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Seroma Formation after Mastectomy with or without Thoracoabdominal Binder – A Randomized Control Trial

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ABSTRACT

The study's main objective is to reduce seroma production post-mastectomy with the help of using thoracoabdominal binders. The randomized controlled trial (RCT) included patients (No=40) that received breast surgery. They were divided into two groups; the control group (No=20) was the one that did Not use the binders, and the study group (No=20), complied with adorning the thoracoabdominal binder for two weeks post-breast surgery. The drainage of both breasts and axillary drains was examined during this duration. The amount of drainage was Noted, and charts were created on that basis. A total of 40 patients initially became a part of this trial, equally divided into two groups of 20 patients each. All of the participants of this group had undergone breast surgery (either mastectomy or MRM) and had to appear for the follow-up examination 2-3 weeks post-surgery. In these follow-up meetings in the outpatient clinic, the drainage charts were maintained, including the levels of drain output and compliance rate of the thoracoabdominal binder group; some patients were excluded from the study due to exclusion criteria.There was No difference between both groups in the drainage output, thus imposing No major impact of thoracoabdominal binders on seroma reduction. Other implications of binders in breast care post-surgery were explored to add to the positive effects of binders. This suggests that more studies need to be done to find the best management methods for postoperative seroma formation.

INTRODUCTION

Breast cancer these Days addresses the most widely recognized cancer among ladies, with more than 2 million new cases in 2018. Its careful treatment depends on oncoplastic medical procedure, a combination of those two disciplines with the last objective of a result adjusted between the best oncologic and therapeutic outcomes. Without a doubt, since its origination, breast remaking has assisted patients with looking "typical" when dressed; all the more, as of late, progressions in careful procedures and clinical advancements have increased present expectations so patients can feel tastefully satisfied and likewise unclothed (Salgarello, 2012). During the many previous years, the straightforward way to deal with breast cancer has developed from extremist mastectomy to the improvement of breast-conserving medical procedures and reconstructive strategies. After an areola or skin-sparing mastectomy, the chance of having played out a prompt remaking addresses an extraordinary benefit for patients, inferable from its critical psychosocial benefits. As of Now, quick implant-based breast remaking (IBR) addresses 81.9% of all breast reconstructive strategies (Masià *et al.*, 2020).

Axillary lymphadenectomy (ALN) remains the standard choice in many cases of breast tumors. Likewise, to agony, hematoma and contamination, the fundamental early unfavorable impact of ALN is the post-usable creation of liquid in the axillary bowl. Seroma development is a consistent component; however, the volume has a wide variety. Subsequently, the pace of symptomatic seromas that require needle yearning goes from 20 to 60% (Kopelman *et al.*, 1999). Seroma is defined as the clear fluid deposited under the primary layer of the skin, which is usually found near the incision site after surgery, typically of reconstructive type (Pogson *et al.*, 2003). This occurs because space is created in such surgical procedures due to tissue removal. Seroma is a typical post-surgery complication in breast cancer. It is considered a common cause of discomfort and irritation in patients, which might result in extending the hospital stay. It can cause problems like an infection on the site of surgery, slow laceration healing, and mortification of the skin flap. Substantial research is being carried out to comprehend the etiology to uncover different means of reduction of seroma formation (de Rooij *et al.*, 2020).

LITERATURE REVIEW

Countless RCTs are being established to reduce complications created by seroma formation. Many studies give a mixed opinion over the insertion of drainage post-surgery as a method of seroma reduction. Florian *et al.* (Ebner *et al.*, 2014) explain that the most common reasons for the introduction of a drain in breast cancer surgery are: (i) reducing the risk of a possible hematoma, (ii) drainage of the seroma of the incision, or (iii) controlling the infections occurring at the surgical site. It has also been stated that Not including a drain might have the following side effects: a larger amount of seroma-related complications. Other risk factors like the size of the breasts, age, number of lymph Nodes with tumors and blood pressure have also been examined in the past years (Droeser *et al.*, 2009; Srivastava *et al.*, 2012).

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Drain

Using a drain has been a typical practice to demolish the dead space made after a medical procedure. The utilization of closed suction drainage in patients who went through mastectomy speeds up injury recuperating and is likewise connected with a lower occurrence of wound contamination, necrosis, and breakdown (Srivastava *et al*., 2012). Research by Bourke *et al* (Bourke *et al*., 1976) found No distinction between utilizing closed suction and creased wound drainage in 51 patients who underwent straightforward mastectomy (Thoren, 1964). In a concentrate by Whitfield and Rainsbury (Whitfield & Rainsbury, 1994), No huge contrast was seen between suctioned and closed siphon drainage on seroma development. The amount of quantity of drain tubes used has been researched. Two randomized trials reported that using different drainage tubes presents No critical benefit on the sum or length of seroma seepage (Petrek *et al*., 1992; Terrell & Singer, 1992).

