- Invasive ductal carcinoma	68 (85%)	32 (80%)	36 (90%)	–
- Invasive Lobular carcinoma	12 (15%)	8 (20%)	4 (10%)	–
Breast bra size:	–	–	–	0.68
- B	8 (10%)	5 (12.5%)	3 (7.5%)	–
- C	37 (46.25%)	19 (47.5%)	18 (45%)	–
- D	35 (43.75%)	16 (40%)	19 (47.5%)	–

- *p*-values obtained from teo-sample *t*-test (*t*) or the Mann-Whitney test (U).
α=0.05. *p*<0.05*, *p*<0.01**, *p*<0.001***.

Table (3): Postoperative data.

	N (%) (n=80)	Jackson N (%) (n=40)	Redivac N (%) (n=40)	*p*-value
Hospital stay (day):		1 (1-2)	1 (1-2)	0.634
Time until drain removal (day)		7-16 (11.5)	4-18 (10.8)	0.348
Clogged drain:	–	–	–	0.03*
Yes	9 (11.25%)	1 (2.5%)	8 (20%)	–
No	71 (88.75%)	39 (97.5%)	32 (80%)	–
Total Amount of drainage:		685.33±126.183	915.27±146.94	0.001*
Seroma:	-	–	–	0.02*
Yes	20 (25%)	5 (12.5%)	15 (37.5%)	–
No	60 (75%)	35 (87.5%)	25 (62.5%)	–
Delayed seroma:	-	–	–	0.36
Yes	5 (6.25%)	1 (2.5%)	4 (10%)	–
No	75 (93.75%)	39 (97.5%)	36 (90%)	–
Amount seroma	Med (IQR) 285 (202.5)	130-190 163.3	100-810 482.5	U: 0.5409
Number of visits	Avg (SD) 3.3 (1.5)	2 (0.5)	4 (1)	*t*: 0.9007
Pain score	Med (IQR) 5 (2)	3 (2)	4.7 (2)	U: <0.001***

Total drain discharge showed a significant decrease in the Jackson drain group (685.33ml) vs. (915.27ml) in the redivac drain group. *p*-value <0.001.

According to number of seroma incidence in patients, Number of cases in group A (Jackson drain) were 5 (12.5%) and 15 (37.5%) in group B (redivac drain) with statistical significance *p*-value 0.02.

Range of amount of seroma aspirated 190-440 ml (mean 278ml) in group A which is significantly less than the range of seroma aspirated 100-810ml (mean 484.5ml) in group B. *p*-value 0.001 shown in Table (3).

Clinic visits for seroma aspiration was in range 2-4 times (mean 2) in group A which is significantly less than visits of group B which was 2-7 times (mean 4.4) in Group B Redivac drain *p*-value 0.013.

In Comparison between the two studied groups regarding incidence of clogged drain, Jackson drain group showed significantly decrease in incidence of clogged drain 2.5% to 20% in redivac drain. *p*-value 0.03 Table (3).

Number of cases complicated with delayed seroma was 1 case (2.5%) in group A got seroma (n=40) while 4 cases (10%) in group B (n=40) with no significance *p*-value 0.36.

The Jackson drain group expressed significantly lower pain scores compared with the redivac drain group ($p<0.05$). Table (3).

DISCUSSION

The use of closed suction drainage has been crucial in recent decades in minimising seroma development. In more recent study, the goal has been to reduce seroma production by eliminating dead space **[21]**.

Several drainage devices have been assessed in order to reduce complication rates such as post-operative bleeding, seroma or hematoma during surgical breast procedures **[22-24]**. With recent technological advances, surgeons should keep up to date on new devices that should make surgery easier and safer. The Jackson-Pratt drain (pure silicone drain) has proven to be a safe and effective drainage tool in all surgical procedures, not just breast surgery **[25]**.

The current study aimed to compare between Jackson-pratt drain and the Redivac drain in oncoplastic breast surgery in seroma formation incidence after removal of the drain. We evaluated the post-operative outcomes. A total of 80 cases were recruited and divided into two equal groups; the first group underwent oncoplastic breast surgery using the Jackson-pratt drain, while the second group underwent the procedure with the latter one. All surgical operations were done by the same surgical team, utilizing the same surgical devices eliminating any difference in dissection and operative time etc, to minimize the effect of our variable surgical approaches.

The BMI appears to be an independent risk factor with a linear relationship to seroma formation **[26,27]**. However The BMI of the included cases in our study had mean values of 31 and 30.1kg/m^2 respectively, with no significant difference between the two groups Van Heurn and P.R. Brink et al., also found no significant difference in BMI between two groups in his study **[28]**. The increased prevalence of obesity in the Egyptian community could explain our higher BMI values compared to the previous study. The prevalence of various comorbidities was comparable across our study groups. Yet, a previous study found no significant differences in the prevalence of systemic comorbidities between the two groups **[29]**.

