Surgical Endoscopy (2019) 33:1147–1154
https://doi.org/10.1007/s00464-018-6374-y

Correlation between laparoscopic transection of an indirect inguinal hernial sac and postoperative seroma formation: a prospective randomized controlled study

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Received: 19 January 2018 / Accepted: 20 July 2018 / Published online: 16 October 2018

Abstract

Background Seroma is the most common early minor complication of inguinal hernia repair. Seromas generally resolve spontaneously within a few weeks, but can sometimes cause other complications. The optimal ways to repair inguinal hernia and handle the hernial sac are still debatable. Large scale, prospective, randomized, controlled studies focusing on the correlation between transection of the hernial sac and seroma formation are scarce.

Methods A total of 159 adult male patients with primary indirect inguinal hernia who underwent laparoscopic transabdominal preperitoneal repair were recruited. The patients were randomized to undergo either complete dissection or transection of the hernial sacs. Patients were followed up at postoperative 7 days, 1 and 3 months, looking specifically for seroma. Seroma was diagnosed via physical examination, and a prestructured form was used to evaluate patient recovery and define the type of seroma present at each follow-up visit.

Results There were 83 patients in the completely dissected group and 76 in the transected group. The overall incidence of postoperative seroma was 12.6% ($n=20$). The χ^2 test demonstrated that significantly more patients developed seroma in the transected group than in the completely dissected group (18.4% vs. 7.2%, $p=0.034$); there were also significant differences between the two groups in the incidences of seroma at postoperative 7 days (18.4% vs. 6.0%, $p=0.016$) and 1 month (14.5% vs. 4.8%, $p=0.037$). Seroma formation was correlated with age, body mass index, use of anticoagulants, hernia type, hernia size, sac size, and operative time. There were no significant differences between the two groups in the degree of postoperative pain and time taken for the resumption of outdoor activities.

Conclusions When using the laparoscopic transabdominal preperitoneal technique for indirect inguinal hernia repair, the risk of postoperative seroma formation is greater after transection compared with complete dissection of the hernial sac.

Keywords Inguinal hernia · Seroma · Laparoscopic repair · Hernial sac · TAPP

A seroma is a sterile accumulation of serum in a circumscribed location in the tissue, and is the most common early minor complication after inguinal hernia repair [1]. Seromas usually resolve within a few weeks; however, this condition can sometimes lead to many other complications. An infected seroma is one of the most challenging complications, and can even result in mesh removal [2] and hernia recurrence [3]. Furthermore, patients can misperceive a seroma as a persistent or recurrent hernia.

The optimal ways to repair inguinal hernias and handle the hernial sacs are still debatable, with only few reports on this issue in the literature. For indirect hernias that are difficult to treat, it is suggested that the hernial sacs are transected to prevent spermatic cord injuries and lower the chance of scrotal hematoma; in contrast, complete dissection of large indirect sacs reportedly carries a risk of harming the cord structures or disturbing the blood circulation to the testis [4]. Failure to dispose of the distal sacs may result in large and potentially cumbersome hematomas, seromas, or pseudohydroceles [4, 5]. The clinical factors reportedly associated with seroma formation include old age, large hernial defects, extension of the hernia into the scrotum, and the

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presence of a residual distal indirect sac. For inguinoscrotal hernias, it has been recommended that the indirect sac is transected near the deep ring, leaving the open distal sac in situ, as removing the whole indirect sac may increase the risks of bleeding, damaging spermatic cord structures, and prolonging the operation [6]. However, Leibl et al. [7] reported that transecting the indirect sac near the deep ring, leaving the open distal sac in situ, is also a risk factor for seroma formation, and that completely dissecting the hernial sac helps to expose the small end of the sac, enabling safe identification of the spermatic cord structures. No previous randomized controlled trial has compared complete dissection versus transection of the inguinal hernial sac, and reported the exact repercussions on postoperative seroma formation. The aim of the present study was to determine whether there was a correlation between transection of the hernial sac and seroma formation after laparoscopic inguinal hernia repair, and to compare the incidence of postoperative seroma formation after transection with complete dissection of the hernial sac.

