Original Article

Comparison of transumbilical single-port laparoscopic cholecystectomy and fourth-port laparoscopic cholecystectomy

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Abstract: This work aims to compare the curative effect of transumbilical single-port laparoscopic cholecystectomy (TUSPLC) and four-port laparoscopic cholecystectomy (FPLC). 200 patients with cholecystolithiasis were enrolled in this study. They were randomly divided into TUSPLC group and FPLC group, 100 cases in each group, and the TUSPLC and FPLC was performed, respectively. The surgical time, intraoperative complication, conversions rate, postoperative pain, postoperative analgesic drug use, incision infection, postoperative hospitalization time and postoperative cosmetic results in two groups were compared. The total conversion rate, conversion rate with Nassar grade II, and conversion rate with Nassar grade III in TUSPLC group were significantly higher than FPLC group (P < 0.01), and the incision cosmetic result after 1 month in TUSPLC group was obviously better than FPLC group (P < 0.01), but the surgical time in TUSPLC group was significantly longer than FPLC group (P < 0.01). There was no significant difference of incision infection, intraoperative complication, and postoperative hospitalization time, incision pain in postoperative first and second day, postoperative use of analgesia drug and incision cosmetic result on discharge day between two groups (P > 0.05). TUSPLC has obvious advantage in treatment of Nassar grade I patients with cholecystolithiasis. It can be used as a supplement for standard laparoscopic gallbladder surgery. It is safe and feasible, without abdominal scar, thus achieving to excellent cosmetic result and high satisfaction in patients.

Keywords: Single-port, four-port, laparoscopic cholecystectomy, comparative study

Introduction

Classic laparoscopic cholecystectomy (LC) has basically replaced the traditional laparotomy [1]. After years of development, LC has obtained great progress in surgical techniques and indications. So far, LC has experienced four-port method [2], three-port method [3], and twoport method [4]. Due to small trauma and quick recovery, the minimally invasive effect has been fully affirmed. LC has become the gold standard in treatment of benign gallbladder diseases for a long time. In recent years, with the development of minimally invasive technique, transumbilical single-port laparoscopic cholecystectomy (TUSPLC) based on the traditional LC technique has appeared. However, the lengths of surgical time are inconsistent due to different surgical apparatus and operational proficiency degree. Podolsky et al. [5] have used self-designed puncture apparatus to

perform 5 cases of TUSPLC, with average surgical time of 120 min. Rao et al. [6] have completed 17 cases of TUSPLC using R-Port device, and the average surgical time is 40 mim. In Tacchino et al. report [7], the average surgical time of TUSPLC is 50 min. Overall, with the development of technology, the surgical time of TUSPLC is being shortened gradually.

TUSPLC is proved to be feasible in treatment of gallbladder diseases [8-19], and can improve the cosmetic effect, reduce postoperative pain, shortened postoperative hospitalization time, and improve postoperative life quality [16, 19]. However, Mynster et al. [20] believe that, this technique has problems such as interference between equipment and patient, increased operational difficulty, prolonged surgical time, and so on. So it is a new kind of "children's toy", and whether it is really beneficial to patients needs to be further confirmed by prospective

random control study. Connor et al. [21] believe that, when popularizing a new technique, whether it is really beneficial to patients should be firstly considered. There is no evidence for that the benefit of TUSPLC outweighs the potential risk, and abolition of three-port laparoscopic cholecystectomy (TPLC) is not necessarily a true progress. Therefore, whether TUSPLC is better than four-port laparoscopic cholecystectomy (FPLC), and whether it is a development direction in abdominal surgery in the future, need to be quantified and confirmed by relevant clinical data. In addition, whether the surgical time, intraoperative complication, intraoperative conversion rate, postoperative pain, postoperative use of analgesic drug, incision infection, postoperative hospital stay, postoperative cosmetic result in TUSPLC and FPLC are different, still needs to be further confirmed. In this study, 200 patients with cholecystolithiasis in our hospital from January 2010 to December 2011 were divided into TUSPLC group and FPLC group. Based on the difficulty grading of LC, the differences between TUSPLC and four-port laparoscopic cholecystectomy (FPLC) were compared, and the advantage of TUSPLC was observed. At the same time, the indications of TUSPLC were investigated, to reduce the incidence of bile duct injury due to excessive demand of cosmetic result.