According to breast size 12.5% of cases (5 cases) were cup size B, 45% of cases (18 cases) were cup size C and 40% of cases (19 cases) were cup size D in Jackson-pratt drain group while 7.5% of cases (3 cases) were cup size B, 45% of cases (18 cases) were cup C and 47.5% of cases (19 cases) were cup size D in redivac group. Among Jackson-pratt drain group (Breast size B) 0 cases got seroma and (breast size C) 2 cases got seroma while (breast size D) 3 cases developed seroma while in redivac drain group (Breast size B) 2 cases got seroma and (breast size C) 7 cases got seroma while (breast size D) 6 cases developed seroma with no significant value.

Regarding the length of hospital stay, which had a median value of 1 day in the two groups There was no obvious difference between the two groups in the current investigation However, compared to this current study hospital stay, some authors reported longer hospital stays (mean=4.33 days). Different management strategies and medical facilities between different centers may help to explain this **[30]**.

In this study, the range of time until drain removal was 7-16 days for Group A Jackson-Pratt drains with a mean of (11.5) and 4-18 days with a mean of (10.8) for Group B Redivac drains ($p>0.05$) with Total drain discharge in the Jackson drain group was noticeably less (685.33ml) than in the redivac drain group (915.27ml) *p*-value 0.001. This could be explained by JP' controlled negative pressure by its internal metal coils in large reservoir, leading to potential reducing the dead space, flap adherence, minimizing fluid collection and prevent further extravasation so decreasing of number until drain removal. When comparing the incidence of clogged drains between the two study groups, Jackson Drain group A showed 1 case (2.5%; n=40), while Redivac drain group B showed 8 cases (20%; n=40) *p*-value 0.03. This current study, which had 80 patients, revealed a 25% seroma incidence rate since 20 of the patients experienced breast seroma. 5 cases (12.5%) in group A (Jackson-pratt drain) got seroma (n=40) while 15 cases (37.5%) in group B redivac drain group (n=40) with (*p*-value 0.02), While J Bonnema reported that there are no differences in seroma production after axillary dissection and subsequent drainage between high and low vacuum after modified radical mastectomy **[27]**.

According to the findings of this study, there was a significant decrease (*p*-value 0.001) in total amount of seroma aspirated with a mean volume of 278ml in the Jackson Pratt group compared to 482.5ml in the redivac group.

In this current study, the number of cases complicated by delayed seroma was 1 (2.5%) in group A (n=40) and 4 (10%) in group B (n=40) with no significant value, (*p*-value 0.36).

The number of clinic visits to assess and aspirate seroma ranged from 2-4 times with a mean value of (2±0.6) in group A and 2-7 times with a mean value of (4.4±1.8) in group B. The persistence of foreign devices under the skin may potentially lead to pain; the average pain score in our study shows that individuals in the Redivac group experiensed more pain than individuals in the Jackson-pratt group as the pure silicone material of JP drain (*p*-value: 0.001).

In this study, we found that the Jackson-pratt drain is superior to the Redivac drain in seroma formation incidence During breast surgeries, Particularly mastectomy or breast reconstructive surgery with flap coverage (flap donor site is the commonest) operations, as the dead space is moderately wider and easily collect fluids than in conservative breast surgery.

Finally, wound drainage appears to be one of the most effective ways to reduce seroma incidence, though there is no agreement on the optimal duration of drainage **[24]**. This study demonstrated that the use of Jackson-pratt drain (pure silicone drain) leads to a decrease postoperative seroma formation, as evidenced by the frequency of seroma production following breast operations using Redivac drain was (37.5%) while with the use of Jackson-pratt drain was 12.5%, indicating that Jackson-pratt drain usage was a significant 0factor in seroma formation after breast surgery (*p*-value=0.02).

Conclusion:

The type of drain is one of many elements that affect seroma, according to the prior research. According to this research, using that new JP drain (pure silicone) has a preventative impact on the development of seroma following surgery breast surgery Compared to traditional Redivac drain, the amount of post-operative drainage was significantly reduced and seroma formation incidence also reduced. We recommend using Jackson-pratt closed suction drain to minimize seroma formation especially in modified radical mastectomy and breast reconstructive surgery by flaps operations. As it appears that Jackson-pratt drain is more beneficial in easily insertion and more difficult in occlusion, minimizing of dead space, less drainage discharge, less seroma formation and less postoperative drain associative pain. All of these points may advocate JP drain high cost, The final cost of patients discomfort as well as multiple clinic visits also changing the broken bottle or clogged tube of radivac drain is favors to Jackson-pratt. Further studies should be conducted in order to obtain results that could be used to determine the expected outcomes of cases and increase statistically power and cost effective value.

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