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SIPHON DRAINS VERSUS SUCTION DRAINS, IN ON-LAY MESH REPAIR OF LARGE VENTRAL DIVARICATION OF RECTI WITH ABDOMINOPLASTY

MUHAMMAD NADEEM UMAR[1], SHAZIA SHAHZADI[2*], TAUSIF AHMED RAJPUT[2]

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Abstract

Objective: To study the positive or negative impact of Siphon drainage as compared to Suction drainage with regards to formation of post-operative seroma or Surgical Site Infection, in cases with relatively large dead space in surgical wounds after divarication of recti repair with On-lay mesh, followed by Abdominoplasty. A prospective randomized clinical study carried out at Riphah International University Hospital, Islamabad from March 2020 to September 2021.

Method: Total of 38 patients with large ventral Divarication of Recti were treated with "On-lay Mesh Repair" and Abdominoplasty with excision of excess skin. These patients were divided into two groups randomly. Patients in the first group received simple tube drain connected to a closed system drainage bag without any suction device, for simple Siphon drainage of their wound. The second group received Vacuderm suction drain connected to a closed-suction vacuum containing plastic bottle for active suction drainage of the wound. In both groups similar closure technique of the wounds was followed which included closure of Divarication of recti defect with polypropylene, On-lay Mesh, quilting, scarpa's fascia apposition with interrupted polyglactin 910 sutures and subcuticular polypropylene 2/0 sutures for skin. Both groups were followed up in the post-operative period with clinical and soft-tissue ultrasound assessment to study the development of any seroma or any Surgical Site Infection, at three pre-determined time intervals.

Results: The patients were followed up at early, intermediate and late stages with clinical and ultra-sonographic examination for seroma formation or SSI. Clinically detectable and Ultrasound proven seroma formation which required needle aspiration was respectively 10.53%% in Group 1 and 10.53% in Group 2, without a significant difference between the two groups (p>0.999). Ultrasonic evidence of seroma formation which did not require drainage was respectively 15.79%, 26.31%, 31.57% in Group 1 (Siphon Drain), and 21.05%, 21.05%, 26.31% in Group 2, and was not significantly different between the two groups (p 0.469; 0.631; 0.619). Surgical Site Infection was seen in 5.26% cases in Group 1 and 5.26% in Group 2, with insignificant difference between the two groups (p>0.999).

Conclusions: The incidence of seroma formation requiring aspiration, seroma formation not requiring aspiration and Surgical Site infections did not show any significant difference between the two groups, each of which was subjected to On-lay mesh repair and provided simple siphon drainage or suction drainage after a ventral divarication of recti repair with excision of excess skin/ Abdominoplasty.

Keywords: Divarication of recti; Ventral; Seroma; Drainage; Drainage Techniques; Hernioplasty; Abdominoplasty; On-lay Mesh repair

1. INTRODUCTION

It has been observed that in about one third of the patients having multiple pregnancies and in about 26% of the patients undergoing exploratory laparotomies, they are followed by late separation of the recti abdominis muscles forming either an incisional hernia or divarication of the recti forming a ventral pseudo-hernia1. Incisional hernias require surgical repair, but divarication of the recti is the commonest after-effect of pregnancies and poor abdominal musculature. Surgical repair of both these conditions is a major undertaking which is associated with a high degree of difficulties like seroma development and Surgical Site Infection2. Despite the fact that various methods of drainage are used at the completion of surgery, in order to prevent these complications, however there is no definite consensus as to which type of drains are most suitable in large surgical wounds with potentially large dead space. Some studies actually suggest that drains might increase chances of Surgical Site infections, especially if left in place for more than 48 hours or with faulty technique of reconstitution of vacuum in these drains or breach of the closed system of drainage3-5.

[1]Department of Surgery, Riphah International University and Hospital, Islamabad, Pakistan

[2]Speech Pathology and Psychology, Shifa Tameer-i- Millat University, Islamabad, Pakistan

*Corresponding author email- psyslp@yahoo.com

There are other closure techniques which are claimed to prevent development of seroma formation, like use of progressive tension sutures between the skin flap and abdominal muscles called "Quilting", which are especially recommended for Abdominoplasty procedures6-8. A Cochrane systematic review to demonstrate the usefulness of either suction or siphon drains prophylactically in such large dead space surgical wounds did not find any study indicating their functionality9. We decided to conduct a randomized clinical trial in our patients undergoing Major Abdominoplasty with Ventral plication and On-lay mesh repair for divarication of recti, to compare the benefits of a simple closed Siphon drainage versus a closed suction drainage system, to study the benefits or disadvantages of one against the other. All patients underwent similar wound closure technique, except the difference in the type of drainage used. Ventral plication with On-lay Mesh, Quilting, double layer fat and dermal approximation interrupted sutures with subcuticular skin closure were used in all patients.