Materials and methods

General data

200 patients with cholecystolithiasis in our hospital from January 2010 to December 2011 were enrolled in this study. The inclusion criteria were as follows: 1) aged 18-70 years, body mass index (BMI) \leq 25 kg/m; 2) no history of surgery on lower digestive tract and pelvic cavity; 3) American Society of Anesthesiologists score (ASA) score: I-III; 4) Nassar grade [22]: I-III (no acute cholecystitis history; **Table 1**). Exclusion criteria [11] were as follows for: 1) hepatic cirrhosis; 2) peritonitis; 3) history of upper abdominal surgery; 4) complicated with other diseases such as cystic abscess, acute cholecystitis, acute pancreatitis and biliary calculi; 5) high-risk group of general anesthesia.

200 patients were randomly divided into TUSPLC group (40 males and 60 females; aged 18-68 years, average 47.5 years; disease course, 1 month to 10 years) and FPLC group

(44 males and 56 females; aged 20-70 years, average 50.5 years; disease course ranging from 2 weeks to 12 years). There were 12 and 8 cases complicated with diabetes in FPLC group and TUSPLC group, respectively, and 16 cases and 15 cases complicated with hypertension in two groups, respectively, with 2 cases with multiple complications in each group. Before surgery, the preoperative fasting blood glucose was controlled below 10 mmol/L, with blood pressure below 140/90 mmHg. There was no significant difference of in gender, age, BMI, ASA score and Nassar grade between two groups (P < 0.05).

Research design

All patients were treated by unified perioperative management, without knowing what kind of surgical mode. According to preliminary laparoscopic detection results and difficulty in LC (Nassar grade, Table 1), patients were divided into Nassar I, II and III group (patients with IV grade were excluded), according to which the TUSPLC and FPLC was performed, respectively. The pain scores of operative day, postoperative first day, and postoperative second day were detected using visual analogue scale (VAS) scoring, with range from 1 score (mild pain) to 10 score (sharp pain). The incision pain on postoperative first, second day and postoperative first month was expressed by grade VI, VII and VIII, respectively. It also was evaluated by whether using analgesic drugs. Postoperative incision cosmetic result was evaluated by VAS scoring, ranging from 0% (worst) to 100% (best). The cosmetic results on discharge day and postoperative one month were expressed by grade IX and X, respectively.

Surgical methods

TUSPLC group: under intravenous anesthesia (head side elevated 20-30°, leaning to left 15°), the laparoscopic operation channel was established and pneumoperitoneum was maintained. A 1.5 cm arc incision was made on lower umbilicus edge, and the rectus sheath was exposed, presenting triangle shape. A 5 mm trocar was directly inserted through the central incision to establish pneumoperitoneum and to observe the abdominal cavity. Other two 5 mm trocars were inserted at upper left and right side of first trocar, respectively. The subcutaneous three channels were not mutu-

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Table 1. Nassar grade of LC

| Nassar grade* | Gallbladder | Cystic duct structure | Adhesion degree |
|---------------|---|--|--|
| I | Soft, no adhesion | Clear, thin | Little adhesion in gallbladder neck or Hartmann bag |
| II | Mucous cyst, cystic stone | Rich in fat | Little adhesion in gallbladder body |
| III | Deep gallbladder fossa, atrophy, acute cholecystitis, Hart- mann bag, common bile duct adhesion, impacted stones | Anatomic abnormalities, short gallbladder tube, expansion, secluded location | The Tight adhesion in gallbladder bottom, hepatic flexure of colon or duodenum |
| IV | Fully enclosed, purulent, gangrene, block | No clear position | Fibrous tissue encasing gallbladder, hepatic flexure of colon or duodenum adhesion |

Note: *Difficulty grading for laparoscopic cholecystectomy.





