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Prospective Randomized Study for Comparison of the Outcome of Suction versus Non-Suction Closed Drainage on Seroma Development after Open Onlay Ventral Hernioplasty in 100 Patients

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Authors' contributions

This work was carried out in collaboration among all authors. All authors had equal role in design, work, statistical analysis and manuscript writing. All authors read and approved the final manuscript.

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ABSTRACT

Introduction: There isn't a widely used definition for seroma but "serous fluid collection in a body space, tissue or organ occurring after surgery or trauma", is defined as seroma. Symptomatic seromas are common in laparoscopic and open ventral hernia repairs, presented in 8 to 12.5% of patients after open repair by clinical examination at the 8 weeks post-operative control. Several operative measures were done to reduce the development of postoperative seromas after hernia repair as an intra-operative technical step (e.g. quilting sutures) or adjunct procedure (e.g. drain application). During ventral hernias repair, surgeons regularly insert a surgical drain to allow the fluid drainage. Closed drains can be either active (suction) drains or passive (non-suction) drains.
Methods: During the period from August 2018 to October 2019, a total of 100 adult patients presented with different types of ventral hernias, underwent open onlay mesh hernioplasty in the gastrointestinal surgery unit, general surgery department, Tanta University. Patients included in this study were randomly allocated into one of the following two groups using the closed envelope method. Group A included 50 patients with suction tube drain and group B included 50 patients with non-suction tube drain.

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Results: There were no statistically significant differences between both groups regarding the patients' demographics. It was evident that with the use of suction drains from 9th POD the mean daily fluid effluent and the mean total amount of fluid effluent during all follow-up days was significantly lower than in non-suction tube drains. Also, the mean time of drain removal was statistically significantly shorter in group A than in group B.
It was found that cases of ultrasonographic and clinically diagnosed seroma, had compensated chronic liver disease, obesity (BMI > 30 kg\m^2), multiple previous abdominal incisions, long period of hernia presence (> 4 years), long-standing partial irreducibility, and large dead space after subcutaneous flap dissection.
Conclusion: Suction drains were removed at a significantly shorter time than non-suction ones under the same rules of management. It also gives significantly lower volume fluid effluent from the 6th POD onwards. Seroma were harder to manage with non-suction tube drains: longer drainage period, worse resolution rates.

Keywords: Seroma; suction drain; non-suction drain.

1. INTRODUCTION

Seroma is defined as serous fluid accumulation after surgery or trauma in a body area, tissue, or organ. The fluid consists of liquids, solutes, plasma proteins such as fibrin and neutrophils [1]. It results from the normal inflammatory reaction of the body to an injury to its tissues (for example surgical trauma or introduction of a foreign body inside tissues) [2].

The development of seroma itself is not usually a complication but is frequently associated with postoperative pain and patient distress and may lead to serious infection with an increased risk of relapse of hernia and wound breakup [2].

Seroma rarely developed following tissue repair, but with the use of synthetic material, the rate of seroma development rises to 17.6%. Seroma formation following mesh repair is common, reported in 20–30% of patients. About 10% of them have a volume higher than 50 cc [3].

Clinical seroma was divided into 5 categories graded from 0 to IV by Morales-Conde in 2012 Table 1.

This classification is established to determine if a specific seroma should be considered as an incident or a complication. Complicated seroma is represented by types III and IV in which medical or invasive therapy is needed while incident seroma is represented by types I and II [4].

1.1 Management of Postoperative Seroma

1.1.1 Preventive treatment

Divided into surgical and non-surgical and their purpose is to reduce the surgically formed dead space [5]. Non-surgical methods include an elastic pressure bandage and abdominal binder [6]. Surgical methods include quilting sutures, negative pressure wound therapy, medical talc, fibrin sealant, surgical drains, and hypertonic saline [7].

1.1.2 Curative treatment

Needle punctures aspiration, drain Placement, sclerosant Injection, and surgical removal [8].

