

Repair of large incisional hernias. To drain or not to drain. Randomized clinical trial¹

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ABSTRACT

PURPOSE: To evaluate the occurrence of seroma and surgical wound infection after surgery.

METHODS: A total of 42 individuals with large incisional hernias were subjected to *onlay* mesh repair. Following the mesh placement, the participants were randomly allocated to two groups. In group 1, closed-suction drains were placed in the subcutaneous tissue, while progressive tension sutures were performed in group 2. The participants were subjected to clinical and ultrasound assessment to detect seroma and surgical wound infection at three time-points after surgery.

RESULTS: The occurrence of seroma at the early, intermediate or late assessments was respectively 19.0%, 47.6%, 52.4% in group 1 and 28.6%, 57.1%, 42.9% in group 2 and was not significantly different between groups (p 0.469; 0.631; 0.619). Surgical wound infection occurred 19% in group 1 and 23.8% in group 2, without a significant difference between the groups (p>0.999).

CONCLUSION: The frequency of seroma and infection did not exhibit significant differences between individuals subjected to *onlay* mesh repair of large incisional hernias with drains or progressive tension sutures without drainage.

Key words: Hernia, Ventral. Seroma. Drainage. Suture Techniques. Herniorrhaphy.

Introduction

In three to 26% of the patients subjected to surgical opening and closure of the abdominal wall, closure might fail, followed by late separation of the muscular-aponeurotic layers, which is known as incisional hernia¹. Most incisional hernias require surgical repair, which is associated with a high incidence of complications, among which seroma formation and infection stand out². Although drains are placed at the end of surgery as an attempt to prevent such complications, there is no concrete evidence in the literature demonstrating their actual benefits or whether they might actually increase the incidence of infection³⁻⁵. Other techniques are also used to prevent seroma formation, including progressive tension sutures, which are recommended by some authors for abdominoplasty⁶⁻⁸. A Cochrane systematic review on the prophylactic use of drains following incisional herniorrhaphy did not locate any study demonstrating their usefulness⁹. We conducted a randomised clinical trial to compare the incidence of seroma and surgical wound infection between patients subjected to large incisional hernia repair by means of the onlay technique, with one group being subjected to the placement of drains, while progressive tension sutures without drains were used in a second group.

Methods

The present randomised clinical trial was approved by the research ethics committees of School of Medicine, Universidade Federal de São Paulo (UNIFESP), Universidade Estadual do Oeste do Paraná (UNIOESTE) and Hospital Universitário do Oeste do Paraná (HUOP) in compliance with the 1964 Declaration of Helsinki and later updates.

The study design and randomisation followed the Consolidated Standards of Reporting Trials (CONSORT) version 2010¹⁰.

The study was register in clinicaltrials.gov public site with the identifier NCT02163460.

All the participants read and signed an informed consent form during the preoperative assessment visit.

Inclusion and exclusion criteria

Individuals with primary or recurrent incisional hernia were assessed at HUOP, and those with longitudinal or transverse ventral hernia secondary to a previous surgical incision, measuring

5 to 15 cm after dissection of the hernial sac and classified as large or very large according to Chevrel's classification, were considered to be eligible¹¹. In individuals with multiple defects, the length between the cranial margin of the most cranial defect and the caudal margin of the most caudal defect was considered¹². Individuals subjected to emergency surgery, with infection, immunosuppressed, younger than 18 or older than 80 years old, ASA III or IV, with a serum albumin concentration lower than 3.0 g/dl or who refused participation were excluded from the study.

Surgical technique

The participants were admitted to the hospital the night before surgery to perform or update the assessment of their surgical risk according to the American Society of Anesthesiologists (ASA) criteria, as well as for measurement of the serum albumin concentration.

Incisional herniorrhaphy surgery was performed following the group's technique systematisation by a resident physician supervised by one of four surgeons professors at the medical course of UNIOESTE and who the using the onlay technique as described by Chevrel^{13,14}. Antibiotic prophylaxis was performed with a single 2g dose of cefazolin at the time of anaesthetic induction followed by a booster 1g dose when the surgery lasted more than three hours.