Figure 1. A: Soft trocar placement; B: Application of intraoperative devices.

ally connected, and rectus abdominis and rectus sheath were used to prevent gas leakage. The reusable soft trocar (Hangzhou Tonglu Medical Equipment Factory, Hangzhou, China) was inserted (Figure 1A), and the intra-abdominal pressure was maintained at 12-15 mmHg. Two single-port laparoscopes were inserted through the left and right trocar (one for traction and exposure, and the other for dissection and separation, Figure 1B). The gallbladder was applied by the forceps to expose the Calot's triangle, followed by alternate separation using flexible electric hook and separating forceps. The front and rear layer of mesocyst was separated, and the Calot's triangle was dissected for full isolation of cystic artery and cystic duct, followed by closure and cut-off using 5 mm Ti-clip. The gallbladder was placed in specimen bag. The fascia between trocars was incised, and the specimen bag and gallbladder were taken out through umbilical incision, followed by closing fascia and skin incision.

FPLC group: under intravenous anesthesia, the pneumoperitoneum was performed using Veress needle. The intra-abdominal pressure was maintained at 12-15 mmHg. The bladder was excised using traditional method. After surgery, the drainage tube was placed according to the situation of gallbladder bed seepage.

Observation indexes

Surgical time, intraoperative complications, intraoperative conversion rate, postoperative analgesic drug use, incision pain on postoperative first and second day, incision infection, postoperative hospital stay, incision cosmetic

results and incision pain on postoperative 1 month were strictly recorded and compared.

Statistical analysis

Statistical analysis was performed using SPSS 13.0 statistical software. *t*-test and chi-square test were performed for analyzing the measurement data and enumeration data, respectively. Postoperative pain, postoperative hospital stay, incision cosmetic results and incision pain on postoperative 1 month in two groups were compared using Mann-Whitney U test.

Results

In TUSPLC group, due to inflammation around gallbladder and cystic duct structure variation, the gallbladder triangle anatomy was difficult in 16 patients. So two-port method or four-port method or laparotomy method was performed. The surgery was successfully completed in other cases, without bile duct injury. All cases were cured, without death. In FPLC group, 1 case was with difficulty in gallbladder triangle dissection and severe adhesion, so the laparotomy was conducted. The surgery was successfully completed in other cases. The observation indexes in two groups were shown in Tables 2, 3. In one month follow-up, the postoperative incision cosmetic result and incision pain in TUSPLC group was obviously better than FPLC group (p < 0.01). Due to surgical difficulty and high technical requirements, the surgical time in TUSPLC group was longer than FPLC group (P < 0.05). However, with the improvement of operation channel and instruments, the surgical time in TUSPLC group was signifi-

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Table 2. Comparison of curative effect of two groups

| Intraoperative and postoperative in | dexes | TUSPLC group | FPLC group | Р |
|--|-------|------------------|-----------------|-------|
| Surgical time (min) | | 43.8 ± 2.69 | 36.1 ± 4.89 | <0.01 |
| Intraoperative complications (cases | 5, %) | 0 | 0 | |
| Postoperative pain | VI* | 2.22 ± 1.73 | 2.33 ± 1.52 | 0.385 |
| | VII★ | 2.39 ± 1.70 | 2.43 ± 1.62 | 0.354 |
| | VIII▲ | 1.61 ± 0.68 | 2.47 ± 1.56 | 0.002 |
| Analgesic drug use on operative day | | 3 | 4 | 0.830 |
| Postoperative hospitalization time (day) | | 3.81 ± 0.85 | 3.86 ± 0.76 | 0.889 |
| Postoperative-cosmetic-result | IX* | 0.822 ± 0.076 | 0.808 ± 0.086 | 0.102 |
| | Χ• | 0.904 ± 0.06 | 0.882 ± 0.047 | 0.003 |
| ntraoperative total conversion rate | | 16 | 2 | 0.001 |
| Incision infection | | 0 | 0 | |

Note: Data were expressed as mean ± SD; *day of surgery; *first postoperative day; *first month in follow-up; *discharge day; *first month in follow-up.