Thoracoabdominal Binders

A thoracoabdominal binder is a wide belt encompassing the thorax and abdomen and supporting the incision. Binders have been around for quite a while, yet their significance has fluctuated over the long run; there has forever been disagreement concerning whether they were great for patients or useless. Accordingly, we led the current randomized controlled trial to explore the clinical impacts of thoracoabdominal binders. We plan to give proof-based ideas to its expected in postoperative consideration for breast surgeries (Jiang *et al*., 2021). Stomach versatile folios (trusses, girdles, stomach belts, longuette, and so forth) (Cheifetz *et al*., 2010; Fagevik Olsén *et al*., 2009; Christopher M Larson *et al*., 2009) are often utilized regularly after laparotomy and ventral hernia fix. The beneficial impacts incorporate, among others, relief from discomfort, decreased chance of seroma development, worked on respiratory capability and postural strength.

In any case, using abdominal binders depends on unclear or No proof. Besides, the clinical impacts of stomach covers have been tested because of an expected gamble of post-usable pneumonic inconveniences (Rothman *et al*., 1966). On the positive side, documentation from a couple of studies infers that stomach fasteners reduce postoperative torment, seroma development, mental distress, and postoperative uneasiness (P. Chowbey *et al*., 2000; Jin *et al*., 2009; Christopher M Larson *et al*., 2009; K. LeBlanc, 2004). Abdominal binders have likewise been shown to upgrade activation, safeguard the patient's injury, help in coughing, and ease deep breathing (Rothman *et al*., 1966).

Lymphedema is a well-kNown condition occurring right after breast surgery, but No agreement has been reached about the best treatment course. Careful methodologies, despite, are getting expanded consideration. Different microsurgical reconstructive procedures plan to reestablish life structures and capability of the lymphatic framework in upper limb breast cancer-related lymphedema (BCRL) (Masia *et al*., 2016).

Since the lymphatic system is a complex vascular system, we concentrate on its life systems and usefulness in every individual patient utilizing symptomatic imaging strategies: lymphoscintigraphy, figured tomography angiography (CTA), indocyanine green (ICG) backhanded lymphography, and magnetic resonance (MR)-lymphography. A preoperative limb lymphoscintigraphy is performed for every patient to evaluate the lymphatic capability of the limb.

MATERIALS & METHODS

Study Design

This is a Randomized Controlled Trial (RCT) based on exploring the effectiveness of using thoracoabdominal binders in seroma reduction post-mastectomy. The Dubai Hospital Ethical Committee examined and approved the study procedure. All participants provided their consent in writing after being fully informed. The participants' privacy was protected throughout the study, and the confidentiality of the data acquired was guaranteed.The patients who consented to participate in this study were allotted to one of the two groups: the thoracoabdominal group, where patients adorned binders post-surgery. At the same time, the other was the control group (without binders). Both groups were carefully observed to compare the seroma drainage amount and other complications (if any).

Setting and Patient Selection

Patients were selected from three different Saudia Arabia regions: central, Northern and southern. Patients who had received breast surgeries such as mastectomy or modified radical mastectomy (MRM) because of invasive breast cancer or ductal carciNoma in situ (DCIS) were qualified for consideration in the present trial. Patients undergoing a breast-enlargement procedure or primary breast reconstructive treatments were barred.

Interim Analysis

The interim analysis for this seroma reduction after MRM or mastectomy trial was initially conducted to identify the effectiveness of thoracoabdominal binders. None of the postoperative methods seemed superior to discontinuing the rest of the practice at that particular interval.

Randomization

According to a PC-created randomization plan, patients will be arbitrarily allocated to one of the two bunches with a 1:1 distribution. Randomization will occur upon the arrival of the medical procedure, half an hour preceding incision closure.

Blinding

Blinding of the procedure was impossible as the patients were physically wearing thoracoabdominal binders, and they could Not hide the main element of the study to make the trial Non-biased.

Pre-op Medications

Patients were given Kefzol (antibiotic) once before the

surgical procedure. These medications were administered to reduce the Surgical Site Infections (SSI) rate.

Surgical Site Infections (SSI) influence the oncologic consideration of breast cancer patients because of postpones in different Treatments, expansions in care expenses, failed recreations, and possibly development in recurring disease rates. The rate of surgical site infections has decisively increased in literature as per the reported cases. The increment range is dramatic as if it skyrocketed from 0.8% to being raised to 26% (Edwards *et al*., 2009; Neumayer *et al*., 2007; Prospero *et al*., 2006).

Surgical Procedure

In simple mastectomy, the whole breast tissue is eliminated; axillary tissues are undisturbed. At times, the "sentinel lymph Node" — the central axillary lymph Node that the metastasizing cancer cells would be supposed to deplete into — is taken out. Individuals who go through a simple mastectomy can typically leave the clinic after a brief stay. Regularly, a drainage tube is embedded during a medical procedure in their chest and joined to a little suction device to eliminate subcutaneous liquid. These are Normally eliminated a few Days after the medical practice as drainage declines to less than 20-30 ml daily. When this procedure is completed on a tumourous breast, it is also performed on a healthy breast to prevent cancer recurrence. The decision of this "contralateral prophylactic" choice has become more run of the mill as of late in California, most outstanding in individuals more youthful than 40, moving from only 4% to 33% from 1998 to 2011. Nonetheless, the potential advantages give off an impression of being negligible, best case scenario, without any genetic markers, as per a huge scope study distributed in 2014 (Kurian *et al*., 2014; Newman, 2014; Tanner, 2014).

Customary Incision Closure

The incision was then closed using conventional, absorbable skin sutures, and None of the modern skin flaps were utilized after the mastectomy.

