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Original Article

A prospective, randomized, controlled trial of three-port laparoscopic cholecystectomy versus conventional four-port laparoscopic cholecystectomy: is the fourth port really required?

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Abstract: Background: Since the advent of four-port laparoscopic cholecystectomy (LC), many modifications have been made that aimed to improve cosmesis and patient prognosis. Here we compared a variety of surgical outcomes such as quality of life three months after surgery between three-port LC and conventional four-port LC. Methods: This study presents an analysis of 245 patients with cholelithiasis who were between 31 and 78 years of age and who underwent elective LC between May 2013 and December 2014. Patients were randomized to undergo either the three-port LC or four-port LC surgery. Operation and hospitalization details were collected. Cosmetic outcome and quality of life of patients were assessed by the validated Patient Scar Questionnaire and MOS-24 questionnaire, respectively, 3 months after surgery. Results: 245 patients were included, and a complete follow-up was possible for 216 patients (88%). The average length of hospital stay, as well as time needed for return to normal activity and work, was significantly shorter in the three-port group than in the four-port group. No significant differences were observed for operating time and bleeding volume. The average hospitalization cost was lower, and, more importantly, patients had a significantly better cosmetic outcome and quality of life scores at 3 months in the three-port group. Conclusion: Three-port LC was as effective as the conventional four-port LC, and it shortened hospital stay, reduced hospitalization cost, and accelerated patient recovery. Moreover, the cosmetic outcome and quality of life were better.

Keywords: Three-port laparoscopic cholecystectomy, surgical outcomes, cosmetic outcome, quality of life

Introduction

The introduction of endoscopy into surgical practice is one of the greatest success stories in the history of modern surgery, and laparoscopy has become a gold standard in the new era of endoscopic surgery [1]. Laparoscopic cholecystectomy (LC) is a classic endoscopic surgery and has been the treatment of choice for symptomatic gallstones [2, 3]. The first LC was performed in 1987 by Phillip Mouret, and the technique was later established by Dubois and Perissat in 1990 [1, 4]. Since then, LC has been the standard treatment for symptomatic gallstones [5]. However, the surgical technique has remained mainly unchanged since the advent of the standard four-port LC [2]. In consideration of the therapeutic effect and patient prognosis, many modifications have been tried during and after surgery regarding port number and size, abdominal drainage, etc. [2, 6-8].

In the standard four-port LC, the fourth (lateral) trocar is used to grasp the fundus of the gallbladder for a better exposure of Calot's triangle. With increasing surgical experience, eliminating this port did not affect the safety and therapeutic effect of the operation and furthermore

improved the LC technique. Patients who received three-port LC suffered less postoperative pain and recovered earlier. In the era of laparoscopic surgery, less postoperative pain, earlier recovery, and better cosmesis are needed to achieve the major goals of better patient care and cost effectiveness [9]. The reduction of port numbers has become a trend because of it leads to better cosmesis, quicker recovery and reduced pain [10, 11]. New techniques for LC have been developed, such as single-port laparoscopic surgery (SPLS) and natural orifice transluminal endoscopic surgery (NOTES) [12, 13].

In this context, we conducted a prospective, randomized, controlled trial of uncomplicated LC using the three-port technique versus the conventional four-port LC. The benefits were measured by various parameters such as the length of hospital stay, average hospitalization cost, and cosmetic outcome, etc. Most importantly, for the first time, quality of life was measured using a MOS-24 questionnaire three months after surgery.

Materials and methods

Patients

The trial was reviewed and approved by the Institutional Review Board of Qilu Hospital, Shandong University. Written consent was obtained from all patients after explaining the methods and aims of the trial.

From May 2013 to December 2014, 245 patients who underwent elective LC because of cholelithiasis at the Hepatobiliary Department of Qilu Hospital, Shandong University, Shandong Province, China, and who met our criteria were enrolled in this study. The exclusion criteria were: (1) Acute biliary pancreatitis confirmed by increased blood amylase and radiological examination (liquidation and/or swelling of the pancreas caused by gall-stone obstruction), (2) Suspected cholangiocarcinoma as assessed by radiological examination, (3) Gallbladder stone combined with choledocholithiasis, and (4) A history of previous upper abdominal surgical intervention. Then, the subjects were grouped randomly into two groups to receive either the three-port or four-port surgery. The baseline characteristics of the subjects, such as age, sex and BMI, were recorded.