Table 3. Comparison of Patient number and interoperation conversion rate with Nassar grading

| Patient number with Neces | TUSPLC | TUSPLC FPLC | | | |
|----------------------------------|------------------|-------------|-------|-------|--|
| Patient number with Nassar grade | | group | group | Р | |
| I | | 80 | 79 | NS | |
| II | | 13 | 14 | NS | |
| III | | 7 | 7 | NS | |
| Intraoperative conversion rate | Nassar grade I | 0 | 0 | NS | |
| | Nassar grade II | 10# | 1 | 0.000 | |
| | Nassar grade III | 6# | 1 | 0.008 | |

Note: P < 0.01 compared to FPLC group. #conversion rate of two-port method and four-port method.

cantly reduced compared with using old tools. The total conversion rate, conversion rate with Nassar grade II, and conversion rate with Nassar grade III in TUSPLC group were significantly higher than the FPLC group (P < 0.01). There was no significant difference of incision infection, intraoperative complication, postoperative hospital stay, infection pain in postoperative first day and day of surgery, postoperative use of analgesia drug and incision cosmetic effect on discharged day between two groups (P > 0.05) (Table 2). All cases were followed up for 1 month, and no residual biliary tract stone, biliary stricture or incision infection was observed. In TUSPLC group, there was no surgical scar in umbilical part, achieving a therapeutic efficacy of minimal invasion, with no abdominal scar. It was safe and feasible.

Discussion

Rapid improvement of endoscopic technique has promoted the development of surgery to

more minimally invasive and cosmetic direction. The traditional laparoscopic surgery has transferred from classic four-port method to miniature laparoscopic operation [23] to TUSPLC [12], which is known as E-NOTES, a type of NOTES [24], and also known as TUES [25]. NOTES needs special equipment, and must incise the stomach, rectum, vagina or bladder and other organs. This inevitably increases the complications and surgical

risk, and reduces the minimally invasive effect. So it is difficult to be popularized in short time. Compared with NOTES, the advantages of E-NOTES are that, the operation is relatively simple and safe, and it is only performed in patients' hidden part. There is only a 1.5 cm incision in umbilical region. After healing, the incision scar is difficult to be observed due to natural umbilical barrier. So it is easy to be accepted by patients. According to present situation of single-port laparoscopic surgery, we apply the reusable laparoscopic soft trocar (5 mm diameter), combined with a series of domestic reusable bent laparoscopic instruments (Hangzhou Tonglu Medical Equipment Factory, Hangzhou, China) (Figure 2), and have obtained good surgical result. In the early stage in application of this surgery, the ordinary endoscopic equipments are used, and the surgical time is extended to 1.5-3.0 h. The main reason may be related to unskilled technology in early stage and inherent disadvantages of TUSPLC

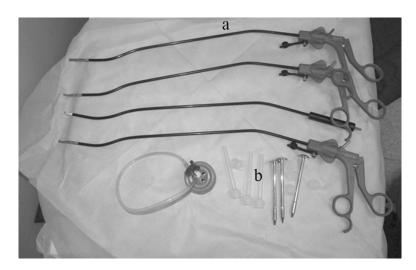


Figure 2. a: Flexible laparoscopic equipment; b: Reusable soft trocar.

such as lack of triangle erect position, limited operation space and equipment activity degree. However, since we use a series of domestic reusable single-port laparoscopic instruments (Hangzhou Tonglu Medical Equipment Factory, Hangzhou, China), the triangular area on rectus sheath surface in deep incision is isolated, and three channels are established, with an inverted triangle among them (the distance is about 5-10 mm). So two 5 mm laparoscopic soft trocars can be placed in, which can prevent the gas leakage. In addition, the reusable bent rigid laparoscopic instruments are applied, which can restore the best operating angle of "triangle" in conventional laparoscopic operation, reduce the mutual interference between devices, avoid the crowding of instrument handle with camera handle. This ensures adequate handle activity range, contributing to surgical operation. With accumulation of patient number, the operator has good laparoscopic operation basis and rich experience, so the surgical time in TUSPLC group is significantly reduced. In this study, although the surgical time in TUSPLC group is longer than FPLC group (43.8) \pm 2.69 vs 36.1 \pm 4.89, P < 0.01), it is close to the mean surgical time of traditional FPLC method. As reported in literatures [26, 27], the average surgical time of TUSPLC is 50.8 min (23-120 min) or 80.76 min (51-156 min). Compared with them, the surgical time of TUSPLC in this study decreases significantly, with satisfactory curative effect.