The aponeurosis was dissected 5 cm beyond the aponeurotic defect. After dissection, the greater thickness of subcutaneous fat was measured with sterile ruler. Recorded the longitudinal and transverse measurements of the aponeurotic defect and was calculated its area by the formula of the ellipse. Approximation of the aponeurotic margins for midline reconstruction was performed using polyglactin 910 #1 sutures. Tension was relieved by releasing incisions performed on the external oblique muscle aponeurosis, 3 cm away from the linea alba, as described by Gibson¹⁵. A macroporous polypropylene monofilament P1 mesh of 100 g/m² (Cousin Biotec) was fixed on the aponeurosis by separate 2-0 polypropylene sutures performed every 2 cm.

The participants were randomised immediately after mesh fixation by a computer-based random number generator and allocated to the two intervention groups.

Interventions

In group 1, a 4.8 mm diameter continuous closed-suction tubular drain (Medsharp Ind. Com. Prod. Hosp. Ltda – Ministério

da Saúde: 80267170001) was placed between the aponeurosis and the subcutaneous tissue caudally to the incision. Next, the subcutaneous tissue approximation was performed with separate absorbable 2-0 polyglactin 910 sutures.

Drains were not used in group 2, but separate absorbable 2-0 polyglactin 910 sutures were placed from the subcutaneous mesh to the aponeurosis every 2 cm by means of the progressive tension suture (or Quilting Sutures) technique, as described by Pollock *et al.*^{7,8}. The flap is advanced with the surgeon's nondominant hand while 2-0 polyglactin 910 sutures are placed from the subcutaneous fat to the aponeurosis. The assistant then stabilizes the flap in place while the surgeon ties the suture. The process of advancement and suture placement are initially placed in the flap lateral side edge, is repeated on lines each 2cm up to midline. This process minimize the dead space and and stabilizes the flap.

Skin closure was performed with simple separate sutures at 1 cm intervals using 4-0 nylon monofilament suture in both groups. Before closing, the skin excess and the previous scar was removed.

The participants were requested to use the support girdles provided by the surgical staff at the hospital and at home during the first 30 days after surgery.

In group 1, the drains were removed when the drained volume was less than 40 ml/24 hours.

Outcomes

All the participants were clinically assessed by the attending staff to detect postoperative complications, seroma formation and surgical site infection, especially on postoperative (PO) days one, three, five, seven, 14–16 and 29–31. The data were recorded on a pre-established form.

All the participants were subjected to abdominal wall ultrasound to assess seroma formation at three time points defined as: early (PO days four to six), intermediate (PO days 14 to 16) and late (PO days 29 to 31). The tests were performed by the radiology staff at HUOP. Seroma was defined as the collection of any volume of subcutaneous fluid without debris. All the participants remained in the hospital until the first ultrasound assessment was performed. The presence of seroma was considered as the main outcome. Clinical seroma was defined as a visible bulge or fluctuation without signs of infection, subclinical seroma was defined as the absence of detectable abnormalities on physical examination but the presence of any volume of fluid collection on abdominal wall

ultrasound, and seroma was defined as all occurrences of fluid collection detected on ultrasound.

Surgical wound infection was prospectively defined according to the criteria formulated by the Centers for Disease Control and Prevention (CDC) in the Guideline for Prevention of Surgical Site Infection, 1999¹⁶.

Sample size calculation

The sample size was calculated based on significance level $\alpha = 5\%$ and 80% power. A two-tailed test for the comparison of the two proportions was used to compare the occurrence of seroma between the groups with drains (50.0%) or progressive tension sutures (10.0%). These references reflect the incidence of seroma in the literature with these techniques in case series and clinical trials and that we considered clinically relevant^{4,8,17}.