Medications after Surgery

Most patients were given 500mg of Kefzol every six hours for two weeks. Some patients were advised to use Kefzol only once for seven Days, and only a few were given Augmentin for 7 Days.

Hospital Stay

The patients have been advised of the duration of their hospital stay as per their post-op condition. Some were even kept in the hospital for about ten Days.

Post-op Complications

Several complications occur post-mastectomy or MRM, including lymphedema, shoulder morbidity and seroma aspiration. The one we encountered during this RCT was a hematoma. Hematoma is a pool of mostly coagulated blood that structures in an organ, tissue, or body space. A hematoma is typically brought about by a messed up vein that was harmed by a medical procedure or a physical injury (Hematoma, toenail, gross, 2013). It can accumulate at any place in the body, including the brain. Not at all like cancer, breast hematomas are mostly harmless. Treatment of a hematoma relies upon its seriousness. Small hematomas might resorb following a couple of Days. More extreme hematomas that keep expanding might expect a medical procedure to deplete the gathered blood or potentially control any draining vessels and reclose the surgical site (Hoda & Cheng, 2017).

Follow up

The patients were told to show up for the follow-up 2-3 weeks before mastectomy or MRM.

Evaluation

The assessment was tentatively directed in the two groups, with the same philosophy and absence of pain convention. The principal factors explored were seroma production, pain before and after the medical procedure, post-op complications, the number of Days the drain was attached, etc. Symptomatic seroma was characterized as an axillary liquid collection initiating inconvenience or pain with clinical consultation.

Exclusion Criteria

The exclusion criteria were based on the following points: (1) Patients unwilling to share their details publicly. (2) Patients who were unable to comprehend the reason behind the study and its extent and, for that reason,

Table 1: Basic history collection of the trial.

No.	Control/ treatment	MRN	Gender	Age	Nationality	Region	Type of surgery	Medical History 1	Previous Surgery at the Same Site	Type of Cancer	Blood Loss	Neoadjuvant Chemotherapy	Tumour Size
1	Control	5119067	Female	30-39	Saudi	Central	MRM	FIBROCYSTIC DISEASE	No	IDC	<50 ml	Yes	2-5 cm

2	Control	5124139	Female	30-39	Saudi	Central	MRM	Obesity	No	IDC	<50 ml	Yes	<2 cm
3	Control	5134046	Female	60-69	Saudi	Central	MRM	HTN, OLF CVA, CKD, ANEMIA	No	IDC	50-100 ml	No	2-5 cm
4	Control	5126836	Female	50-59	Saudi	Central	Mastectomy	PostmeNopausal	No	IDC + DCIS	<50 ml	No	>5 cm
5	Control	5115887	Female	40-49	Saudi	Central	MRM	0	No	IDC	<50 ml	Yes	>5 cm
6	Control	5121765	Female	40-49	Saudi	Central	MRM	DM, HTN	No	ILC Grade 2, ERPR+, HER2-	<50 ml	Yes	>5 cm
7	Control	5117080	Female	60-69	Saudi	North	MRM	DM	No	IDC	<50 ml	Yes	>5 cm
8	Control	5119007	Female	50-59	Saudi	North	MRM	DM, BA	No	IDC	50-100 ml	Yes	>5 cm
9	Control	5122177	Female	50-59	Saudi	North	MRM	DM, HTN	No	IDC	>100 ml	Yes	>5 cm
10	Control	5115119	Female	40-49	Saudi	Central	Mastectomy	HTN, ESRD	No	IDC	<50 ml	Yes	2-5 cm
11	Control	949454	Female	40-49	Other	Central	MRM	0	No	IDC	<50 ml	Yes	2-5 cm
12	Control	832501	Female	50-59	Saudi	Central	Mastectomy	DM, HTN	Yes	DCIS	<50 ml	Yes+radiation	<2 cm
13	Control	5121971	Female	50-59	Saudi	Central	Mastectomy	0	No	IDC Right Breast	<50 ml	No	2-5 cm
14	Treatment	5130888	Female	50-59	Saudi	Central	MRM	0	No	IDC	<50 ml	No	>5 cm

15	16	17	18	19	20	21	22	23	24	25
Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
5112130	5124091	5117948	5022257	5130820	480130	995456	41435	5124615	5123218	5120824
Female	Female	Female	Female	Female	Female	Female	Female	Female	Female	Female
50-59	50-59	50-59	30-39	40-49	30-39	70-79	70-79	50-59	40-49	50-59
Saudi	Saudi	Saudi	Saudi	Saudi	Saudi	Saudi	Saudi	Saudi	other	Saudi
Central	South	North	Central	North	Central	central	North	central	Central	Central
MRM	MRM	Mastectomy	MRM	Mastectomy	MRM	Mastectomy	MRM	Mastectomy	MRM	MRM
DM, HTN, FAMILY HISTORY OF UTERINE CARCINoMA	BA	0	0	0	Osteosarcoma Right Femur, LEFT BREAST CANCER	DM, HTN, LEFT BREAST CANCER, BA	DM, HTN	DM, HTN	0	0	0
No	No	No	No	Yes	No	No	No	No	No	No	No
Poorly Differentiated CarciNoma	IDC Grade 3	IDC Grade 3	Hyperplasia Atypical WITH ICD	IDC Grade 1	IDC	DCIS	IDC	IDC	IDC	IDC	IDC
50-100 ml	<50 ml	<50 ml	<50 ml	<50 ml	50-100 ml	<50 ml	<50 ml	<50 ml	<50 ml	<50 ml	<50 ml
Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes
>5 cm	2-5 cm	2-5 cm	2-5 cm	2-5 cm	2-5 cm	<2cm	2-5 cm	<2cm	2-5 cm	2-5 cm	2-5 cm

Table 2: Data of drain collection and post-op condition.