Table 1. Classification of postoperative seroma after ventral hernia repair as proposed by Morales-Conde [4]

Seroma type	Definition	Clinical significance
0	No clinical seroma	No clinical seroma
I	Clinical seroma lasting <1 month	Incident
II	Clinical seroma lasting >1 month	
III	Symptomatic seroma that may need medical treatment: minor seroma related complications	Complication
IV	Seroma that needs to be treated: major seroma-related complications	

1.2 Aim of the Work

The aim of this study was to compare suction and non-suction closed drains in the development of seroma after open onlay ventral hernioplasty.

2. PATIENTS AND METHODS

The current study is a prospective randomized clinical trial that was conducted on 100 eligible adult patients with different types of ventral hernias, who were submitted to elective mesh hernia repair in the gastrointestinal and laparoscopic surgery unit-general surgery department at the Tanta university hospitals during the study period (August 2018 to October 2019). All patients presented with ventral abdominal wall hernias aged ≥ 18 years and submitted to onlay mesh hernia repair are included in this study. Patients submitted to other types of repair (without mesh or another one than the onlay mesh repair), complicated hernias, contaminated surgical field, and patients < 18 years were excluded from this study.

Included patients were divided into 2 equal groups. Suction tube drains were used in group A patients while non-suction tube drains were used in group B patients after onlay mesh hernioplasty. Allocation of patients to any group was randomized using the closed envelope method. Preoperatively, all patients were evaluated by thorough clinical evaluation and laboratory investigations as needed. Pelvi-abdominal ultrasound (US) and endoscopy in patients with hepatic disease were done.

2.1 Operative Techniques

The abdominal skin was treated with local antifungal therapy before the operation and disinfected carefully the night of surgery. Low molecular weight heparin was given 12 hours before surgery and below knees elastic stocking in the operative day morning to those at risk to develop DVT. All patients were operated under general anesthesia. All patients received intravenous antibiotic with induction of anesthesia (ceftriaxone 1 gm) after sensitivity test. All patients underwent open onlay ventral mesh hernioplasty with polypropylene mesh. Skin incision was made relative to the size and site of the hernia swelling and subcutaneous dissection of the hernia was performed to expose the edges of the defect. If the contents of the sac were reduced freely, the sac was inverted. Otherwise, the sac was opened, freed from adhesions, the contents were reduced, and the defect was closed by Proline® 1 sutures, then, a polypropylene mesh was positioned onlay, extending at least 5 cm all around the defect. The mesh was fixed, one cm from the periphery all around, by interrupted non-absorbable Proline® 2/0 sutures to the underlying external oblique aponeuroses and rectus sheath. Through a separate stab, a subcutaneous suction drain was inserted after mesh fixation in group A while a non-suction tube drain was inserted in group B. Some large ventral hernias required more than one drain. Subcutaneous tissue was sutured using continuous Vicryl® 3/0 sutures and skin closure was done using Proline® 2/0 suture.

2.2 Postoperative Management and Follow-Up

Antibiotic injections were continued for 3 more days and patients were discharged on oral amoxicillin-clavulanic acid 1 gm /12 hours for 5 days. Prophylactic low molecular weight heparin was given subcutaneously in a single daily dose for one week to those at risk to develop DVT. Oral fluids were allowed after 4 hours and a light diet after 12 hours. Patient mobilization was allowed after complete recovery of anesthesia and a physiotherapy program for movement and chest exercise was started in the 1st POD morning. Abdominal binders were applied starting from the operative day for 2 weeks. The wound was checked on 3rd POD for complications as seroma, infection, and dehiscence. The drain was also checked for the daily effluent measurement and its color. The patients were discharged once they are on regular oral intake without any complication necessitating staying in the hospital with the drain. On discharge, they were given instructions regarding wound and drains care and daily fluid effluent was recorded on a follow-up chart. The drains were removed once their daily effluent is less than 30 ml daily for 2 consecutive days without suspicion of being occluded. Follow up of patients was done in the outpatient clinic weekly during the first month then at 3 and 6 months for the presence of seroma, wound infection, or recurrence. They are examined clinically and by US.