2. METHODS

A prospective randomized clinical study was carried out at Riphah International University Hospital, Islamabad from March 2020 to September 2021. This prospective randomized clinical trial was approved by the research ethics committees of Riphah International University and Shifa Tameer e Millat Universities in Islamabad, Pakistan in compliance with the 1964 Declaration of Helsinki and later updates. The randomization procedure and the study design followed the Consolidated Standards of Reporting Trials (CONSORT) version 201010.

All participants provided written informed consent after briefing and counselling and psychological first aid provided by surgical residents and/or Consultants, during the preoperative evaluation visits.

Inclusive and exclusive criteria

For standardization purposes only female patients with history of multiple pregnancies and clinically demonstrated large divarication of recti were included in this study. Individuals with history of midline exploratory laparotomies or vertical caesarian sections were excluded, as were all patients with post-operative incisional hernias11. All patients undergoing only Major Abdominoplasty were included while those undergoing minor abdominoplasty were excluded [12]. Individuals with any signs of intertrigo under abdominal fold were first adequately treated before becoming a part of the study group. Patients younger than 33 or older than 55 years were excluded, as were those patients who had Diabetes Mellitus, H/O Hepatitis B or C, IHD, ASA III or IV, BMI more than 38, those with a serum albumen concentration lower than 3.0 g/dl or those who rejected participation.

Surgical technique

All the prospective participants in this study were admitted to their private rooms in the hospital one night before their scheduled surgery. Pre- anesthesia assessment was performed to update the assessment of their surgical risk according to the American Society of Anesthesiologists (ASA) criteria, as well as for PT, INR, APTT, Liver and Renal function tests including measurement of the serum albumen concentration.

Major Abdominoplasty surgery was performed by the Surgical Unit's Standardized protocol, by the same Consultant surgeon in all cases. In every patient the skin flap was raised up to xiphi sternum, and after ensuring hemostasis, ventral plication of the ventral divarication of recti was performed with single layer polypropylene 1 continuous running suture, in two parts, interrupted just above and below the umbilical stump. In four patients, 2 (10.53%) from each group, it was felt necessary to relieve the tension on ventral plication by giving releasing incisions on the external oblique muscle aponeurosis 3 cm away from the linea alba, as described by Gibson15. Same brand On-lay mesh reinforcement of this ventral plication was used with macro porous polypropylene (polypropylene) mesh, tacked in place with interrupted 2/0 polypropylene sutures every 2cms, as described by Chevrel [13,14]. This was followed by progressive tension sutures between the skin flap and abdominal wall musculature aponeurosis for quilting and obliteration of potential dead space, followed by excision of excess skin. Scarpa's fascia approximation and dermal interrupted polyglactin 910 2/0 approximation was done, followed by 2/0 polypropylene subcuticular running skin closure. The only difference between the randomly selected two groups' participants was the choice of drainage type used in each case before Scarpa's fascia closure. Similar drains placement inside the wound and similar sites for separate stab incisions in skin for bringing the drains out and anchoring were used. Two drains of 16 Fr diameter were used in each case. Antibiotic prophylaxis was executed with a 2g I/V dose of Cefoperazone-Sulbactam combination of single brand, 20 to 30 minutes before skin incision. 1 G dose was repeated at 4 hours after the first dose, and subsequently 2G after 8 hours, then every 12 hours for next 3 doses.

Interventions

In Group 1, two 16Fr Nelaton catheters were placed between the muscular aponeurosis layer and the subcutaneous tissue in the caudal part of the transverse abdominoplasty incision with tips raised to umbilical level. The drains were brought out through separate stab incisions in each groin, below the incision line, and anchored with silk 1 sutures. Next the Scarpa's fascia was approximated with interrupted Polyglactin 910 2/0 sutures and skin was closed in two layers. The drains were connected to drain bags for simple siphon drainage of the wound, in a closed drainage system.