Comparison results of postoperative pain with VAS scoring between traditional LC and TUSPLC

showed that, in the 1st and 2nd postoperative day, there is no significant difference of incision pain between two groups (grade VI, 2.33 ± 1.52 $vs 2.22 \pm 1.73$, P = 0.385; grade VII, $2.43 \pm 1.62 \text{ vs } 2.39$ \pm 1.70, P = 0.354), with comparative analgesic drug use (3 vs 4, P = 0.830). Tsimoviannis et al. [28] find that, the incision pain at postoperative 12th h in TUSPLC group was markedly relieved, with significantly decreased shoulder pain at postoperative 6th h and disappearance of all pain at postoperative 24th h, and the amount of used analgesic

is significantly reduced. This is contrary to our research results, which may be related to surgical incision length and apparatus prepared in our department. In TUSPLC group of this study, the 1.5 cm incision around the umbilicus is made, and the rectus sheath is exposed. Then three 5 mm trocars are directly inserted through the central incision. The single-hole apparatus occupies small space, and not excessively pulls the abdominal muscle and surrounding skin. So at the day of surgery, the pain sense in patients in TUSPLC group is comparative with FPLC group. This is consistent with the view of Saad et al. [29]. However, there is no significant difference of amount of used analgesic drugs at the day of surgery between two groups. This may be due to the relatively low pain level which can be endured by patients.

According to our results, in follow-up of one month, the incision pain in FPLC group are significantly higher than TUSPLC group (1.61 ± $0.68 \text{ vs } 2.47 \pm 1.56$, P = 0.002), which may be related to trocar placement. For FPLC, 1 cm trocar is placed in right side below cartilago ensiformis. This position is convenient to get gallbladder. If gallbladder is full of stones or the stone is greater than 1 cm. Expanding the incision and cutting rectus abdominis and nerve tissue below cartilago ensiformis are needed, leading pain under cartilago ensiformis. However, TUSPLC method does not need this operation. The umbilical incision size is about 1.5 cm. If the gallbladder stone is larger, the navel subcutaneous three ports can be fused to increase the incision. In addition, there is no

muscle nerve tissue below umbilicus, so the pain is not obvious. On the first and second postoperative day, there is no significant difference of pain between two groups. On the first postoperative month, the cosmetic result in TUSPLC group is better than FPLC group (0.904) \pm 0.882 vs 0.06 \pm 0.047, P = 0.003). The reason is that, in TUSPLC group, the umbilical scar is almost invisible, while that in FPLC group affects the final cosmetic result. The instruments used in TUSPLC are cheaper, without using expensive special equipment. In addition, the operating apparatus are reusable. The incision infection, intraoperative complications, postoperative hospitalization time, postoperative pain on first and second day, postoperative analgesia drug use and incision cosmetic effect on discharge day in TUSPLC group are comparative to those in FPLC group, which is consistent with previous studies [16, 19, 30]. These are easy to be accepted by patients, and no postoperative bleeding, bile leakage, bile duct injury or incision infection occurs, indicating that TUSPLC is safe, feasible and effective. One month follow-up after indicates that, in TUSPLC group, the umbilical incision can be concealed by umbilicus fold, with no obvious abdominal scar. So the beauty effect is obvious, with litter psychological impact on patients. However, in 16 patients with Neisser II and III in TUSPLC group, the anatomic variation, deep gallbladder fossa, atrophy, Hartmann bag and common bile duct adhesion or impacted stones, gallbladder bottom tight adhesion, and the mild intestinal adhesion of hepatic flexure of colon and duodenum lead to uncertain surgical safety in a confined space. So the two-port method and fourport method is performed, companied with laparotomy. There is significant difference between TUSPLC group and FPLC group (χ^2 = 11.966, P = 0.001) (**Table 3**). The reason may be that, TUSPLC has defects such as lack of triangle erect position, limited operation space and equipment activity, leading to some difficulties in anatomy of gallbladder triangle. So the intraoperative conversion rate is higher than that in FPLC group. This indicates that, the advantage of TUSPLC is presented in patients with Neisser classification I, but not Neisser grade II and III.

In conclusion, with the improvement of single-port laparoscopic operational channel and application of reusable single-port laparoscopic instruments, TUSPLC technique is more suitable for patients with Nassar grade I, with

greater advantage in cosmetic result and incision pain after 1 postoperative month. So it has significant clinical application value. However, in order to ensure the surgical safety of operation, its indication should be strictly applied. Larger multi-center clinical research should be conducted for further investigating the advantage and diagnostic standard of TUSPLC.

Disclosure of conflict of interest

None.

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