2.3 Statistical Analysis

Data were analyzed using IBM SPSS software package version 20.0. Qualitative data were described using number and percent. The

Kolmogorov-Smirnov test was used to verify the normality of distribution. Quantitative data were described using a range (minimum and maximum), mean, and standard deviation. Significance of the obtained results was judged at a 5% level.

3. RESULTS

Seventy-nine females and twenty-one males were randomly assigned to one of two equal groups in this prospective study. The demographic findings (age, gender, BMI) revealed no significant differences between the groups. The follow-up period in this study ranged from 6 to 14 months with similar means in both groups. The hernia characteristics, in terms of type, reducibility, and duration were also similar in both groups. Three risk factors were identified in the population of this study (multiparity, obesity [BMI ≥ 30 kg/m^2] and smoking), and five associated comorbidities were identified (hypertension, chronic liver disease, diabetes mellitus, chronic chest disease, and ischemic heart disease), with no significant differences in the distribution between the two groups Table 2.

At 3rd POD, all the patients still had their drains. The mean daily fluid effluent was 234.5 ± 57.93 ml/day in group A versus 223.90 ± 63.58 ml/day in group B with no statistically significant difference between both groups (p = 0.332). At 6th POD, all the patients still had their drains. The mean daily fluid effluent was 157.30 ± 53.17 ml/day in group A Vs. 173.78 ± 53.28 ml/day in group B with no statistically significant difference between both groups (p = 0.070). At 9th POD, 38 patients in group A and 49 patients in group B still had their drain. The mean daily fluid effluent was significantly lower in group A than in group B (86.62 ± 42.58 ml/day Vs. 116.94 ± 50.08 ml/day, p = 0.002). At 12th POD, 22 patients in group A and 45 patients in group B still had their drains.

The mean daily fluid effluent was significantly lower in group A than in group B (55.45 ± 28.57 ml/day versus 90.67 ± 31.12 ml/day, p < 0.001).

At 15th POD, 10 patients in group A and 31 patients in group B still had their drains. The mean daily fluid effluent was significantly lower in group A than in group B (23.80 ± 5.05 ml/day Vs. 63.07 ± 26.47 ml/day, p < 0.001). At 18th POD, 10 patients (10%) still had their drains. All of them in group B with a mean daily fluid effluent of 27.0 ± 2.98 ml/day (Table 3).

Regarding the mean total amount of fluid effluent during all follow-up days it was significantly lower

Table 2. Patients' demographics, clinical presentation, risk factors, comorbidities, types of hernia, and disease duration

		Group A (n=50)	Group B (n=50)	P
Patients' demographics	Age	46.48 ± 9.85 (26 - 65)	44.75 ± 12.61 (19 - 75)	N. S
	Gender (F / M)	39 / 11	40 / 10	N. S
	BMI	33.49 ± 6.08 (25 –55.5)	34.03 ± 6.44 (25 – 55)	N. S
Clinical presentation	Abdominal swelling	50	50	N. S
	Persistent abdominal pain	30	25	N. S
	Low backache	10	13	N. S
	History of irreducibility	2	4	N. S
Risk Factors	Multiparity	39	39	N. S
	Obesity BMI > 30	36	31	N. S
	Smoking	4	8	N. S
Comorbidities	Hypertension	7	5	N. S
	Chronic liver disease	4	7	N. S
	D.M	7	3	N. S
	Chronic chest disease	2	3	N. S
	Ischemic heart disease	3	0	N. S
Type of hernia	Para umbilical	31	31	N. S
	Incisional	11	16	N. S
	Epigastric	8	3	N. S
Disease duration	≤ 2 years	22	24	N. S
	> 2 - 4 years	10	9	N. S
	> 4 - 6 years	3	3	N. S
	> 6 years	15	14	N. S

in group A than in group B (485.06 ± 95.63 ml Vs. 637.12 ± 133.20 ml, p < 0.001). It was found that with the use of suction drains and from 9th POD the mean daily fluid effluent was significantly lower than in non-suction tube drains. Also, the mean time of drain removal was statistically significantly shorter in group A than in group B (11.38 ± 2.13 days versus 14.74 ± 3.39 days) (p < 0.001).