In Group 2, two 16Fr suction drains (Vacuderm) were placed in similar fashion and brought out through separate stab incision in both groins and anchored. These were then connected to compressed plastic suction bottles (Vacuderm), for closed suction drainage of the wound by elastic recoil property of the drainage bottles.

In both groups separate absorbable 2/0 Polyglactin 910 sutures were placed from the subcutaneous fat layer to the musculo-aponeurotic layer every 2cms as progressive tension sutures (Quilting), as described by Pollock et al.7,8. The flap was stretched inferiorly by the surgeon's non-dominant hand while the quilting suture was passed through the musculo-aponeurotic layer and overlying

scarpa's fascia. The skin flap was then stabilized by the assistant while the surgeon tied the knots. The process of quilting started in the superior parts of the wound and progressed downwards/ inferiorly in lines of sutures every 2 cms. apart, until wound edges were reached. The excess skin was excised, the drains were placed in the caudal part of the wound with tips curving upwards to umbilical level, between the quilting sutures.

Skin closure was performed in two layers. Firstly, interrupted 3/0 polyglactin 910 dermal approximation sutures were applied at 1 cm intervals, and this was followed by 3/0 polypropylene continuous sub-cuticular sutures, interrupted at three places, after every fourth part of the wound, for ease of removal.

The participants were provided with support girdles to be worn continuously at the hospital and at home during the first 30 days after their surgery.

In both groups, the drains were removed when the total drained volume in both drains was less than 40 ml over previous 24 hours.

Outcomes

All the study participants were followed up and clinically assessed by the Surgical team daily for the first 5-7 days before discharge (Early phase), 14-16 days (Intermediate phase) and 29-31 days (Late phase) post-op. Any and all post-operative complications were recorded on a pre-designed follow up proforma, with special reference to seroma formation and Surgical Site infection.

All the study participants went through abdominal wall ultrasound examination at Days 5-7 (Early phase), at days 14-16 (Intermediate phase) and at Days 29-31 (Late phase) especially for the purpose of detecting Sub-clinical seroma formation. This examination was performed by Specialists in Radiology in the presence of a member of the surgical team. Any volume of collection of fluid under the wound or subcutaneous fat layer was labelled as a Seroma. All post-operative study participants were required to stay in the hospital until the first Ultrasound examination had been carried out on the 5th to 7th post-op day, and until their drains had been removed.

The presence of seroma was considered as the main outcome. A seroma was labelled as Clinical Seroma, when a physical bulge or fluctuation was detected in any part deep to the skin flap, but without any signs of infection. Fluid collection under the skin flap which was only detected on ultrasound examination, in the absence of any detectable findings on clinical examination, was labelled as Sub-Clinical Seroma.

The criteria formulated by the Centers for Disease Control and Prevention (CDC) in the Guideline for Prevention of Surgical Site Infection, 1999 was used to define Surgical Site Infection [16].

3. STATISTICS

The preliminary statistical analysis of all the data composed in the present study was descriptive. quantitative (numerical) variables, including mean, standard deviation, median, maximum and minimum values were calculated. The qualitative (categorical) variables were measured as absolute and relative (percent) frequencies. Student's t-test for independent samples was used to compare the groups of participants. Pearson's chi-square test, and for data verification Mann-Whitney test were used.

4. RESULTS

38 females with large ventral divarication of Recti underwent Plication of the divarication with superimposed On-lay mesh reinforcement and Major Abdominoplasty. All of them had undergone 2 or more pregnancies, and had completed their families. 16 (42.1%) had undergone multiple Caesarian Sections via Pfennensteil incision. General characteristics of each of the study participants were obtained and recorded on a specially designed proforma. Follow up findings were similarly recorded on this proforma for each patient.