No.	Mets to LNs	Antibiotics Coverage	Height	Weight	BMI	Drain 1	Drain 2	Removal of Drain on Post-Op Day No.	Physiotherapy Exercises	Patient Compliance with Wearing the Belt	Post-op complications
1	N1	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	175	79.3	25.9	111ml TO 5ml	120ml TO 25ml	Day 14	Yes	Control Group	No
2	N0	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	163	89.6	33.7	200ml TO 20ml	130ml TO 10ml	Day 14	Yes	Control Group	No
3	N2	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	148.5	72.9	33	160ml TO 30ml	130ml TO 10ml	Day 14	Yes	Control Group	No
4	N0	Kefzol Once Pre-Op, Post-Op Augmentin 7 Days	164	62.7	23.3	132ml TO 20ml	0	Day 9	Not needed	Control Group	No
5	N2	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	150	97.1	43.2	210ml TO 10 ml	115ml TO 10ml	Day 33	Yes	Control Group	No
6	N2	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	158	87.3	35	150ml TO 65 ml	100ml TO 10ml	Day 18	Yes	Control Group	No
7	N2	Kefzol Once Pre-Op	150	54.4	24.2	167ml TO 15ml	110ml TO 5ml	Day 14	Yes	Control Group	No
8		Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	166	85.5	31	140ml TO 23ml	120ml TO 5ml	Day 14	Yes	Control Group	No

9	N3	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	159	67.5	26.7	150ml TO 30ml	120ml TO 10ml	Day 14	Yes	Control Group	Hematoma Post-Op Day 3
10	N0	Kefzol Once Pre-Op	164	76.9	28.6	100ml TO 5ml	0	Day10	Not needed	Control Group	No
11	N1	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	155	69.7	29	150ml TO 40ml	110ml TO 10ml	Day 14	Yes	Control Group	No
12	N0	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	155	64	26.6	170ml TO 10ml	0	Day 14	Not needed	Control Group	No
13	N0	Kefzol Once Pre-Op and Post-Op for 7 Days	156	56	23.7	130ml TO 10ml	0	Day 14	Not needed	Control Group	No
14	N1	Kefzol Once Pre-Op and Post-Op for 7 Days	153	76.9	32.9	140ml TO 10ml	124ml TO 5ml	Day 9	Yes	Yes	No
15	N3	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	164	82.1	30.5	122 ml TO 10ml	120ml TO 5ml	Day 14	Yes	Yes	No
16	N1	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	168	73	25.9	220ml TO 10ml	160ml TO 5ml	Day 14	Yes	Yes	No
17	N1	Kefzol Once Pre-Op, Post-Op Augmentin 7 Days	158	71.4	28.6	150ml TO 30ml	0	Day 14	Not needed	No	No

18	N1	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	150	58.4	26	120ml TO 20ml	50ml TO 5 ml	Day 14	Yes	Yes	No
19	N0	Kefzol Once Pre-Op and Post-Op for 7 Days	160	86.6	34.5	190ml TO 10ml	0	Day 14	Not needed	Yes	No
20	N3	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	163	90	53	200ml TO 10ml	170ml TO 10ml	Day 14	Yes	Yes	No
21	N0	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	156	73.2	30.1	150ml TO 15ml	0	Day 14	Not needed	Yes	No
22	N1	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	142.5	77.2	38	144 ml TO 10ml	110ml TO 10ml	Day 14	Yes	Yes	No
23	N0	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	147	80.4	37.2	110 to 5ml	0	Day 14	Not needed	Yes	No
24	N1	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	158	72	28.8	130ml TO 20ml	120ml TO 5ml	Day 14	Yes	Yes	No
25	N1	Kefzol Once Pre-Op, Keflex 500 Mg q6hrs 2 Weeks	162	70.7	26.9	110ml TO 25ml	150ml TO 10ml	Day 14	Yes	Yes	No

did Not sign the consent form. (3) Patients who never showed up for a follow-up. (4) Those whose drainage charts were Not managed were also excluded.

RESULTS AND DISCUSSION

As per the research, no recognizable difference was found in the group of patients wearing the thoracoabdominal binders compared to the patients not wearing the binder in the quantity of seroma production.

Statistical Analysis

When the values of the drain removal of the control group (G1) and treatment group (G2) are compared statistically, the standard deviation of Drain 1 of the control group (s=16.753) and that of the treatment group (s=7.5252) vary greatly as it gives us the p-value of 0.01249. This shows a distinguishable difference, but the SD values of Drain 2 (G1= 6.95 & G2 = 3.964) did not show a distinct difference with the p-value of 0.07272, implementing the non-significant difference in the SD of both groups. This

nullifies the difference in the first drain and thus brings us back to the conclusion that there was no remarkable difference in the seroma production of the binder and non-binder groups. (All the calculations were performed using SPSS (IBM SPSS Statistics for Windows, version 25, New York, USA).