Postoperative complications occurred in 15 patients, 6 of them in group A and 9 in group B. One patient had multiple complications (Table 4). Subcutaneous hematoma was diagnosed in six patients, 2 in group A and 4 in group B at the 3rd POD by ecchymosis observed during dressing. US was performed to confirm the diagnosis. None required blood transfusion. All of them were managed conservatively till complete absorption of the hematoma. Superficial skin gangrene developed in 1 patient in group A only, who was managed by daily dressing and chemical debridement by collagenase containing ointment. Partial wound dehiscence (at the level of the skin) occurred in 2 patients, 1 in each group. They were managed by conservative treatment with daily dressing till completely healed with secondary intention. Complete wound dehiscence developed in 3 patients in group B who underwent CST because of large incisional hernia. The mesh was taken and covered by healthy granulation tissue. They were managed by conservative treatment with daily dressing till completely healed with secondary intention. Superficial wound infection developed in 7 patients diagnosed by redness with minimal wound discharge, 3 in group A and 4 in group B. Patients were treated conservatively with daily dressing and specific antibiotics. Culture and sensitivity of the discharge was performed for all cases of partial and complete dehiscence and wound discharge. There was no statistically significant difference between both groups regarding postoperative complications.

Postoperative US was used routinely in our study to detect seroma formation at 1,2,3 and 4 weeks postoperatively then at 3 and 6 months. In the present study, rate of seroma detected by US at 3rd and 4th weeks postoperatively was significantly lower in group A than group B.

Many seromas were detected by US only, in our study we used both US and clinical assessment for seroma detection. At 3rd week postoperatively when all drains had already been removed, 25 patients presented with seroma detected by US while, 15 patients presented with clinically symptomatic seroma which was expected, as most participants were obese, which makes their physical examination more difficult, and the fluid collections were small. Most of US detected seromas did not exhibit clinical reflection and were resorbed within 90 days without sequelae, while only 10 of them required intervention.

At 3rd postoperative week, clinically symptomatic seroma were present in 15 patients, 4 in group A

Table 3. The daily fluid effluent was estimated until the time of drain removal

		Group A (n=50)	Group B (n=50)	P
Daily fluid effluent at all follow-up periods	At 3rd POD (ml/day)	234.5 ± 57.93 (150 – 325)	223.9 ± 63.58 (150 – 350)	0.332
	(day/ml) POD th6t A	157.3 ± 53.17 (80 – 225)	173.78 ± 53.28 (100 – 250)	0.070
	At 9th POD (ml/day)	86.62 ± 42.58 (30 – 150)	116.94 ± 50.08 (30 – 175)	0.002*
	At 12th POD (ml/day)	55.45 ± 28.57 (30 – 100)	90.67 ± 31.12 (30 – 125)	< 0.001*
	At 15th POD (ml/day)	23.80 ± 5.05 (15 – 30)	63.07 ± 26.47 (30 – 100)	< 0.001*
	At 18th POD (ml/day)	-	27.0 ± 2.98 (22 – 30)	-
	Total fluid effluent (ml)	485.06 ± 95.63 (305 –680)	637.12 ± 133.2 (370 – 863)	< 0.001*
Time of drain removal		11.38 ± 2.13 (8 – 15)	14.74 ± 3.39 (8 – 18)	< 0.001*