Table 1 Distribution of general characteristics the participants per intervention group

	GROUP 1 (SIPHON DRAINAGE) (n = 19)	GROUP 2 (SUCTION DRAINAGE) (n = 19)	Total (n = 38)
GENDER			
Female	19 (50%)	19 (50%)	38
Male	-	-	-
AGE (years)			
Mean	45.5	42.4	42.4
Median	47.0	44.0	44.0
Minimum-maximum	31.0-54.0	30.0-55.0	30.0-55.0
Standard deviation	10.6	13.9	13.9
BMI CLASSIFICATION			
Normal[g]	1 (5.26%)	0 (0%)	1 (2.63%)
Overweight[h]	7 (36.84%)	9 (47.36%)	16 (42.10%)
Obese[i]	11 (57.89%)	10 (52.63%)	21 (55.26%)
CARDIAC RISK			
ASA I	11 (57.89%)	14 (73.68%)	25 (65.79%)
ASA II	8 (42.10%)	5 (26.31%)	13m (34.21%)
SERUM ALBUMEN[j] (g/dl)			
Mean	3.9	3.8	3.9
Median	3.9	3.8	3.9
Minimum-maximum	3.4-4.7	3.1-4.7	3.1-4.7
Standard deviation	0.3	0.5	0.4

a. Pearson's chi-square test, bFisher's test, c Student's t-test for independent samples

b. body mass index up to 24.99 kg/m2, hbody mass index from 25 to 29.99 kg/m2, ibody mass index equal to or greater than 30 kg/m2; jmeasured one day before surgery.

In our series an incidence of post-operative sub-clinical seroma formation in Group 1 (Siphon drainage group) was 3 (15.79%), 5 (26.31%) and 6 (31.57%) in the Early (5-7 days), Intermediate (14-16 days) and Late (29-31 days) phases respectively. In Group 2 (Suction drainage group) the incidence was 4 (21.05%), 4 (21.05%) and 5 (26.31%) respectively. The incidence of Clinical Seroma formation requiring one or more needle aspirations for drainage was 2 (10.53%) in Group 1 and 2 (10.53%) in Group 2. All 4 (10.53%) cases with Clinical Seroma formation were detected in the intermediate phase (14-16 days) and

underwent 1 or more needle aspirations over the next week. All of them had recovered by the late phase examination. 1 (5.26%) patient in Group 1 and 1 (5.26%) patient in Group 2 were found to have minor superficial wound infection in the intermediate phase, with 1 patient having infection in umbilical stitches and 1 in the midline portion of main abdominoplasty incision. Both patients recovered with Oral antibiotics, topical antibiotic creams and dressings over the next 5-7 days. The whole prevalence of Sub-Clinical Seroma formation in the whole 38 study participants was 7 (18.42%), 9 (23.68%) and 13 (34.21%) in the Early, Intermediate and Late phases. The overall incidence of Clinical Seroma formation requiring needle aspiration was 4 (10.53%) in the Intermediate follow up phase only. The overall incidence of Surgical Site Infection was 2 (5.26%) detected in Intermediate phase only. There was no significant difference between the cases receiving Siphon or Suction drainage with regards to the development of seroma (p=0.451) or postoperative infection (p=0.660). The participants were randomly distributed into two groups of 19 each, with Group 1 receiving Siphon Drains while the Group 2 received Suction Drains. No patient was lost to follow-up, and all patients underwent clinical and Ultrasound examination in early, intermediate and late phases as previously instructed to them. No participant died or exhibited serious complication requiring removal of the mesh repair in the 30-day postoperative follow-up. Only four patients required relaxing Rectus Abdominis Aponeurosis incisions, two from group 1 and two from group 2. The average body mass index (BMI) of the sample was 35.5 kg/m^2, varying from 32.1 to 39.2 kg/m^2 the results of the inferential comparison show that both Group 1 (Siphon drains) and Group 2 (Suction drains) exhibited the same profile as summarized in Table 2 below:

Table 2 Data

	GROUP - 1 (SIPHON DRAINAGE)	GROUP - 2 (SUCTION DRAINAGE)	TOTAL
SEROMA (Sub-Clinical)			
Early Phase (5 to 7 Days)	3 (15.79%)	4 (21.05%)	7 (18.42%)
Intermediate Phase (14 to 16 Days)	5 (26.31%)	4 (21.05%)	9 (23.68%)
Late Phase (29 to 31 Phase)	6 (31.57%)	5 (26.31%)	13 (34.21%)
SEROMA (Clinical)			
Early Phase (5 to 7 Days)	0 (0%)	0 (0%)	0 (0%)
Intermediate Phase (14 to 16 Days)	2 (10.53%)	2 (10.53%)	4 (10.53%)
Late Phase (29 to 31 Phase)	0 (0%)	0 (0%)	0 (0%)
SURGICAL SITE INFECTION			
Early Phase (5 to 7 Days)	0 (0%)	0 (0%)	0 (0%)
Intermediate Phase (14 to 16 Days)	1 (5.26%)	1 (5.26%)	2 (5.26%)
Late Phase (29 to 31 Phase)	0 (0%)	0 (0%)	0 (0%)