Statistics

The initial statistical analysis of all the data collected in the present study was descriptive. In regard to the quantitative (numerical) variables, summary measures including mean, standard deviation, median, maximum and minimum values were calculated, and one-dimensional scatterplots were constructed. The data corresponding to the qualitative (categorical) variables were assessed as absolute and relative (percent) frequencies.

Inferential analysis was performed to confirm or refute the evidence found in the descriptive analysis. For that purpose, Student's t-test for independent samples was used to compare the groups of participants.

In the inferential analysis, the significance level (α) was established as 5%. The statistical analyses were performed using software R version 2.15.2.

Results

A total of 42 individuals with large incisional hernias were subjected to incisional herniorrhaphy, by the technique standardized by Chevrel, at HUOP – UNIOESTE from May to December 2012. In the sample, 10 (23.8%) were recurrent hernias, seven of whom had one previous repair. The other three patients had three previous surgeries each. Patients with recurrent hernias had a 30% postoperative infection rate against 18.75% in the non-recurrent. The incidence of postoperative seroma was 80% in recurrent hernias and 62.5% for non-recurrent hernias. There

was no significant difference between the cases recurrent or non-recurrent in the development of seroma (p=0.451) or postoperative infection (p=0.660).

The participants were randomised to receive subcutaneous drainage or progressive tension sutures. There was no loss of follow-up and all cases were analysed. No participant died or exhibited recurrence of hernia along the 30-day postoperative follow-up.

The average time elapsed from hernia diagnosis to

surgery was 42 months, varying from three to 300 months.

Only five patients required relaxing incisions, two from group 1 and three from group 2.

The average body mass index (BMI) of the sample was 30.69 kg/m², varying from 19.5 to 44.13 kg/m².

The results of the inferential comparison show that both group 1 (drains) and group 2 (progressive tension sutures) exhibited the same profile (Table 1).

TABLE 1 – Distribution of the participants’ general characteristics per intervention group.

	Group 1 (n = 21)		Group 2 (n = 21)		Total (n = 42)		p
Gender							
female	15	71.4%	14	66.7%	29	69.0%	0.739 ^a
male	6	28.6%	7	33.3%	13	31.0%	
Age (years)							
mean	55.5		52.4		54.0		0.421 ^c
median	57.0		54.0		55.5		
minimum–maximum	36.0–71.0		26.0–78.0		26.0–78.0		
standard deviation	10.6		13.9		12.3		
BMI classification							
normal ^g	1	4.8%	5	23.8%	6	14.3%	0.278 ^b
overweight ^h	7	33.3%	6	28.6%	13	31.0%	
obese ⁱ	13	61.9%	10	47.6%	23	54.8%	
Smoking							
yes	4	19.0%	6	28.6%	10	23.8%	0.469 ^a
no	17	81.0%	15	71.4%	32	76.2%	
Cardiac risk							
I	13	61.9%	16	76.2%	29	69.0%	0.317 ^a
II	8	38.1%	5	23.8%	13	31.0%	
Serum albumin ^j (g/dL)							
mean	3.9		3.8		3.9		0.434 ^c
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		

^aPearson’s chi-square test, ^bFisher’s exact test or its extension, ^cStudent’s t-test for independent samples

^gbody 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.

The groups did not differ as to the presence of seroma at the early, intermediate or late postoperative assessments (Table 2).

TABLE 2 – Distribution of the hernia characteristics according to surgical procedure.

