Prospective randomized comparison of transumbilical two-port laparoscopic and conventional laparoscopic varicocele ligation

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We have established a novel method named transumbilical two-port laparoscopic varicocele ligation (TTLVL) for varicocele, which is still needed to evaluate. In this study, 90 patients with left idiopathic symptomatic varicoceles of grades II–III according to the Dubin grading system were randomly assigned to TTLVL (n = 45) and conventional laparoscopic varicocele ligation (CLVL) (n = 45). The demographic, intraoperative, postoperative, and follow-up data were recorded and compared between the two groups. All the procedures in the two groups were completed successfully with no intraoperative complications and no conversions to open surgery. No significant difference was found in the operative time, resuming ambulation, bowel recovery, postoperative hospital stay, and postoperative resolution of scrotal pain between the two groups (P > 0.05). However, the postoperative mean visual analog pain scale scores for TTLVL group were all less at 24 h, 48 h, 72 h, and 7 days postoperatively compared to CLVL (P = 0.001, 0.010, 0.006, and 0.027, respectively). The mean patient scar assessment questionnaire score in postoperative month 3 was 29.7 for TTLVL group compared with 32.1 for CLVL group (P < 0.001). There was no testicular atrophy observed in both groups during the follow-up period. The study shows that TTLVL is a safe, feasible, and effective minimally invasive surgical alternative to CLVL for the treatment of varicocele. Compared with CLVL, TTLVL may decrease postoperative pain and improve the cosmetic outcomes.

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INTRODUCTION

Varicocele is the most common curable cause of male infertility, which is found in approximately 15% of the male population and in up to 35% of men with primary infertility and 81% of men with secondary infertility. The varicocele repair could improve the semen parameters, reduce sperm DNA damage and seminal oxidative stress, and improve sperm ultramorphology.¹ There are several treatment options including percutaneous embolization, inguinal varicocelectomy, subinguinal microscopic varicocelectomy, and laparoscopic varicocelectomy. However, the ideal treatment for varicocele is still controversial.²⁻⁵ Laparoscopic varicocelectomy ligation is regarded in recent years as a safe, effective, and minimally invasive method with the similar results to that of others.⁶⁻¹² However, conventional laparoscopic varicocelectomy ligation (CLVL) usually requires three ports, which affects the cosmetic results. More recently, umbilical laparoendoscopic single-site surgery (U-LESS), with its advantages of small invasiveness, quick recovery, and good cosmetic effect, is becoming a new minimally invasive surgery for this disease.⁶⁻⁹ However, there is still an obvious scar at the umbilicus which decreases the cosmetic outcome. Since March 2010, we have established a novel method named transumbilical two-port laparoscopic varicocele ligation (TTLVL) and applied it in the treatment of varicocele leading to an excellent result. In this study, we will compare it with CLVL in terms of intraoperative, postoperative, and follow-up data.

MATERIALS AND METHODS

Patients

From November 2010 to September 2013, we prospectively evaluated 90 patients with left idiopathic symptomatic varicoceles of grades II–III according to the Dubin grading system. The characteristics of the patients are listed in Table 1. The diagnosis of a varicocele was established mainly by clinical examination, Doppler ultrasonography of the scrotum and abdominal ultrasonography to rule out a secondary varicocele caused by retroperitoneal tumors, kidney tumors, lymphadenopathy, etc. The seminal fluid analysis was performed preoperatively and repeated postoperatively every 3 months for 1 year.

Inclusion criteria included infertility, abnormal semen parameters, or scrotal pain for the varicocele on the left side. Exclusion criteria were asymptomatic varicocele with normal semen parameters or childhood varicocele with normal testicular volume. Patients were randomly assigned to receive TTLVL (n = 45) and CLVL (n = 45) using computerized random number tables. All patients who underwent surgery in both groups completed the study (Figure 1).
The study was approved by the Committee of Ethics of Gannan Medical University in Ganzhou, China. Each patient or a direct relative provided written informed consent with full comprehension of the potential surgical risks. All the procedures including TTLVL and CLVL were performed by one of two surgeons (ZX and ZG), who were experienced in the both procedures so that the both procedures were performed by the both surgeons.

**Surgical technique**

Under general anesthesia, the patient was placed supine in the Trendelenburg position. Operating surgeon stood on the right side of the patient while the assistant stood on the left side and controlled the laparoscope.

For TTLVL, one 5-mm port was placed at the left umbilical edge for a 5-mm 30° laparoscope, or a 5.4-mm flexible-tip 0° laparoscope (Olympus Medical, Tokyo, Japan) and the other 5-mm port was placed at the right umbilical edge for the conventional laparoscopic instruments (Figure 2a). The intraperitoneal CO₂ pressure was maintained at 15 mmHg. The adhesion between the intestine/mesentery and the varicoceles were dissected if necessary. Two retroperitoneal incisions were made in the two lateral aspects from the point 3 cm superior to the internal inguinal ring along the spermatic vessels using an electric crook (Figure 3a). After the spermatic vessels, including arteries, veins, and lymphatics, were dissected using the electric crook, one end of a long 7#-silk thread was put into the abdominal cavity through the right port and thrown to the intestine/mesentery and the varicoceles were dissected if necessary. Another ligation was finished at a different place of the spermatic vessels using the same method. The two umbilical skin incisions were closed by a 5-0 absorbable suture with no drain.