Table 4. Postoperative complications

Postoperative complications	Group A (n=50)	Group B (n=50)	P
Hematoma	2	4	N. S
Superficial skin gangrene	1	0	N. S
Partial Wound dehiscence	1	1	N. S
Complete wound dehiscence	0	3	N. S
Superficial wound infection	3	4	N. S

Table 5. Evaluation of seroma weekly in the 1st month and then at 3rd and 6th months

		Group A (n=50)	Group B (n=50)	P
Postoperative radiological seroma diagnosis	At 1st week	2	6	N. S
	At 2nd week	5	11	N. S
	At 3rd week	8	17	0.038*
	At one month	4	12	0.029*
	At three months	1	4	N. S
	At six months	-	-	N. S
Postoperative seroma development at 3rd postoperative week	Time (Days)	14.88 ± 5.84 (7 – 21)	14 ± 6.06 (7 – 21)	N. S
	Volume (ml)	68.13 ± 42 (20 – 150)	95.65 ± 73.57 (20 – 250)	N. S

Table 6. Predisposing factors for seroma formation in both groups

	Group A (n=50)	Group B (n=50)	P
Compensated chronic liver disease	4	7	N. S
BMI > 30 kg/m2	36	31	N. S
Presence of multiple previous abdominal operations	12	14	N. S
Long Period of hernia presence > 4 yrs.	18	17	N. S
Long-standing partial irreducibility	20	22	N. S
Large dead space after subcutaneous flap dissection	24	21	N. S

Table 7. Correlation between seroma occurrence and its predisposing factors (n=25)

		Total (n=25)		Group A (n=8)	Group B (n=17)	p
		No.	%	No.	No.	
BMI	< 30 kg/m2 (n=33)	5	20	2	3	N. S
	≥ 30 kg/m2 (n=67)	20	80	6	14	
previous abdominal incisions	< 3 (n=74)	9	36	3	6	N. S
	≥ 3 (n=26)	16	64	5	11	
Long Period of hernia presence	< 4 yrs (n=65)	9	36	4	5	N. S
	≥ 4 yrs (n=35)	16	64	4	12	
Long standing partial irreducibility	Yes (n=42)	18	72	5	13	N. S
	No (n=58)	7	28	3	4	
Size of dead space	< 500 cm2(n=55)	3	12	1	2	N. S
	≥ 500 cm2(n=45)	22	88	7	15	

and 11 in group B, all of them complaining from abdominal discomfort associated with skin tension (10 patients), fluid wave (5 patients) and wound disruption (5 patients). No significant difference was found between both groups regarding clinical seroma diagnosis.

Seroma required intervention in 10 patients, 5 of them underwent US-guided aspiration (2 in group A and 3 in group B) in whom the volume of seroma was between 20 – 50 cm^3. Aspiration was done in two sessions. Four of them needed US-guided drain insertion (one in group A and 3 in group B) in whom the volume of seroma was between 50 – 250 cm^3 and only one patient in group B needed surgical drainage : he had thick turbid seroma with multiple septations. There was no statistically significant difference between both groups regarding symptomatic seroma management.

The follow-up period ranged from 6 to 14 months with a mean of 9.94 ± 2.55 months in group A & 10.22 ± 2.58 months in group B and no hernia recurrence was reported during this period.

4. DISCUSSION

Seroma formation remains a significant problem after mesh hernioplasty, the cause of which is multifactorial: large dead space, traumatic dissection, shear forces among layers, release of

inflammatory mediators and presence of a routinely used strange body as mesh [9].

To decrease the incidence of seromas, a variety of techniques have been described. Their main target is to obliterate the dead space including quilting sutures, fibrin sealants, external compression, and use of drains after surgery. It should be noted that a meticulous surgical technique and careful attention to surgical planes of dissection and hemostasis are essential [10].

The age of our patients ranged from 19 to 75 years with a mean of 45.61 years. which is similar to that reported in other studies [11,12,13].