Primary Outcome

The quantity of drain extracted the first time ranged from 5ml to 65ml in the control group, while in the treatment group, the range was from 5ml to 30 ml. In the second drain removal, the field dropped from 0ml to 25ml in the control group, while the treatment group's range fell from 0ml to 10ml (Table No.2). However, since only 25 patients were left for the conclusive results, the result's significance declined. Also, the statistical analysis suggests otherwise.

The sizes of the tumors extracted (Table No. 1), BMI, body weight (Table no. 2) etc., are also mentioned in the tables. The size of the tumor barely affects seroma production, but the increased body weight and BMI may increase the levels of seroma production (Srivastava *et al.*, 2012).

Secondary Outcomes

Although there was no major difference in the seroma production of the patients undergoing mastectomy or MRM, many other positive changes were detected in this RCT.

Pain

Binders worked as a pain-relief mechanism as they applied enough pressure on the thoracoabdominal region to relieve the patients of postoperative pain after the surgery. In another study (Daniel & Matheson, 1969), it was also evident that abdominal binders acted as pain-relieving equipment. It was a short study following in a logical order, where patients were their control group (n=16). This study was conducted on patients who had to undergo major abdominal surgeries and wore binders for only about 10 minutes. The patients brought to attention that they felt a minor difference in the feeling of pain while wearing the binder. They felt less pain than those without the abdominal binder.

Pulmonary Stress

The patient reported that the stress in breathing was significantly reduced for those wearing the binders compared to those not. To support this statement, one RCT (C. M. Larson *et al.*, 2009) (n=23) reported the aid of abdominal binders in the pulmonary function stating that the vital capacity of the lungs increased recognizably in the binder group compared to the control group.

Physical Activity

As it is common knowledge, shoulder immobility is also frequent post-breast surgery. The patients wearing a binder showed less discomfort while moving their hands than the non-binder group. Still, the hand movement remained restricted. An approach supported by most breast surgeons is to suggest that patients limit signs at the shoulder to move away from the midline to no more prominent than 90 and that active upper extremity physiotherapy is postponed until drainage catheters have been eliminated (Vitug & Newman, 2007).

Also, a study (Rothman *et al.*, 1966) suggested that abdominal binders greatly help with the patient's physical functions. (Where physical function means a six-minute walk) (n=75). The two groups were examined for the distance they walked in the given time before the surgery and five days following the surgery. It was concluded that the binder group walked a significantly longer distance on day 5 than the non-binder group, which supports our statement claiming improvement in hand and shoulder movement post-surgery with the help of a thoracoabdominal binder. Nevertheless, still, the results are ambiguous when compared to other research.

It is safe to say that binders may help in improving physical function. Still, more studies need to implement thoracoabdominal binders as safe and beneficial post-op care equipment.

Discomfort

Discomfort is one of the main reasons many patients disagree with using a binder. The feeling of uneasiness and constantly being compressed may be a difficulty most people do not want to endure. The pressure binder applied to the incision site may be uncomfortable to some, but it benefits as a pain-relieving compression for others. In one RCT, 21 out of 28 patients (in the abdominal binder group) claimed no discomfort due to the adherence to the binder, while only 7 reported pain (Jiang *et al.*, 2021).

Seroma formation is considered one of the most recurrent complications post-breast surgery, be it a mastectomy, Modified Radical Mastectomy, or even reconstructive surgery (Agrawal *et al.*, 2006; Carless & Henry, 2006; Kumar *et al.*, 1995; Woodworth *et al.*, 2000). Needle aspiration for seroma removal is a common cause of post-op clinical visits (Hashemi *et al.*, 2004). This is why seroma reduction using different measures has become the goal of breast surgeons to make breast surgery possible with lesser pain and complications.

Seroma accumulation causes the skin to stretch and causes it to sag as well, creating an even more discomforting and unpleasing appearance. Suppose the seroma formation continues for an extended period. In that case, it causes a delay in the healing of the wound, may cause skin flap necrosis, and be associated with surgical site infections and arm lymphedema (Kuroi *et al.*, 2006).

The pathophysiology or the cause of seroma is still vague (Ebner *et al.*, 2014), but the leading cause, as per many RCTs and Meta-analyses, is considered dead space (Agrawal *et al.*, 2006; de Rooij *et al.*, 2020; Kuroi *et al.*, 2006; Van Bastelaar *et al.*, 2016; van Bemmel *et al.*, 2011). One of the main reasons for this RCT is to study the results of applying pressure with the help of a thoracoabdominal

binder to compress the dead space and reduce seroma production. Although the findings of this RCT are unclear and do not present extraordinary evidence in support of the usage of binders for the reduction of seroma formation, a couple of other larger studies do give positive outcomes analyzing the use of binders in seroma reduction, pain management and improvement in physical activity (lesser shoulder morbidities) (Rothman *et al.*, 1966).