For CLVL, a 10-mm or 5-mm port was placed in the subumbilical position for the laparoscope, and a 10-mm and a 5-mm (or two 5-mm) ports for conventional laparoscopic instruments were placed on the right and left the ventral median line, 2–3 cm below the horizontal line to the umbilicus. Two retroperitoneal incisions were made in the two lateral aspects from the point 3 cm superior to the internal inguinal ring along the spermatic vessels using an electric crook (Figure 2b). After the spermatic vessels, including arteries, veins, and lymphatics, were dissected, they were ligated by two separated 7#-silk threads. The skin incisions were closed by a 5-0 absorbable suture with no drain.

**Assessment of patients’ scar**

The satisfaction of patients in terms of the scar was assessed by the Patient Scar Assessment Questionnaire (PSAQ: minimum/best score, 28; maximum/worst score, 112)° after postoperative month 3.

**Statistical analysis**

All statistical analysis was performed with SPSS® version 14.0 (IBM Corp., Armonk, NY, USA). All continuous response variables were presented by mean ± s.d. and compared using unpaired t-test. Pearson's Chi-squared test was used to compare categorical data. A value P < 0.05 was considered statistically significant.

**RESULTS**

The two groups were comparable regarding patient age, BMI, Dubin grading, and indications for varicocelectomy (Table 1).

All the procedures in the two groups were completed successfully with no intraoperative complications, no conversions to open surgery, and no need for ancillary ports. No significant difference was found in the operative time, resuming ambulation, bowel recovery, postoperative hospital stay, and postoperative resolution of scrotal pain between the two groups (Table 2). However, the postoperative mean visual analog pain scale (VAPS) scores for TTLVL group were less than that for CLVL group at 24 h, 48 h, 72 h, and 7 days postoperatively (P = 0.001, 0.010, 0.006, and 0.027, respectively) (Table 2 and Figure 4).

At follow-up, the umbilical scar of each patient who underwent TTLVL was hidden and difficult to find (Figure 5a). However, the scar in the abdomen of each patient who underwent CLVL was obvious (Figure 5b). The mean PSAQ score in postoperative month 3 was 29.7 for TTLVL group compared with 32.1 for CLVL group. The difference was also statistically significant in favor of the TTLVL group (P < 0.001) (Table 2). There were 3 (6.7%) of 45 patients in

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**Table 1: Patient characteristics**

| Indication for varicocelectomy (%) | TTLVL (n=45) | CLVL (n=45) | P   |
|-----------------------------------|-------------|-------------|-----|
| Scrotal pain                       | 16 (35.6)   | 18 (40.0)   |     |
| Infertility                        | 13 (28.9)   | 14 (31.1)   |     |
| Abnormal semen parameters          | 16 (35.6)   | 13 (28.9)   |     |

TTLVL: transumbilical two-port laparoscopic varicocele ligation; CLVL: conventional laparoscopic varicocele ligation; BMI: body mass index; s.d.: standard deviation.

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**Figure 1: Patient allocation.**

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**Figure 2: Operation location:** (a) Two 5-mm ports were inserted at the umbilical edge for the laparoscope and laparoscopic instruments in transumbilical two-port laparoscopic varicocele ligation (TTLVL). (b) A 10-mm port was inserted at the umbilical edge for laparoscope. One 10-mm port and a 5-mm port were inserted into abdominal cavity in the right and left ventral median line for laparoscopic instruments in conventional laparoscopic varicocele ligation (CLVL).
**DISCUSSION**

Varicocelectomy, a kind of surgical treatment is a main method for varicocele, the aim of which is to interrupt the venous reflux within the spermatic veins. Several surgical techniques via high retroperitoneal, inguinal, microsurgical inguinal, and laparoscopic approaches have been reported, but with no most ideal treatment. Although some reports indicated that the microsurgical varicocelectomy may lead to a lower incidence of postoperative hydrocele formation, the operating time is considerably longer than that for other procedures. The high retroperitoneal, inguinal varicocelectomy may cause many injuries and slower recovery.

In recent years, with the development of laparoscopy, laparoscopic varicocelectomy ligation is becoming increasingly popular in clinical practice for its many advantages, such as less invasiveness, quicker recovery, improved cosmesis, magnified and clear surgical visual field, and treating bilateral lesions during one procedure. For the purpose of decreasing invasiveness and improving appearance, ULESS was established, which represents an extension of the minimally invasive surgery. There were several reports showing that U-LESS varicocelectomy yielded superior cosmetic results with less pain compared with conventional laparoscopic varicocelectomy.