Materials and methods

The present prospective, randomized, controlled study was conducted in a single surgical unit of the Department of General Surgery at the Qilu Hospital of Shandong University, Jinan. From May 2015 to September 2017, 159 consecutive adult male patients with primary indirect inguinal hernia who underwent laparoscopic transabdominal preperitoneal repair performed by an experienced surgeon were registered and randomly assigned to either the completely dissected group or the transected group. Randomization was achieved via random numbers generated using Excel software. The inclusion and exclusion criteria are listed in Table 1.

Demographic characteristics

The demographic characteristics of the patients were defined by the following variables: age, body mass index (BMI), hospital stay, comorbidities such as diabetes mellitus, chronic constipation, and hypertension, use of anticoagulants, nicotine abuse, ASA classification, and hernia-related details including type, duration, and size measured during physical examination.

Preoperative management

Standard preoperative work-up for laparoscopic procedures was done, including chest radiography, electrocardiogram, routine blood tests, indicated pulmonary function testing, and nutritional instruction. Prophylactic antibiotics and urinary catheters were not used unless specifically indicated.

Table 1 Inclusion and exclusion criteria

Inclusive criteria
Adult male patients with primary inguinal hernia
ASA I, II or III compensated
Exclusive criteria
Recurrent hernia
Patients with contraindications of laparoscopic surgery, such as
Poor cardiopulmonary function or any vital organ dysfunction
ASA III not compensated or ASA IV
Ileus
Blood coagulation disorder
History of several abdominal surgery
Conversion to open repair

ASA American society of anesthesiologists

Operative technique

The whole procedure was a standardized transabdominal preperitoneal technique similar to that described by Krishna et al. [8]. Pneumoperitoneum up to 12 mmHg was created with CO_2 using a Veress needle through a 10 mm cambered incision precisely located at the upper edge of the umbilicus, and a standard 10 mm trocar was placed 1 cm below the umbilicus for insertion of the 10 mm 30° laparoscope. Two extra 5 mm trocars were placed approximately horizontal on either side of the umbilicus at the lateral borders of the rectus abdominis muscle to form a triangulation. After the standardized and precise dissection, the size of the hernial sac and internal ring were measured with a rod under the laparoscope. The hernial sac was then either completely dissected from the spermatic cord and testicular vessels after parietalization (completely dissected group) or partially dissected and then transected (transected group). If a contralateral hernial sac was found, it was treated in the same way. After gentle blunt dissection, an appropriately sized space was created to accommodate a self-adhesive large-sized (10.3 cm × 15.7 cm) lightweight polypropylene mesh (Bard® 3D Max, no. 0117311 and 0117321) that had been preshaped to fit the defect perfectly; the mesh was rolled and introduced via the 10 mm umbilical port into the created space, and then unrolled to cover the entire myopectineal orifice on the hernia side(s) without fixation. The peritoneal flap was closed using 2–0 prolene in a continuous suture pattern (covering the mesh completely).

Postoperative assessment

Patients were given regular postoperative instructions on discharge, including using a compressive dressing for 10 days, resuming normal activity when able, and temporary abstinence from physical labor for 3 months.

The primary outcome of the present trial was the occurrence of seroma within 3 months after hernia repair. We prospectively followed up the patients at postoperative 7 days, 1 and 3 months, looking for signs or symptoms of seroma. Regular physical examination to diagnose seroma was performed at each follow-up visit by the same surgeon; ultrasound and CT scan were not used for seroma diagnosis. The duration of follow-up was extended to 6 months only when a seroma was still present at the 3 month postoperative follow-up examination. A prestructured form was designed to record seroma-related complications, treatments, seroma classification [9], and postoperative pain based on a visual analog scale where 0 indicated no pain and 10 indicated the worst pain imaginable; the time taken for the resumption of outdoor activity was also included. Univariate logarithmic regression analysis was carried out using SAS® (version 3.5.0), while the Statistical Package for Social Sciences software (SPSS®, version 24.0) was used for the rest of the statistical analyses.

