A randomised controlled study on the effects of hernial sac stump fenestration on ultrasound seroma prevention in laparoscopic Type III inguinal hernia repair

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Original Article

Background: The incidence of ultrasound seromas has significantly increased after large hernial sac surgery. Several methods are available for preventing ultrasound seromas, but the clinical results are poor. It has also been demonstrated that hernial sac stump fenestration during laparoscopic incisional hernia repair surgery can significantly decrease the incidence of ultrasound seromas.

Materials and Methods: Ninety patients aged 18–75 years who were treated in our hospital for primary Type III indirect inguinal hernia from March 2017 to March 2018 were randomised to a preventive fenestration group and a control group. All patients underwent transabdominal preperitoneal repair. The number of ultrasound seromas in the inguinal regions and ultrasound seroma volume on day 6 and months 1 and 3 after surgery in the two groups were compared. The secondary outcomes included length of surgery, urinary retention, acute pain, chronic pain, length of hospitalisation, recurrence rate and other complications.

Results: There were no significant differences in demographic characteristics. Ultrasound seroma incidence and ultrasound seroma volume on day 6 and months 1 and 3 after surgery were significantly lower in the preventive fenestration group than that in the control group. There were no significant differences in the length of hospitalisation or incidence of acute pain or urinary retention between the two groups.

Conclusions: Hernial sac stump fenestration after hernial sac transection in inguinal hernia repair surgery is a simple method that can effectively reduce post-operative ultrasound seromas.

Keywords: Hernial sac fenestration, indirect inguinal hernia, ultrasound seromas

INTRODUCTION

Compared with open surgery, laparoscopic inguinal hernia repair surgery has advantages such as mild post-operative pain, faster recovery and low recurrence rate.1-4 However, post-operative ultrasound seromas are more common in

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these types of surgeries. Fan[8] reported that the incidences of ultrasound seromas 1 and 6 days and 1 month after laparoscopic inguinal hernia repair surgery were 25.6%, 60.3% and 13.2%, respectively. Li and Ruze[6,7] reported that the incidences of seromas 1 week and 1 month after laparoscopic inguinal hernia repair surgery were 12.9%–18.4% and 2.9%–14.5%, respectively, and the incidence of ultrasound seromas had significantly increased after a large hernial sac surgery. Small ultrasound seromas can be spontaneously absorbed, but larger ones can cause pain or even the illusion of hernial recurrence to both patients and physicians. This causes some patients to return to the hospital multiple times for diagnosis and treatment, thus decreasing patient satisfaction.[9] The prevention of ultrasound seromas after laparoscopic inguinal hernia repair surgery is a major problem for hernia surgeons. One study found that large hernial sac and scrotal hernial sac were the main factors for ultrasound seromas. Currently, there are many methods available to prevent ultrasound seromas (e.g., inserting a drainage tube in the preperitoneal space), but the clinical results are poor.[9] It has also been demonstrated that hernial sac stump fenestration during laparoscopic incisional hernia repair surgery can significantly decrease the incidence of ultrasound seromas.[10] The clinical effects of hernial sac stump fenestration during laparoscopic inguinal hernia repair surgery require further study. We conducted a randomised controlled study to compare the ultrasound seroma prevention effects between hernial sac stump fenestration and hernial sac stump non-treatment during laparoscopic inguinal hernia repair surgery.

MATERIALS AND METHODS

Study population
This study was conducted at the Department of Gastrointestinal Surgery in the Second Affiliated Hospital of Kunming Medical University. Annually, the department conducts laparoscopic inguinal hernia repair surgery on 800 patients. Patients enrolled in this study were diagnosed with indirect inguinal hernia during consultation at the surgical outpatient clinic. The inclusion criteria were (1) male, (2) primary indirect inguinal hernia, (3) age 18–75 years and (4) Type III hernia according to the Gilbert classification.[11] The exclusion criteria were (1) direct inguinal hernia, irreducible hernia, recurrent hernia or incarcerated hernia; (2) history of lower abdomen surgery or peritonitis; (3) coagulation disorder; (4) severe psychiatric disorder; (5) chronic pain or long-term drug abuse and (6) significant comorbidities. The trial lasted from 1 March 2017, to 1 March 2018.

The trial was approved by the Ethics Committee of the Second Affiliated Hospital of Kunming Medical University according to the Ethical Principles for Medical Research Involving Human Subjects in the Declaration of Helsinki published by the World Medical Association. All surgeries were conducted in accordance with good clinical practice and Chinese laws. All patients provided signed informed consent. All surgeries were completed by the same surgeon, who held an associate director title.

Randomisation and blinding
A computer-generated random sequence was used to randomise the two groups. Patients were randomised 1:1 to a preventive fenestration group and a control group (untreated hernial sac stump). During the post-operative follow-up period, the surgeon and the radiologist evaluated the clinical and ultrasound evidence for seromas, surgical outcomes and complications. The patients, the surgeon and the radiologist were blinded to treatment allocation. All data were collected prospectively.