TTLVL, a modified U-LESS for the treatment of varicocele, was established by ourselves and applied in our clinical practice broadly. We initially compared this novel method with CLVL. Concerning the two groups, the patients were almost the same, and all the procedures were performed by one of two surgeons so that the both procedures were performed by the both surgeons to avoid bias. Apart from comparable intraoperative and postoperative parameters, such as operative time, bowel recovery, postoperative hospital stay, recurrent varicocele,
and postoperative improvement of semen parameters, TTLVL yields lower VAPS and PSAQ score than CLVL. Thus, TTLVL not only had a comparable surgical effect to CLVL but had less pain and better cosmetic outcome, which satisfied the patients who were subjected to varicocelectomy. The patients who undergo the varicocelectomy are usually younger. They often place more importance on the number of incision scars than older patients.\textsuperscript{14} TTLVL need only two 5-mm ports which are less than that of CLVL with three ports. What is more, the two-ports for TTLVL are both at the umbilical edge which could lead to better cosmetic result because the scar will be hidden and difficult to find in the future.

For the ligation of the internal spermatic vein, a 7#-silk thread was used. There is some difficulty in knotting via a single port. In the early stages of this approach, we used a knot tier to complete the knotting. When the surgeon was proficient, the knot could be completely finished in the abdominal cavity by only one forceps. In this study, the shortest time for TTVL was only 18 min. Using silk thread was safer than a Titanium clip. Friedersdorff et al.\textsuperscript{14} and Kang et al.\textsuperscript{15} used Hem-o-loc clips to ligate the incompetent internal spermatic veins in their U-LESS varicocelectomy. Glassberg et al.\textsuperscript{16} and Al-Hunayan et al.\textsuperscript{17} used a vascular sealing system to complete the varicocele ligation in the laparoscopic varicocelectomy. Compared with Hem-o-loc and vascular sealing system, the 7#-silk thread is much cheaper, which could decrease the economic burden of patients.

Numerous studies have revealed an improvement in the semen parameters the following varicocelectomy.\textsuperscript{11,18,19} However, some studies have not demonstrated any beneficial effect.\textsuperscript{20} This discrepancy might be the result of several factors that include variations in patient populations among studies, methods of assessment, the expertise of medical personnel, low patient numbers, and variation in semen parameters within an individual, along with other possible factors.\textsuperscript{21} Our study showed that TTLVL and CLVL both resulted in significant improvement in semen parameters, which was comparable to previously reported results.\textsuperscript{11,18,19}

Preservation of the testicular artery is a controversial issue. Some studies have showed that testicular artery ligation has no deleterious effect on the testicular blood supply and semen parameters if the arteries of the vas deferens and cremaster were spared.\textsuperscript{15,22} Recent meta-analyses and study have shown that preservation of the internal spermatic artery may be result in similar clinical outcomes of semen analysis and higher recurrence rate in varicocelectomy.\textsuperscript{21,123} In the current study, we could not preserve the spermatic artery in all procedures. As a result, no testicular atrophy was found at the follow-up and a good postoperative improvement of semen parameters was obtained in the both groups.

Al-Hunayan et al.\textsuperscript{17} introduced their two-trocar laparoscopic varicocelectomy in 2006. Two trocars were used in their operation, including one 5-mm trocar at the umbilicus for the camera and one 5-mm suprapubic trocar for the forceps. In addition, the Veress needle was inserted percutaneously about 1 cm medial to the anterosuperior iliac spine and was used to dissect the incompetent internal spermatic veins free. Differently, two-ports were both inserted at the umbilical edge in our two-port method, which resulted in less pain and a good cosmetic outcome because of the hidden umbilical scars.

There were some limitations in the study. The patients with bilateral varicocele were not included in the study for the sake of the convenience of the comparison. Furthermore, there were no exact details of some possible confounding factors such as a follicle-stimulating hormone, testosterone, and testicular volume to be reported.

CONCLUSION

TTLVL is a safe, feasible, and effective minimally invasive surgical alternative to CLVL for the treatment of varicocele. Compared with CLVL, TTLVL may decrease postoperative pain and improve the cosmetic outcomes. Of course, TTLVL may be regarded as a bridge to U-LEES due to its simple operation.

AUTHOR CONTRIBUTIONS

GXZ, JY, DZL, ML, and XFZ, participated in the design of the study, performed the operations, collected the clinical data and wrote the article; YHY, RHX, and YJX performed patient follow-up and collected clinical data; XZ, QLL, and FLL collected patient information and performed the statistical analysis; BJ, RQX, and KLX helped to draft the manuscript. All authors read and approved the final manuscript.

COMPETING INTERESTS

The author declares no competing interests.

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