Ethics approval

This registered clinical trial was approved by the local ethics committee, and written informed consent was obtained from all patients for the whole procedure and for later publication of their personal data.

Results

After excluding 32 patients due to inadequate follow-up visits and missed appointments, a final total of 159 qualified patients were ultimately included. Patients who were not diagnosed with seroma at the first or second follow-up visits (at postoperative 7 days and 1 month) were not required to attend the third follow-up visit (at postoperative 3 months), and the clinical visits after 6 months were not included in the statistical analysis. Hence, the follow-up duration ranged from 1 to 6 months, and the average follow-up duration was 3.1 ± 0.7 months. There were 83 patients in the completely dissected group and 76 in the transected group. The classification system of Gilbert [10] was applied to describe the complexity of hernias in the present study, and the unpaired Students' *t*-test showed that there were no significant differences between the two groups in any assessed parameter (Table 2).

The numbers of patients who developed postoperative seroma in the total group (including all 159 study participants), the completely dissected group, and the transected group were 20 (12.6%), 6 (7.2%), and 14 (18.4%), respectively; the χ^2 test showed that there was a significant difference between the groups in the incidence of postoperative seroma formation ($p = 0.034$). The seroma occurrence, postoperative pain at each follow-up visit, and time taken for the resumption of outdoor activity in the two groups were analyzed using the Students' *t*-test (Table 3). Of the 20 patients with seroma (Table 4), 17 (85.0%) were asymptomatic, and the seroma absorbed spontaneously within 3 months in 13 (65%). In the four asymptomatic patients with a seroma still present at 3 months postoperatively, aspiration was not used due to concerns regarding contamination; aspiration was needed for 2 patients in the completely dissected group because the bulges on the abdomen were unaltered in size, and for 1 patient in the transected group for whom the seroma caused substantial discomfort. In total, the seroma resolved within 6 months in 19 of 20 patients (95%), while 1 patient with obesity (BMI 35.3 kg/m^2) in the completely dissected group had a persistent seroma at 6 months postoperatively that eventually resolved after several more aspirations (Fig. 1). No drainage was used in any patient. There were no significant differences between the two groups in the overall comparison of follow-up data from patients with seroma (Table 5). As most seromas did not cause further problems, the impact of seroma was analyzed by comparing the time taken for the resumption of outdoor activity and the postoperative pain of patients with seroma versus those without seroma; this analysis revealed that those with seroma reported a significantly greater degree of pain at postoperative 1 and 3 months than those without seroma (Table 6).

A univariate logarithmic regression analysis was performed to identify whether the development of seroma was correlated with factors such as age, BMI, hospital stay, comorbidities, ASA classification, hernia duration, hernia type, hernia size, hernial sac size, and operative time by comparing patients who developed postoperative seroma with those who did not. Significant correlations were found between seroma formation and age, BMI, use of anticoagulants, hernia type, hernia size, hernial sac size, and operative time (Table 7).

The mortality in the present series was 0%. No other seroma-related complications like hernia recurrence, infection, or mesh rejection occurred during the study period.