	Group 1 (n = 21)		Group 2 (n = 21)		Total (n = 42)		p
Hernia size (cm)							
mean	9.4		9.3		9.3		0.950 ^d
standard deviation	3.2		3.2		3.2		
Subcutaneous fat thickness (cm)							
mean	3.5		2.8		3.1		0.131 ^d
standard deviation	1.2		1.4		1.3		
Hernia defect area (cm ²)							
mean	40.8		41.8		41.3		0.910 ^d
standard deviation	26.1		31.2		28.4		
Surgical time (minutes)							
Mean	114.3		124.0		119.1		0.310 ^c
Standard deviation	24.5		35.4		30.5		
Early postoperative US							
without seroma	17	81.0%	15	71.4%	32	76.2%	0.469 ^a
with seroma	4	19.0%	6	28.6%	10	23.8%	
infection	-	-	-	-	-	-	
Intermediate postoperative US							
without seroma	7	33.3%	6	28.6%	13	31.0%	0.843 ^b
with seroma	10	47.6%	12	57.1%	22	52.4%	
infection	4	19.0%	3	14.3%	7	16.7%	
Late postoperative US							
without seroma	6	28.6%	7	33.3%	13	31.0%	0.852 ^b
with seroma	11	52.4%	9	42.9%	20	47.6%	
infection	4	19.0%	5	23.8%	9	21.4%	

^aPearson's chi-square test, ^bFisher's exact test or its extension, ^cStudent's t-test for independent samples, ^dMann-Whitney test.

A total of 22 participants (52.4%) exhibited seroma at the intermediate ultrasound assessment but only two of them developed surgical wound infection, which was detected at the late assessment. Five participants exhibited symptoms that required drainage of the seromas. In 15 participants, resorption of the fluid collection occurred without any need of intervention in up to 90 days.

From the 22 seromas detected at the intermediate assessment, 14 (63.6%) were ultrasound findings, and eight (36.4%) were found on both ultrasound and clinical examination.

Five seromas were detected at the late ultrasound assessment only and were not accompanied by clinical changes. Five cases of seroma detected at the intermediate assessment exhibited resorption of fluid collection before the late assessment.

All participants of the study, regardless using or not drains, were divided according to the presence or not of seroma at early, intermediate and late assessments, and were analysed according to several variables: use of drains, gender, age, BMI

classification, cardiac risk, hernia size, subcutaneous fat thickness and surgical time. No significant differences were found between participants with and without seromas, except for shorter surgical time in the participants who exhibited seroma at the intermediate assessment ($p=0.011$).

Nine participants (21.4%) exhibited surgical wound infection at up to 30 days after surgery. The occurrence of surgical wound infection did not exhibit a difference between the groups (Table 3).

One participant required mesh removal. The results of the univariate analysis showed that the occurrence of surgical wound infection within up to 30 days after surgery was not associated with the use of drains ($p>0.999$), gender ($p=0.695$), age ($p=0.815$), BMI classification ($p=0.676$), cardiac risk ($p=0.422$), hernia size ($p=0.181$), subcutaneous fat thickness ($p>0.999$), smoking ($p=0.181$), recurrent hernia ($p=0.660$) or surgical time ($p=0.055$) (Table 3).

TABLE 3 – Distribution of the participants' general characteristics according to occurrence of infection until postoperative day 30.

	with infection (n = 9)		without infection (n = 33)		Total (n = 42)		p
Use of drain							
yes	4	44.4%	17	51.5%	21	50.0%	> 0.999 ^b
no	5	55.6%	16	48.5%	21	50.0%	
Gender							
female	7	77.8%	22	66.7%	29	69.0%	0.695 ^b
male	2	22.2%	11	33.3%	13	31.0%	
Age (years)							
mean	53.1		54.2		54.0		0.815 ^c
standard deviation	12.1		12.5		12.3		
BMI classification							
normal	1	11.1%	5	15.2%	6	14.3%	0.676 ^b
overweight	4	44.4%	9	27.3%	13	31.0%	
obese	4	44.4%	19	57.6%	23	54.8%	
Cardiac risk							
I	5	55.6%	24	72.7%	29	69.0%	0.422 ^b
II	4	44.4%	9	27.3%	13	31.0%	
Hernia size (cm)							
mean	10.6		9.0		9.3		0.181 ^d
standard deviation	2.5		3.3		3.2		
Subcutaneous fat thickness (cm)							
mean	3.2		3.1		3.1		> 0.999 ^d
standard deviation	1.8		1.2		1.3		
Smoking							
yes	4	44.4%	6	18.2%	10	23.8%	0.181 ^c
no	5	55.6%	27	81.8%	32	76.2%	
Recurrent hernia							
yes	3	33.3%	7	21.2%	10	23.8%	0.660 ^c
no	6	66.7%	26	78.8%	32	76.2%	
Surgical time (minutes)							
mean	136.3		114.4		119.1		0.055 ^c
standard deviation	28.7		29.7		30.5		

^bFisher's exact test or its extension, ^cStudent's t-test for independent samples, ^dMann-Whitney test.