Each enrolled subject was given a random number and ranked numerically according to the value of the random number of the subject, which was assigned in Excel. Then, subjects with odd numbers were assigned to group A (the three-port LC group), and subjects with even numbers were assigned to group B (the four-port LC group).

Surgical management

All operations were performed in the hepatobiliary department of Qilu Hospital by an experienced surgeon who had completed more than 1000 laparoscopic cholecystectomies. Surgery for both the three-port group and the four-port group involved inserting two 10-mm ports, one at the umbilicus and one below the xiphoid and one or two additional 5-mm ports in the right upper abdomen. During surgery, the gallbladder bed was gently and attentively exposed, while all of the ductules that were suspected to be blood vessels or bile ductules were clamped. The gallbladder bed was splayed with an electric scalpel (80-90 volts) after gallbladder removal. The abdominal cavity was irrigated with 250-500 ml of sterilized normal saline solution before abdominal closure. Drainage was not routinely used; however, when drainage was necessary, these cases were excluded in order to assess only a single variable, as drainage may affect a variety of surgical outcomes.

Postoperative management

Antibiotics were used before surgery and up to 24 h after surgery to prevent infection. All patients were encouraged to stand up and drink a small amount of water on the same day of surgery. In addition, greasy foods were avoided for a week after surgery.

Outcome measurements of discharge time, length of hospital stay, and hospitalization expenses were collected from the medical records. The operation note recorded operating time and blood loss volume. A visual analogue score (VAS) was recorded on admission and 24 hours after surgery. All patients were told to come back for a check-up 3 months later and answer the Patient Scar Questionnaire as well as the MOS-24 questionnaire at that time. The times that were required for a return to normal