Table 2 Comparison of demographics, comorbidities, and hernia characteristics of patients in two groups

Variables	Completely dissected ($n=83$)	Transected ($n=76$)	p value
Demographic characteristics			
Age (years)	53.4 ± 18.2	50.1 ± 20.4	0.406
BMI (kg/m^2)	24.5 ± 3.2	24.9 ± 2.9	0.436
Hospital stay (days)	5.7 ± 2.4	5.5 ± 3.2	0.571
Smoking	31.3%	30.3%	0.886
Anticoagulant use	6.0%	13.2%	0.132
ASA	1.8 ± 0.5	1.6 ± 0.7	0.149
I	26.5%	46.1%	
II	68.7%	43.4%	
III	4.8%	10.5%	
Operative time (min)	65.9 ± 27.5	62.0 ± 19.4	0.298
Comorbidities			
Chronic constipation	8.4%	11.8%	0.479
Diabetes	3.6%	5.3%	0.615
Hypertension	18.1%	15.8%	0.704
Hernia characteristics			
Hernia duration			0.654
≤ 1 month	21.7%	21.1%	
≤ 6 months	27.7%	25.0%	
≤ 1 year	15.7%	13.2%	
≤ 5 years	13.3%	18.4%	
> 5 years	21.7%	22.4%	
Hernia type			0.649
Unilateral indirect hernia	85.5%	82.9%	
Bilateral indirect hernia	14.5%	17.1%	
Irreducible hernia	1.2%	3.9%	0.285
Hernia size (cm^2)	20.8 ± 20.4	23.8 ± 22.1	0.388
Sac size (cm^2)	23.3 ± 20.9	23.1 ± 24.5	0.954
Hernia classification			0.582
Type I	15.7%	17.1%	
Type II	66.3%	68.4%	
Type III	18.1%	14.5%	

Data are expressed as mean ± SD or as percentages

BMI body mass index

Students' t-test was used and a p value of < 0.05 is considered significant

Discussion

There is currently no consensus on the best way of handling the inguinal hernial sacs, and even the exact cause of seroma is not yet completely understood; therefore, we decided to perform the present study. The overall occurrence of seroma in our research was 12.6% using diagnosis only via physical examination to identify a suspected bulge in the abdomen and/or fluid wave, especially when patients reported abdominal discomfort or tension on the skin. Susmallian et al. [11] suggested that when ultrasound instead of physical examination is used for diagnosis, seroma is detected in 100% of laparoscopic hernia repairs. The main reason that imaging techniques were not routinely used for seroma diagnosis in the present study was the concern that extra fees or tests would probably result in patients' unwillingness to continue follow-up visits, leading to the eventual reduction of participants. Moreover, asymptomatic seroma found on ultrasound or CT scan does not have clinical significance. Despite the possibility that some seromas were undetected, having the same surgeon performing all of the physical examinations is a good way of minimizing variations in seroma diagnoses; hence, we consider that the present results are trustworthy.

In our trial, most seromas did not cause any further problems except for more pain, which is not what we usually consider a serious concern; however, the short duration

Table 3 Comparison of seroma occurrence, postoperative pain, and time of resuming outdoor activity

	Completely dissected ($n=83$)	Transected ($n=76$)	p value
Seroma occurrence			
Overall occurrence	7.2%	18.4%	0.034*
Seroma at 7 days	6.0%	18.4%	0.018*
Seroma at 1 month	4.8%	14.5%	0.042*
Seroma at 3 months	2.4%	6.6%	0.201
Seroma at 6 months	1.2%	0	–
Postoperative pain			
Pain at 7 days	1.7 ± 1.0	1.6 ± 1.1	0.502
Pain at 1 month	0.9 ± 0.8	0.9 ± 0.8	0.933
Pain at 3 months	0.4 ± 0.6	0.5 ± 0.5	0.285
Time of resuming outdoor activity (days)	5.2 ± 5.2	5.4 ± 5.0	0.840