Discussion

Incisional hernia repair still poses a challenge to surgeons as a function of its high rate of complications, among which seroma and surgical wound infection stand out². Those complications occur due to the considerable amount of subcutaneous tissue that is detached in herniorrhaphy using the onlay technique and are more frequent among obese patients, which corresponded to most

of the participants in the present study. Obesity represents a risk factor for hernia, as well as for repair complications¹⁸. Obesity is the main contraindication to hernia surgical repair, according to the survey of surgeons conducted by Evans in the United States, for which reason most such patients are referred for surgical treatment at reference centres¹⁹.

The most widely mentioned mechanisms for seroma formation are blood and lymphatic vessel injury during dissection,

dead-space formation, shear forces among layers and the release of inflammatory mediators. In the case of incisional herniorrhaphy, the presence of a routinely used strange body, i.e., the mesh, is added to those factors²⁰. Despite this evidence, previous surgeries fibrosis and foreign bodies (suture remains, mesh) present in patients with recurrent hernias 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 most widely used procedure to prevent seroma formation consists of the placement of drains in the subcutaneous tissue; however, several studies indicated that drains not only fail to prevent seroma formation but may even increase the risk of infection^{3, 4}. A Cochrane review on this subject did not find any evidence demonstrating a benefit of the use of drains⁹.

The fixation of the subcutaneous tissue to aponeurosis, which seemingly reduces the dead space and minimises the shear forces, was originally described by Baroudi and Ferreira in 1998 for abdominoplasty without drainage⁶. Further detail was added by Pollock⁷, and the technique was then reproduced by others²¹⁻²³. In 2012, Janis, from the University of Texas, suggested to using the progressive tension suture technique in large incisional herniorrhaphy procedures²⁴. Some authors, such as Birolini C, highlights the importance of fixing the mesh to the aponeurosis with running sutures of absorbable polyglactin 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 (63.4%), 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 52.4%. The data in the literature exhibit wide variation ranging from 0% to 100% as a function 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 90 days without sequelae, while only 22.7% of the cases required some intervention.

The occurrence of surgical wound infection was high in the present sample (21.4%) and did not correlate with any of the assessed variables, nor did its incidence exhibit significant difference between the groups. That lack of correlation and differences might have been due to beta error, as the sample size had not been calculated for that outcome. In the study by Memmon²⁸, the incidence of infection among individuals with a profile similar to that of the participants in the present study and subjected to the same surgical procedure was 21.67%. Most studies that reported on the occurrence of infection did not explain how the diagnosis was performed, and most of them are retrospective studies. For those reasons, we believe that our results exhibit less bias and are closer to the real situation in large surgical procedures performed with the onlay technique. In the study conducted by Barbaros²⁹ in 2007, the incidence of infection was reported as 0%; however, the mesh had to be removed in 17.3% of the cases, which can only be justified by the occurrence of infection. In a prospective randomised clinical trial, Misra³⁰ detected infection in 33% of the patients subjected to the onlay technique. In some retrospective case-series, the reported incidence of infection was 0%, which we believe not to be possible in this group of patients¹³. As a function of the discrepancy among the data available in the literature, we suggest that all studies employ the CDC criteria for the diagnosis of infection in a prospective manner¹⁶.

Conclusions

There was no significant difference in the incidence of seroma formation or surgical wound infection between the individuals who underwent placement of continuous suction drains in the subcutaneous tissue and those treated with the progressive tension suture technique. The incidence of both complications was high, and thus novel surgical techniques should be investigated for their prevention.

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