In the current study, we found that from 9th POD till the time of drain removal the mean daily fluid effluent was significantly lower with the use of suction drains than in non-suction tubal drains. Moreover, the mean total volume of postoperative drainage was significantly lower in group A than group B (485.06 ± 95.63 ml versus 637.12 ±133.20 ml; P < 0.0001). Also, the mean time of drain removal was statistically significantly shorter in group A than in group B (11.38 ± 2.13 days versus 14.74 ± 3.39 days; P < 0.0001). Alhussini et al. [14] used suction drains of 14F in 180 patients who underwent onlay hernia repair associated with abdominoplasty in 55 patients and reported higher mean daily and total fluid effluent in the 1st five days postoperatively in which tissue reaction to mesh and formation of exudate are higher. They had delayed drain removal up to 16 days postoperatively. Eltantawy et al. [15] used non-suction tube drains of 24F in 25 patients who underwent onlay hernia repair associated with abdominoplasty. In all cases, reported higher mean daily and mean total volume of fluid effluent were with a delayed mean time of drain removal (volume dependent) of 20.5 ± 4.2 days. This may be explained by the large dead space developed in all cases.

Janis et al. [16] in their systematic review reported that there was a significantly lower rate of seromas with volume-controlled drain removal than time-controlled drain removal.

In our study, volume-controlled drain removal was used in all cases when output ≤ 30 ml in two successive days. Hamila et al. [17] compared between time-controlled (on the 4th postoperative day) to volume-controlled (less than 20 ml / 24 hours) drain removal after sublay hernia repair in 58 patients and reported that there was no significant difference in the incidence of seroma, hematoma and wound infection, after prosthetic ventral and incisional hernias repair, between patients who underwent time-controlled or volume-controlled drain removal. Their explanation is that there is a rapid decrease in levels of cytokines (IL-1ra, IL-6, IL-10, IL-1 alpha) between the 1st and the 4th POD. This suggests that a drainage period of 4 days would be sufficient. So, the drainage can be removed even if it is still productive.

Schmidt et al. [18] reported in their study on 200 patients comparing suction drainage with gravity drainage on wound drainage they found that there is no significant advantage in liquid quantum, hematoma, and the frequency of complications. So, the economically favorable gravity drainage can replace the more expensive suction drainage in most cases.

Westphalen et al. [19] performed both clinical and radiological assessment (by US at 1,2 and 4 weeks postoperatively) for seroma and detected seroma by US only for 52.4% of patients at 2nd-week assessment when all the drains had already been removed and within 90 days only 22.7% of the seromas exhibit clinical reflection that required some intervention.

In our study, the mean volume of seroma was 68.13 ± 42.0 ml in group A and 95.65 ± 73.57 ml in group B. Klink et al. [20] used suction drains in his study and reported a mean seroma volume of 77 ± 88 ml.

Our study coincide with what was reported by Kaafarani et al. [21] as most cases of seroma occurred in patients with compensated chronic liver disease, obesity (BMI > 30 kg\m^2), multiple previous abdominal incisions, long period of hernia presence (> 4 years), long-standing partial irreducibility and large dead space after subcutaneous flap dissection.

Our end point of this study will be facing any serious complications in our cases.

5. CONCLUSION

This study revealed that suction drains were removed at a significantly shorter time than non-suction ones under the same rules of management. It also gives significantly lower volume fluid effluent from the 6th POD onwards.

Incidence of seroma occurrence mor with non-suction drain than suction one.

The evaluation for postoperative seroma should be done mainly by clinical examination and US done only in suspected cases as the US may give an increased rate of seroma which may be considered sequelae, not a complication.

We found no statistical significance in the time taken for seroma to develop after drain removal, in its volume size between suction and non-suction tube drains and in seroma development rate after drain removal.

Follow up of patients is very important with continue study on more patients to get definite conclusion.

ETHICAL APPROVAL AND CONSENT

This study was approved by the local ethical committee of the faculty of medicine of Tanta University, and each patient signed an informed consent before being enrolled in the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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