Data are expressed as mean ± SD or as percentages

* Students' t-test was used and a p value of < 0.05 is considered significant

of follow-up makes it impossible to assess the differences between the two groups in long-term outcomes. Due to the potential risk of unexpected consequences from seroma, many surgeons have created methods to decrease seroma formation. Daes [12] suggested that reduction and fixation of the distal sac high and laterally to the posterior inguinal wall would benefit patients with large inguinoscrotal hernias and sacs extending deep into the scrotum. Reddy et al. [13] reported that inverting the lax transversalis fascia by tacking it to the pubic ramus lowers the incidence of postoperative seroma formation in direct hernia repairs. Some other controversial ways suggested to reduce the incidence of seroma, such as placing suction drains or performing evacuating punctures, have been shown to be ineffective, because they failed to avoid the appearance of seroma and enhanced the risk of potential contamination [14]. No hernia repair performed in the present study involved the use of drainage or other therapeutic methods as measures to prevent seroma formation; the only factor that played a role in reducing seroma formation was the complete dissection of hernial sacs, which proved to be effective. When a hernial sac is transected and left in situ, increased exudation is more likely to happen, which accounts for the seroma formation.

Anticoagulants are reportedly one of the risk factors for seroma formation, as leakage of plasma fluid (serum) can

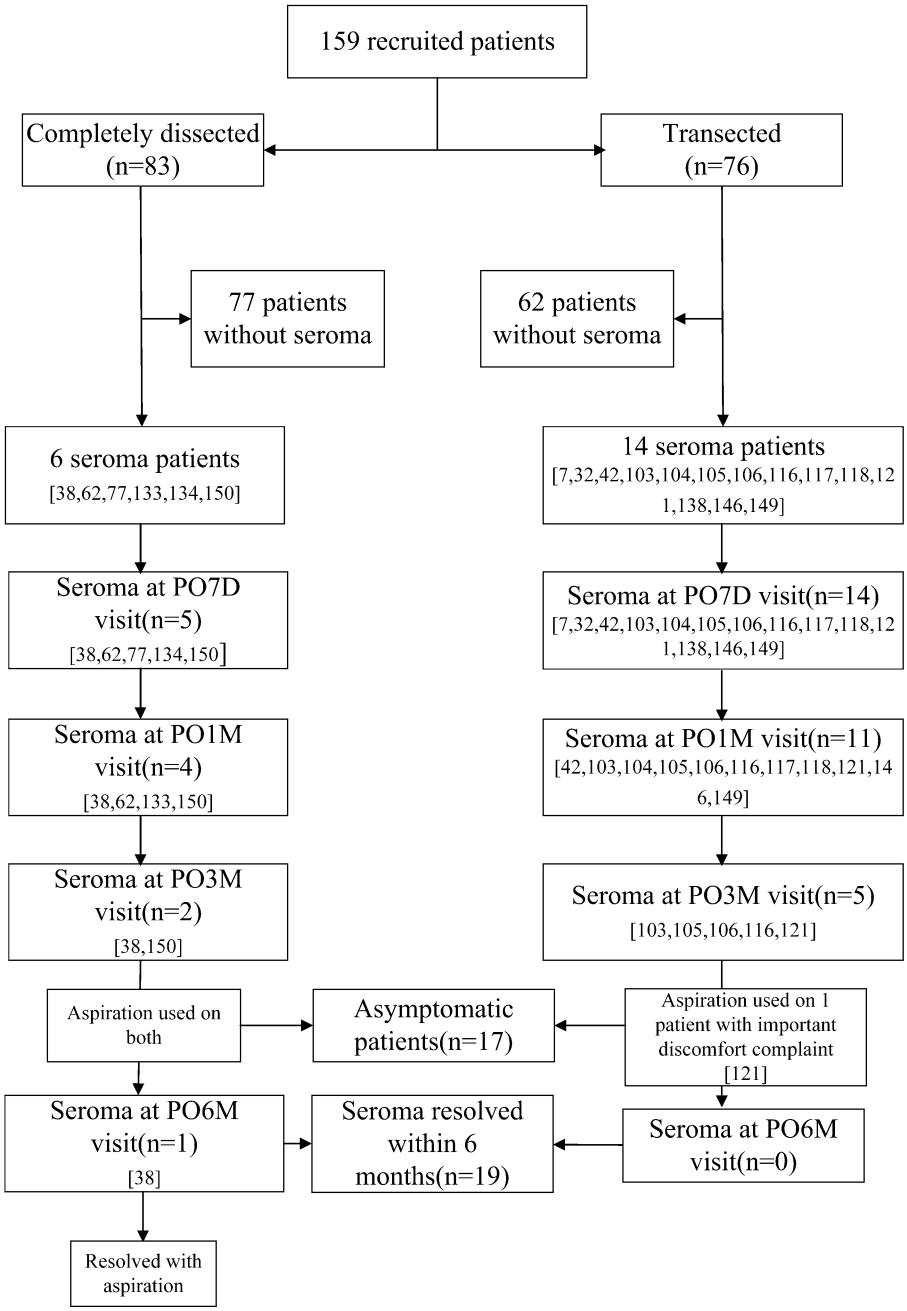
Table 4 Details of seroma patients

	Patient's number	Age	BIM (kg/m^2)	Hernia type	Hernia classification	Sac size (cm^2)	Seroma duration (m)	Seroma type	Seroma treatment
Completely Dissected ($n=6$)	38	31	35.3	UIH	II	15	> 6	IIIa	Aspiration
	62	47	29.1	BIH	II	18	< 3	IIa	
	77	61	26.8	BIH	III	44	< 1	I	
	133	65	20.5	BIH	III	108	< 3	IIa	
	134	62	27.6	UIH	II	32	< 1	I	