One of the studies (Kontos *et al.*, 2008) shows that pressure dressings (which can be modified into thoracoabdominal binders) make a significant difference in seroma production post-mastectomy. Two hundred patients were randomized into two groups; one of them was the PD (pressure dressing) group, while the other was non-PD. All the different surgical techniques and pre and postoperative supervision were kept similar. Their discoveries are in favor of PD as a viable, economical and simple to-apply technique for the decrease (a) of the time with drains in situ after MRM, (b) the number of patients producing seromas and (c) of the seroma aspirations. This might diminish further complexities, require clinical consideration, and cut expenses (Kontos *et al.*, 2008).

The use of such pressure dressings, binders and compressions of the wound has been discovered widely in other horizons of innovative surgery (P. K. Chowbey *et al.*, 2000; K. A. LeBlanc, 2004). However, it is still in the early stages of breast surgery. More widespread, larger and more organized studies need to be executed to accumulate more and more verification and evidence to make the use of binders a common practice in the field of surgery (Rothman *et al.*, 1966).

Pain management post-surgery is one of the extensively recognized uses of binders in other fields of study. Once again, in breast surgery, the use is limited. Thus, the findings are ambiguous on whether it is beneficial or not. However, the mechanical support it provides to the wound decreases patients' discomfort due to incisional pain. The pressure the binder applies supports the incision and even helps in wound healing to a small extent (Rettenmaier *et al.*, 2017).

Arm morbidity is one of the most inconvenient long-lasting complexities of breast cancer therapy and essentially affects the regular routines of breast cancer survivors (BCS). Despite its significance, persistent arm morbidity is moderately under-investigated (Kwan *et al.*, 2002). Arm and shoulder morbidity reduces the quality of life of (BCS) greatly. Binders have shown slight improvement in shoulder movement in a few patients. This is also a reason to consider more research devoted to thoracoabdominal binder applications to determine their effectiveness, as references have been provided for inappreciable improvement in physical activity with the help of binders in this RCT.

Cancer is fatal, so most patients also have mental health issues. Surgeries also bring out different levels of anxiety in most patients. This psychological stress worsens post-surgery due to the thought of any negative symptoms related to the operation (Rhodes *et al.*, 2000). An RCT (Cheifetz *et al.*, 2010) compared the pre and postoperative stress levels in patients divided into binder and no-binder groups to study the use of binders. The outcome suggested that the stress level remained the same in the binder group and rose significantly in the non-binder group. Similarly, a prospective controlled study (Daniel & Matheson, 1969) was held for a similar cause; it was detected that the psychological distress caused by coughing was exponentially reduced in the binder group compared to the others.

The main reason behind the better emotional response in the binder group is the feeling of being held by the pressure of the binder wrapping around the incision. The pain of coughing post-surgery acts like trauma; thus, the compression provided by the binder eases that pain and helps reduce stress levels. It also facilitates the breathing process by covering the pain caused by the wound at the surgical site, and easy breathing also aids in the help of relieving depressive thoughts.

As per the fore mentioned studies, binders help manage postoperative psychological distress; some patients feel extremely uncomfortable in the tightness of a thoracoabdominal binder. This discomfort is personal and non-scientific (Rothman *et al.*, 1966). This study concludes that using binders causes no compromise to pulmonary function.

CONCLUSION

For the sake of actual implementation, the current investigation is uncertain as to the impact of thoracoabdominal binders on seroma development. Although there is faint evidence in favor of a slight reduction in the production of free fluid, the lack of concrete evidence and other factors like increased BMI etc., masking the impacts of compression by the binders make its effectiveness ambiguous. Insubstantial evidence is also mentioned in the binder groups' positive pain management effects, emotional and physical distress, and moving capability. Thus, more large-scale studies and comparative meta-analyses need to be taken to justify using thoracoabdominal binders in patients post-mastectomy and MRM. B binders can help make breast surgery care post-surgery less painful and more economical for the patients, resulting in fewer clinic visits.

LIMITATION

One restriction of this study was puzzling due to neoadjuvant chemotherapy and axillary clearance. Axillary clearance and neoadjuvant chemotherapy have been demonstrated to expand the chances of patients undergoing seroma production.

Another limitation may be the small size of the groups. Most trials require more cases to ensure the results are not constricted to a small environment or group of people.

Also, the lack of versatility, as the entire trial is based in one country, may restrict the results to a certain environment. The pathophysiological reason for seroma formation is

still ambiguous. Still, some surgeons might suggest that the BMI, other medical conditions and surgery at the same site before breast surgery may be a reason behind it. Moreover, in our data [table no.1], it can be seen that most patients suffer from conditions like diabetes mellitus and hypertension. In table no. 2, we can see the raised BMIs of some patients, which may cause hindrances in evaluating the accurate results.

REFERENCE

Agrawal, A., Ayantunde, A. A., & Cheung, K. L. (2006). Concepts of seroma formation and prevention in breast cancer surgery. *ANZ Journal of surgery, 76*(12), 1088-1095.

Bourke, J., Balfour, T., Hardcastle, J., & Wilkins, J. (1976). A comparison between suction and corrugated drainage after simple mastectomy: a report of a controlled trial. *Journal of British Surgery, 63*(1), 67-69.

Carless, P. A., & Henry, D. A. (2006). Systematic review and meta-analysis of the use of fibrin sealant to prevent seroma formation after breast cancer surgery. *Br J Surg, 93*(7), 810-819. https://doi.org/10.1002/bjs.5432

Cheifetz, O., Lucy, S. D., Overend, T. J., & Crowe, J. (2010). The effect of abdominal support on functional outcomes in patients following major abdominal surgery: a randomized controlled trial. *Physiotherapy Canada, 62*(3), 242-253.