Study interventions
The procedure for laparoscopic inguinal hernia surgery was carried out in strict accordance with the Operating Guidelines for Laparoscopic Inguinal Hernia Surgery stipulated by the Chinese Society of Surgery. In this study, after the Bogros space and Retzius space were freed, the hernial sac was transected at the inner hernial ring. Peritonealisation of the spermatic cord for 6–8 cm was performed, and the proximal end of the transected hernial sac was sutured and sealed, while the distal hernial sac was excluded. In the preventive fenestration group, after hernial sac transection [Figure 1], the assistant pushed the bottom of the hernial sac out from the ring [Figure 2] and used a dissecting forceps to lift the bottom of the hernial sac. Around 2 cm × 2 cm of hernial sac wall was resected from the bottom of the hernial sac using an electric scissors [Figure 3], and attention was paid to haemostasis. The hernial sac was then reduced into the scrotal sac [Supplementary Video 1]. The hernial sac stump was not treated in the control group. EasyProsthes™ lightweight three-dimensional repair patches (Beijing, China), 12 cm × 16 cm, were used but not fixed. All surgeries were completed by the same surgical team.

Seroma definition
Ultrasound seroma is defined as a mass that does not increase in size with coughing and can be observed clinically. Further, the mass is confirmed as a fluid-containing structure using B-ultrasound at the inguinal region.
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Primary results
The number and volume of ultrasound seromas at the inguinal region on day 6 and months 1 and 3 after surgery were compared between the two groups.

Secondary results
The secondary outcomes included length of surgery, length of hospitalisation, urinary retention, acute pain, chronic pain (pain persisting for 3 months), recurrence rate and other complications. Pain was measured using the visual analogue scale (VAS) (range: 0–10). A 10-cm line was drawn and marked equidistant, 0–10, with 0 meaning no pain and 10 meaning the most severe pain. Patients with a VAS >5 were considered to have acute pain.

Sample size calculation and statistical analysis
Sample size calculation was based on a retrospective analysis of hernial sac stump fenestration in inguinal hernia repair surgery from 1 June to 1 December, 2016. The incidence of seromas 6 days post-operatively after hernial sac stump fenestration was assumed to decrease by 50%. With a confidence interval of 95% and a power of 80%, the sample size per group was estimated to be at least 45. Prospective data such as demographics, hernia characteristics and hernia treatment were collected and analysed. Analysis was performed using SPSS version 18.0 (SPSS Inc., Chicago, IL, USA). All continuous variables were expressed as mean and standard deviation, and independent sample \( t \)-tests were used for analysis. The Chi-square test was used for all categorical variables. A difference of \( P < 0.05 \) was considered statistically significant.

RESULTS

From 1 March 2017, to 1 March 2018, 125 consecutive patients were screened, among which 90 were ultimately enrolled and randomised. The main reasons for exclusion were refusal to participate in the study, direct inguinal hernia and significant comorbidities [Figure 4]. All patients were male with Gilbert Type III hernia, had a hernial defect >3 cm and had undergone transabdominal preperitoneal repair. Seventy-seven patients had unilateral indirect inguinal hernia. There was no significant difference in hernial size before surgery between the two groups (23.6 \( \pm \) 6.3 cm\(^2\) vs. 22.8 \( \pm \) 5.9 cm\(^2\), \( P > 0.05 \)). There were no significant differences in demographic characteristics, such as age, sex, body mass index, hernial size and follow-up duration between the two groups [Table 1].

Table 2 shows the surgical outcomes. The total incidences of ultrasound seromas on day 6 and months 1 and 3 after
surgery were 32.2% and 16.7% and 6.7%, respectively. The incidences of ultrasound seromas on day 6 and months 1 and 3 after surgery in the preventive fenestration group were significantly lower than that in the control group (4.4% vs. 60.0%, \( P < 0.001 \) and 0 vs. 33.3%, \( P < 0.001 \) and 0 vs. 13.3%, \( P < 0.001 \), respectively). Ultrasound seroma volumes on day 6 and months 1 and 3 after surgery in the preventive fenestration group were significantly lower than that in the control group (4.4% vs. 60.0%, \( P < 0.001 \) and 0 vs. 33.3%\(, P < 0.001 \) and 0 vs. 13.3%\(, P < 0.001 \), respectively). The length of surgery in the preventive fenestration group was longer than that in the control group (54.3 ± 8.5 min vs. 50.6 ± 7.30 min, \( P < 0.05 \)). There was no significant difference in the number of patients with acute pain after laparoscopic hernia repair surgery or length of hospitalisation between the two groups.

## DISCUSSION

Laparoscopic inguinal hernia repair surgery has many advantages, but ultrasound seromas have troubled clinicians and patients. In this study, we employed a simple technique to solve this problem. We conducted a randomised controlled trial to evaluate the effects of hernial sac stump fenestration on ultrasound seroma prevention after laparoscopic inguinal hernia repair surgery.