	150	62	29.7	BIH	III	39	< 6	IIb	Aspiration
Transected ($n=14$)	7	71	22.4	UIH	II	32	< 1	I	
	32	69	27.8	UIH	II	15	< 1	I	
	42	65	27.9	BIH	II	17	< 3	IIa	
	103	77	29.7	BIH	III	38	< 6	IIb	
	104	75	26.7	BIH	III	39	< 3	IIa	
	105	54	27.4	UIH	III	40	< 6	IIa	
	106	83	26.0	BIH	III	140	< 6	IIa	
	116	59	29.0	UIH	III	48	< 6	IIb	
	117	64	27.8	BIH	II	17	< 3	IIa	
	118	45	26.0	BIH	II	16	< 3	IIa	
	121	54	31.9	UIH	III	160	< 6	IIIc	Aspiration
	138	66	22.6	UIH	II	21	< 1	I	
	146	32	25.4	BIH	III	44	< 3	IIa	
	149	72	25.3	UIH	III	72	< 3	IIa	

Sac size on each side was added up for patients with bilateral indirect hernias

UIH unilateral indirect hernia, *BIH* bilateral indirect hernia

Fig. 1 Flowchart of follow-ups



Patients' numbers are shown in the brackets

be caused by anticoagulants [15]. The correlations that we found between seroma formation and age and BMI were similar to previous studies [8, 16]. In patients with obesity, the wound cavity is disproportionately enlarged, promoting seroma formation [17]. We also found correlations between seroma formation and hernia size, hernial sac size, and operative time. Hernias that are larger-sized or with the hernial sacs extending into the scrotum are more likely to result in seroma formation [8]. Furthermore, larger hernial sacs require a longer operative time and more extensive and substantial tissue disruption, increasing the risk of creating a space in which serum can accumulate. In agreement with our findings, Reddy et al. [18] suggested that the best way of preventing seroma formation was to handle the tissues as gently as possible, and to avoid creating any dead space in which a seroma could form. However, even before this, apart from performing complete dissection of the hernial sacs when the spermatic cord and other structures are secured, we would like to emphasize the importance of precise and blunt dissection, careful and clear identification of blood vessels, and minimizing the use of electrocoagulation, which contributes