Chowbey, P., Sharma, A., Khullar, R., Mann, V., Baijal, M., & Vashistha, A. (2000). Laparoscopic ventral hernia repair. *Journal of Laparoendoscopic & Advanced Surgical Techniques, 10*(2), 79-84.

Chowbey, P. K., Sharma, A., Khullar, R., Mann, V., Baijal, M., & Vashistha, A. (2000). Laparoscopic ventral hernia repair. *J Laparoendosc Adv Surg Tech A, 10*(2), 79-84. https://doi.org/10.1089/lap.2000.10.79

Daniel, W., & Matheson, N. (1969). Postoperative abdominal support. *Journal of the Royal College of Surgeons of Edinburgh, 14*(5), 294-296.

de Rooij, L., van Kuijk, S. M., van Haaren, E. R., Janssen, A., Vissers, Y. L., Beets, G. L., & van Bastelaar, J. (2020). A single-center, randomized, non-inferiority study evaluating seroma formation after mastectomy combined with flap fixation with or without suction drainage: protocol for the Seroma reduction and drAin fRee mAstectomy (SARA) trial. *BMC cancer, 20*(1), 1-8.

Droeser, R., Frey, D., Oertli, D., Kopelman, D., Peeters, M. B.-V., Giuliano, A., Dalberg, K., Kallam, R., & Nordmann, A. (2009). Volume-controlled vs no/short-term drainage after axillary lymph node dissection in breast cancer surgery: a meta-analysis. *The Breast, 18*(2), 109-114.

Ebner, F., deGregorio, N., Vorwerk, E., Janni, W., Woeckel, A., & Varga, D. (2014). Should a drain be placed in early breast cancer surgery? *Breast Care, 9*(2), 116-116.

Edwards, J. R., Peterson, K. D., Mu, Y., Banerjee, S., Allen-Bridson, K., Morrell, G., Dudeck, M. A., Pollock, D. A., & Horan, T. C. (2009). National Healthcare Safety Network (NHSN) report: data summary for 2006 through 2008, issued December 2009. *American journal of infection control, 37*(10), 783-805.

Fagevik Olsén, M., Josefson, K., & Wiklund, M. (2009). Evaluation of abdominal binder after major upper gastrointestinal surgery. *Advances in Physiotherapy, 11*(2), 104-110.

Hashemi, E., Kaviani, A., Najafi, M., Ebrahimi, M., Hooshmand, H., & Montazeri, A. (2004). Seroma formation after surgery for breast cancer. *World journal of surgical oncology, 2,* 1-5.

Hematoma, toenail, gross. (2013). https://webpath.med.utah.edu/ATHHTML/ATH040.html

Hoda, S. A., & Cheng, E. (2017). Robbins basic pathology. In: Oxford University Press US.

Jiang, N., Hao, B., Huang, R., Rao, F., Wu, P., Li, Z., Song, C., Liu, Z., & Guo, T. (2021). The clinical effects of abdominal binder on abdominal surgery: a meta-analysis. *Surgical Innovation, 28*(1), 94-102.

Jin, J., Schomisch, S., & Rosen, M. J. (2009). In vitro evaluation of the permeability of prosthetic meshes as the possible cause of postoperative seroma formation. *Surgical Innovation, 16*(2), 129-133.

Kontos, M., Petrou, A., Prassas, E., Tsigris, C., Roy, P., Trafalis, D., Bastounis, E., & Karamanakos, P. (2008). Pressure dressing in breast surgery: is this the solution for seroma formation? *J buon, 13*(1), 65-67.

Kopelman, D., Klemm, O., Bahous, H., Klein, R., Krausz, M., & Hashmonai, M. (1999). Postoperative suction drainage of the axilla: for how long? Prospective randomised trial. *The European journal of surgery, 165*(2), 117-120.

Kumar, S., Lal, B., & Misra, M. C. (1995). Post-mastectomy seroma: a new look into the aetiology of an old problem. *J R Coll Surg Edinb, 40*(5), 292-294.

Kurian, A. W., Lichtensztajn, D. Y., Keegan, T. H., Nelson, D. O., Clarke, C. A., & Gomez, S. L. (2014). Use of and mortality after bilateral mastectomy compared with other surgical treatments for breast cancer in California, 1998-2011. *JAMA, 312*(9), 902-914.

Kuroi, K., Shimozuma, K., Taguchi, T., Imai, H., Yamashiro, H., Ohsumi, S., & Saito, S. (2006). Effect of mechanical closure of dead space on seroma formation after breast surgery. *Breast Cancer, 13*(3), 260-265. https://doi.org/10.2325/jbcs.13.260

Kwan, W., Jackson, J., Weir, L. M., Dingee, C., McGregor, G., & Olivotto, I. A. (2002). Chronic arm morbidity after curative breast cancer treatment: prevalence and impact on quality of life. *J Clin Oncol, 20*(20), 4242-4248. https://doi.org/10.1200/jco.2002.09.018

Larson, C. M., Ratzer, E. R., Davis-Merritt, D., & Clark, J. R. (2009). The effect of abdominal binders on postoperative pulmonary function. *Am Surg, 75*(2), 169-171.