In this study, the incidence of ultrasound seromas at day 6 after surgery was significantly lower in the preventive fenestration group compared with that of the control group (2 vs. 27), and ultrasound seromas spontaneously disappeared at the 1-month follow-up after surgery in those two patients. In the control group, there were 15 and 6 patients with ultrasound seromas at months 1 and 3 after surgery, respectively. The ultrasound seromas that were present at month 3 disappeared after multiple punctures and drainage. Ultrasound seroma volume in the preventive fenestration group at day 6 after surgery was significantly lower than that in the control group, and ultrasound seromas disappeared 1 month after surgery. In the control group, ultrasound seroma volumes at months 1 and 3 after surgery were 20.8 ± 8.1 ml and 15.7 ± 3.3 ml, respectively. The length of surgery was longer in the preventive fenestration group than that in the control group by 3.70 min, mainly because hernial sac fenestration increased the length of surgery. There were no significant differences in the incidence of post-operative acute or chronic pain, early recurrence or other complications between the two groups. These results showed that hernial sac stump fenestration can significantly reduce the incidence of post-operative seromas, does not increase complications and can increase patient satisfaction.

During laparoscopic inguinal hernia surgery, tissue spaces caused by the stripping of the hernial sac are the main reason for ultrasound seromas. The surgical dissection wound continuously exudes liquid that flows into the distal hernial sac stump, which is lowest in the inguinal region. The hernial sac stump forms a closed cavity with inner ring adhesions, resulting in the ultrasound seromas that are commonly seen in clinical practice.\(^8\) Ultrasound seromas mostly spontaneously disappear 2–3 months after inguinal hernia surgery;\(^12,13\) but during that period, they cause anxiety, dissatisfaction and discomfort for patients and affect their normal life and work. In addition, ultrasound seromas in some patients do not completely disappear.

### Table 1: Baseline demographic characteristics

|                       | Preventive fenestration group | Control group | \( P \) |
|-----------------------|-------------------------------|---------------|--------|
| Age (year), mean±SD   | 61.50 (7.38)                 | 63.10 (6.45)  | >0.05  |
| BMI (kg/m\(^2\))      | 22.6±4.1                     | 23.7±3.9      | >0.05  |
| Sex, n (%)            |                               |               |        |
| Male                  | 45 (100)                      | 45 (100)      | >0.05  |
| Female                | 0 (0)                         | 0 (0)         | >0.05  |
| Hernia type, n (%)    |                               |               |        |
| Unilateral            | 38 (84.4)                     | 39 (86.7)     | >0.05  |
| Bilateral             | 7 (15.6)                      | 6 (13.3)      | >0.05  |
| Size of hernial defect, n (%) |                   |               |        |
| >3 (cm)               | 45 (100)                      | 45 (100)      | >0.05  |
| <3 (cm)               | 0                             | 0             | >0.05  |
| Hernial size (cm\(^2\)), mean±SD | 23.6±6.3                     | 22.8±5.9      | >0.05  |
| Follow-up time (month), mean±SD | 12.6±1.5                     | 12.5±1.7      | >0.05  |

BMI: body mass index, SD: standard deviation
over time. For small hernial sacs, there is a tendency for complete excision of the hernial sac. For large or scrotal hernial sacs, complete stripping of the hernial sac is not only time-and-effort intensive but also increases the risk of spermatic cord injury and bleeding. Therefore, it is recommended that hernial sac transection be carried out.

A certain proportion of patients will develop ultrasound seromas if the distal hernial sac is excluded but not treated after transection. To prevent ultrasound seromas, Daes transected large hernial sacs before pulling the distal hernial sac from the preperitoneal space and used tacks to fix these sacs on the ipsilateral anterior abdominal wall. Although this method can somewhat reduce the amount of fluid that enters the scrotum from the preperitoneal space and reduce ultrasound seromas, it increases surgical cost and duration, and a large proportion of patients still develop ultrasound seromas. Some studies found that preperitoneal drainage could significantly reduce post-operative seromas, but this is difficult to apply in clinical practice for the following reasons: (1) fluid exudation from the wound on the preperitoneal space is a continuous process that usually persists for 1 week, (2) inserting a drainage tube causes discomfort for patients and increases the potential risk of infection and lastly, (3) the process prevents patients from being discharged earlier.

The hernial sac stump fenestration technique used in this study is simple, can significantly reduce ultrasound seromas and has good results. The principles of this technique are that the fenestration of the bottom of the hernial sac is similar to the excision of tunica vaginalis, and there are abundant blood and lymphatic vessels in the spermatic cord and Dartos fascia that can rapidly reabsorb exudates. Hence, fluid exudated from the surgical wound can be quickly absorbed by the spermatic cord and Dartos fascia after fenestration, thereby reducing ultrasound seromas.

This study has two main limitations. First, it was a single-centre study with a small sample size; multicentric studies with large sample sizes are needed for validation. Second, we considered only Type III hernias and did not perform a detailed analysis of hernial size.

CONCLUSIONS

Preventive fenestration in laparoscopic inguinal hernia repair surgery is a simple, safe and effective method that can significantly reduce ultrasound seromas without increasing recurrence or the risk of acute or chronic pain.

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Conflicts of interest
There are no conflicts of interest.

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