Table 5 Comparison of follow-up record of seroma patients

	Completely dissected ($n=6$)	Transected ($n=14$)	p value
Time of resuming outdoor activity (days)	5.8 ± 3.7	5.9 ± 3.4	0.989
Postoperative pain			
Pain at 7 days	1.7 ± 0.5	1.6 ± 0.8	0.950
Pain at 1 month	1.2 ± 0.8	1.3 ± 0.6	0.713
Pain at 3 months	0.7 ± 0.5	0.7 ± 0.5	0.842
Seroma duration (months)			
< 1	2	3	
< 3	2	6	
< 6	1	5	
> 6	1	0	
Seroma classification			0.938
I	2	3	
IIa	2	8	
IIb	1	2	
IIIa	1	0	
IIIc	0	1	
Seroma treatment			
Aspiration	2	1	

Data are expressed as number of patients or mean ± SD

Students' t-test was used and a p value of < 0.05 is considered significant

Table 6 Comparison of seroma and non-seroma patients on time of resuming outdoor activity and postoperative pain

	Seroma patients ($n=20$)	Non-seroma patients ($n=139$)	p value
Time of resuming outdoor activity (days)	5.9 ± 3.4	5.2 ± 5.3	0.594
Postoperative pain			
Pain at 7 days	1.7 ± 0.7	1.6 ± 1.1	0.870
Pain at 1 month	1.3 ± 0.6	0.8 ± 0.8	0.012*
Pain at 3 months	0.7 ± 0.5	0.4 ± 0.6	0.035*

Data are expressed as mean ± SD

* Students' t-test was used and a p value of < 0.05 is considered significant

to less exudation, reducing seroma formation. Patients in the transected group with bilateral indirect hernias had both hernial sacs transected, and there was a significantly greater incidence of seroma formation in patients with bilateral versus unilateral hernia ($p < 0.01$); transection on both sides at least doubled the chance of seroma development after the hernia repair, which provides a simple explanation for the correlation between hernia type and seroma, indicating that transection does increase the risk of postoperative seroma formation.

Table 7 Results of univariate logarithmic regression analysis

Variables	OR	2.5%	97.5%	p
Age	1.03	1.00	1.06	0.040*
Hospital stay	1.16	0.99	1.36	0.070
Hernia duration (vs. ≤ 1 month)				
≤ 6 months	3.20	0.71	22.55	0.165
≤ 1 year	1.52	0.17	13.51	0.685
≤ 5 years	3.05	0.54	23.42	0.221
> 5 years	2.67	0.53	19.61	0.262
Chronic constipation	0.99	0.15	3.96	0.992
Diabetes	1.17	0.06	7.36	0.889
Hypertension	0.51	0.08	1.91	0.382
Use of anticoagulants	6.19	1.85	19.93	0.002*
Smoking	0.96	0.32	2.56	0.933
Hernia size	1.02	1.01	1.04	0.009*
Bilateral hernia (vs. unilateral hernia)	10.91	3.90	31.82	0.000**
Operative time	1.02	1.00	1.04	0.022*
Sac size	1.04	1.02	1.06	0.000**
BMI	1.42	1.19	1.76	0.000**
ASA (vs. ASA I)				
ASA II	2.44	0.82	8.98	0.133
ASA III	2.65	0.34	15.64	0.296

* $p < 0.05$

** $p < 0.001$

Conclusion

Although seromas are generally considered acceptable and are thought to have no substantial impact on recovery [19], seroma can lead to unexpected complications such as infection, mesh removal, and even hernia recurrence in some cases. Hence, surgeons should still apply proper attention and effort to reducing seroma formation. Compared with complete dissection of the hernial sacs, transection leaves an open distal sac, carrying a greater risk of postoperative seroma formation, despite no clinically significant differences being detected in our study. To reduce seroma formation, indirect hernial sacs need to be dissected as completely as possible, while protecting the important structures from injury.

Acknowledgements The authors thank Ph.D. student Alim Dayim for performing logarithmic regression analysis.

Compliance with ethical standards

Disclosures Rexiati Ruze, Zhibo Yan, Qunzheng Wu, Hanxiang Zhan, and Guangyong Zhang all have no conflicts of interest or financial ties to disclose.

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