Larson, C. M., Ratzer, E. R., Davis-Merritt, D., & Clark, J. R. (2009). The effect of abdominal binders on

postoperative pulmonary function. *The American Surgeon, 75*(2), 169-171.

LeBlanc, K. (2004). Laparoscopic incisional and ventral hernia repair: complications—how to avoid and handle. *Hernia, 8*(4), 323-331.

LeBlanc, K. A. (2004). Laparoscopic incisional and ventral hernia repair: complications-how to avoid and handle. *Hernia, 8*(4), 323-331. https://doi.org/10.1007/s10029-004-0250-5

Masià, J., Group, i. W., Salgarello, M., Cattelani, L., Parodi, P. C., Ribuffo, D., Onesti, M. G., Berna, G., Cawthorn, S. J., & Bozza, F. (2020). The largest multicentre data collection on prepectoral breast reconstruction: The iBAG study. *Journal of surgical oncology, 122*(5), 848-860.

Masia, J., Pons, G., & Nardulli, M. L. (2016). Combined surgical treatment in breast cancer-related lymphedema. *Journal of reconstructive microsurgery, 32*(01), 016-027.

Neumayer, L., Schifftner, T. L., Henderson, W. G., Khuri, S. F., & El-Tamer, M. (2007). Breast cancer surgery in Veterans Affairs and selected university medical centers: results of the patient safety in surgery study. *Journal of the American College of Surgeons, 204*(6), 1235-1241.

Newman, L. A. (2014). Contralateral prophylactic mastectomy: is it a reasonable option? *JAMA, 312*(9), 895-897.

Petrek, J., Peters, M., Cirrincione, C., & Thaler, H. (1992). A prospective randomized trial of single versus multiple drains in the axilla after lymphadenectomy. *Surgery, gynecology & obstetrics, 175*(5), 405-409.

Pogson, C., Adwani, A., & Ebbs, S. (2003). Seroma following breast cancer surgery. *European Journal of Surgical Oncology (EJSO), 29*(9), 711-717.

Prospero, E., Cavicchi, A., Bacelli, S., Barbadoro, P., Tantucci, L., & D'errico, M. (2006). Surveillance for surgical site infection after hospital discharge: a surgical procedure–specific perspective. *Infection Control & Hospital Epidemiology, 27*(12), 1313-1317.

Rettenmaier, M. A., Micha, J. P., Lopez, K. L., Wilcox, A. M., & Goldstein, B. H. (2017). A Prospective, Observational Trial Assessing the Efficacy of Abdominal Compression in Reducing Laparoscopic-Induced Shoulder Pain. *Surg Innov, 24*(6), 552-556. https://doi.org/10.1177/1553350617718080

Rhodes, V. A., McDaniel, R. W., Homan, S. S., Johnson, M., & Madsen, R. (2000). An instrument to measure symptom experience. Symptom occurrence and symptom distress. *Cancer Nurs, 23*(1), 49-54. https://doi.org/10.1097/00002820-200002000-00008

Rothman, J. P., Gunnarsson, U., & Bisgaard, T. (1966). Abdominal binders may reduce pain and improve physical function after major abdominal surgery-a systematic review. database, 2013.

Salgarello, M. (2012). Breast Reconstruction: Current Techniques. BoD–Books on Demand.

Srivastava, V., Basu, S., & Shukla, V. K. (2012). Seroma formation after breast cancer surgery: what we have learned in the last two decades. *Journal of breast cancer, 15*(4), 373-380.

Tanner, L. (2014). Double mastectomy doesn't boost survival for most. https://web.archive.org/web/20140914001755/; http://bigstory.ap.org/article/double-mastectomy-doesnt-boost-survival-most

Terrell, G., & Singer, J. (1992). Axillary versus combined axillary and pectoral drainage after modified radical mastectomy. *Surgery, gynecology & obstetrics, 175*(5), 437-440.

Thoren, L. (1964). Z-plasty and suction drainage in radical mastectomy. *Acta chirurgica Scandinavica, 128*, 75-84.

Van Bastelaar, J., Beckers, A., Snoeijs, M., Beets, G., & Vissers, Y. (2016). Flap fixation reduces seroma in patients undergoing mastectomy: a significant implication for clinical practice. *World journal of surgical oncology, 14*(1), 1-5.

van Bemmel, A. J., van de Velde, C. J., Schmitz, R. F., & Liefers, G. J. (2011). Prevention of seroma formation after axillary dissection in breast cancer: a systematic review. *Eur J Surg Oncol, 37*(10), 829-835. https://doi.org/10.1016/j.ejso.2011.04.012

Vitug, A. F., & Newman, L. A. (2007). Complications in breast surgery. *Surgical Clinics of North America, 87*(2), 431-451.

Whitfield, P., & Rainsbury, R. (1994). Suction versus siphon drainage after axillary surgery for breast cancer: a prospective randomized trial. *Journal of British Surgery, 81*(4), 547-547.

Woodworth, P. A., McBoyle, M. F., Helmer, S. D., & Beamer, R. L. (2000). Seroma formation after breast cancer surgery: incidence and predicting factors. *The American Surgeon, 66*(5), 444-451.