The outcomes of the univariate investigation displayed that the rate of surgical wound infection within up to 30 days after surgery was not related with the use of Siphon or Suction drains (p>0.999), gender (p=0.695), age (p=0.815), BMI classification (p=0.676), cardiac risk (p=0.422), Divarication size (p=0.181), subcutaneous fat thickness (p>0.999) or surgical time (p=0.055). Pearson's chi-square test, Fisher's exact test or its extension, Student's t-test for independent samples and Mann-Whitney test were used for data verification.

5. DISCUSSION

Large Ventral Divarication of Recti with Major Abdominoplasty still pose a difficult task to surgeons because of the high number of difficulties, among which seroma and surgical wound infection stand out2. These complications happen due to the significant amount of subcutaneous tissue that is separate in Abdominoplasty, especially when using the On-lay technique for mesh strengthening. These difficulties are more common among the obese patients, which links to the fact that most of the patients experiencing these procedures are obese as were most of the participants in the present study. Obesity represents a risk factor for divarication repairs, as well as for repair problems like seroma development and wound infection [18]. Obesity is usually linked with poor abdominal musculature and divarication of the recti especially when compounded with several pregnancies, and is the main issue to wound healing in these patients, as shown by the survey of surgery results conducted by Evans in the United States, for which cause most such patients are sent for surgical treatment at specialized places [19].

The most widely suspected causes of seroma formation are blood and lymphatic vessel injury during dissection, formation of dead-space, presence of shear forces among layers and the release of inflammatory mediators. In the case of On-lay Mesh repair, the presence of a routinely used foreign body, i.e., the mesh, is added to those factors20. Despite this evidence, fibrosis due to previous surgeries and any foreign bodies (suture remains) present in patients with multiple caesarian sections in our sample did not correlate with the formation of postoperative seroma or infection, perhaps the sample size was not calculated for this purpose.

The maximum extensively used procedure thought to prevent seroma formation contains of the location of drains in the subcutaneous tissue; though, many studies showed that drains not only fail to prevent seroma formation but may even increase the risk of infection, especially when kept for more than 72 hours [3, 4]. A Cochrane review on this subject did not find any evidence representative a benefit of the use of drains [9].

Baroudi and Ferreira in 1998 described the use of fixation sutures between subcutaneous Scarpa's fascia and the musculo-aponeurotic layer, which theoretically obliterate the dead space and reduce the shear forces, for abdominoplasty without drainage6. Further refinements were added by Pollock7, and the technique was then reproduced by others [21-23]. The progressive tension sutures technique was described by Janis from University of Texas in 2012, for use in large incisional hernioplasty method24. Birolini C, highlight the importance of fixing

the mesh to the aponeurosis with running joins of absorbable polyglactin 910 to prevent the formation of dead space and complications25. In the present study, the frequency of seroma formation did not exhibit significant difference between the groups, and most seromas were detected at the intermediate assessment when all the drains had already been removed. These findings agree with the results reported by other authors, according to which the peak incidence of seroma formation occurs approximately two weeks after surgery, when prophylactic drains would be useless [6, 21, 26]. In the present study, many seromas were detected by ultrasound only (39.21%), which was expected, as most participants were obese, which makes their physical examination more difficult, and the fluid collections were small. A similar frequency was reported by Tsimoyiannis and Klink, who also performed ultrasound assessment [17, 27].

The incidence of seroma at the intermediate postoperative assessment was 23.68%. The data in the literature show extensive difference ranging from 0% to 100% as a fun ction of the definition of seroma, the diagnostic methods and experimental design employed in the various studies. In the present study, the vast majority of the seromas did not exhibit clinical repercussion and were resorbed within 30 days without sequelae, while only 10.53% of the cases required some intervention.

6. CONCLUSIONS

There was no substantial modification in the prevalence of seroma formation or surgical wound infection between the patients who experienced placement of continuous suction drains in the subcutaneous tissue and those preserved with the siphon drains closed system. The occurrence of seroma development was moderately high although the incidence of wound infection in our series was low, and thus the search for novel surgical techniques to minimize the incidence of difficulties in these chief surgeries continues.

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