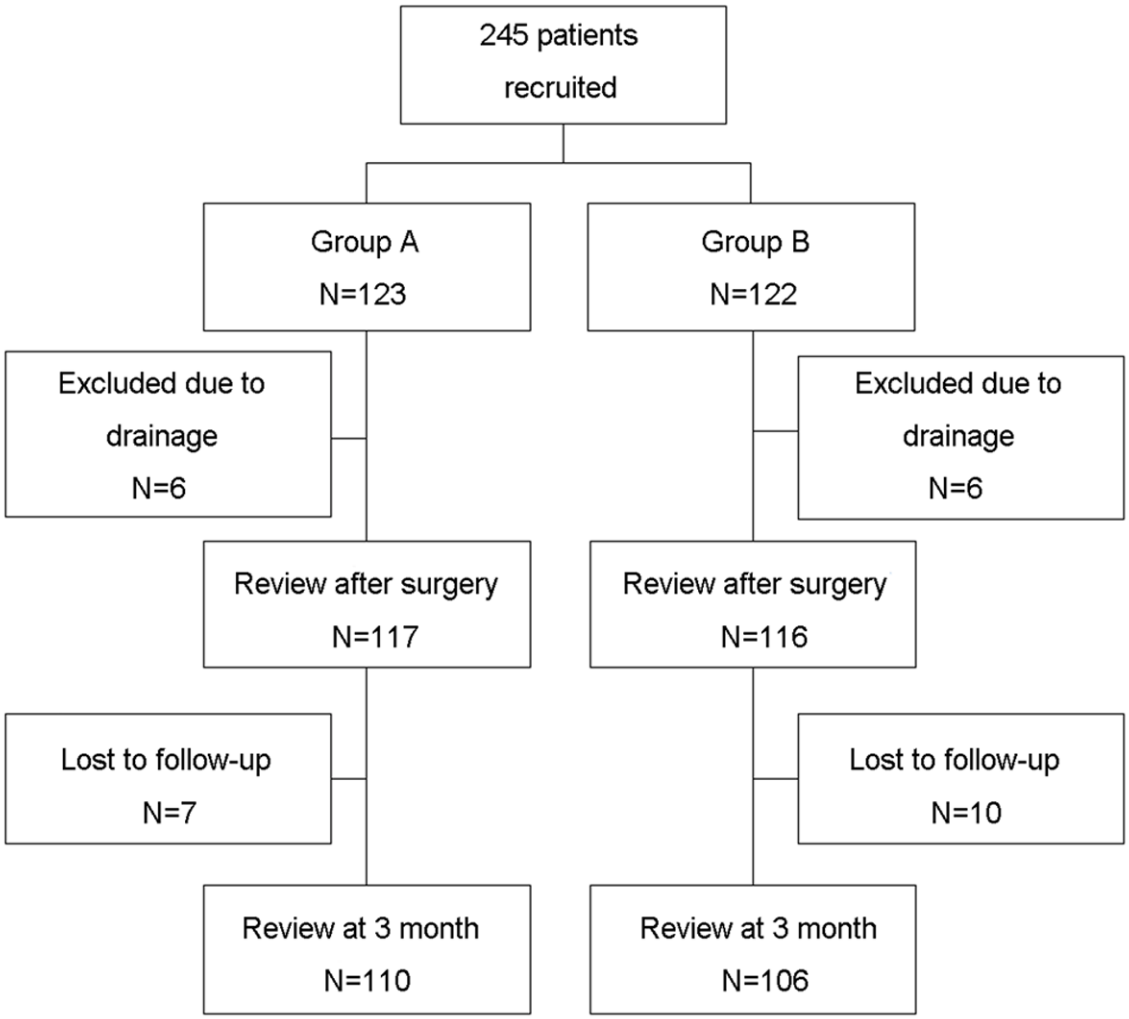

Figure 1. Flow chart showing the outcomes for the 245 patients enrolled in the trial.

activity and a return to work were also recorded at this check-up.

Cosmetic assessment was undertaken 3 months after surgery using the validated Patient Scar Questionnaire when the patients returned for a check-up (the questionnaire was sent to the patients who did not return). The MOS-24 questionnaire for the assessment of the quality of life was administered at the same time. Data were also collected using telephone interviews.

The Patient Scar Questionnaire was divided into five categories: appearance, symptoms, scar consciousness, satisfaction with appearance and satisfaction with symptoms. Each category had a series of questions with four possible responses, which were scored from 1 to 4; a low score indicated a favorable cosmetic outcome. The MOS-24 questionnaire, which was used to assess quality of life, consists of six subscales: physical functioning, role functioning, social functioning, mental health, health perceptions and body pain. Here we excluded the subscale of body pain as the questionnaire records the pain experience of the previous four weeks. The VAS was obtained 24 hours after surgery in order to substitute for the pain score. Each score was obtained by the sum of its related items. Scores were linearly transformed to a scale from 0 to 100, with 0 and 100 assigned to the lowest and highest possible scores, respectively.

Statistical analysis

All data were collected retrospectively by one blinded assessor. Variables are expressed as

Table 1. Baseline characteristics of subjects (N=143)

	Group A (N=110)	Group B (N=106)	*P* Value
Age (yr)	53.2±12.1	52.6±13.2	0.6332
Sex ratio (M/F)	47/63	40/66	0.4895
BMI (kg/m^2)	23.1±2.2	23.7±2.8	0.3312
VAS	4.9±1.3	5.2±1.4	0.3753

Age data are given as mean ± SD.

Table 2. Surgical outcomes

	Group A (N=110)	Group B (N=106)	*P* Value
Mean operating time (min)	65.2±25.3	63.9±29.6	0.2030
Bleed volume (ml)	16.1±14.5	15.7±15.1	0.3320
Conversion to open surgery	0	0	
Complications	0	1 (wound infection)	
VAS	2.3±2.1	4.3±2.6	<0.01
Length of hospital stay (days)	2.2±1.5	3.6±1.7	<0.05
Hospitalization cost (RMB)	13587±1053	15678±993	<0.05
Discharge time (hours)	17±7.5	22±8.8	<0.05
Return to normal activity (hours)	12±3.8	20±4.3	<0.01
Return to work (days)	5.3±2.7	7.8±2.5	<0.05
Short-term mortality	0	0	

Age data are given as mean ± SD.

mean ± standard deviation (SD). Student's t test was used to evaluate the significance of each parameter, and the Mann-Whitney U test was used for the visual analogue scores because the scores were not normally distributed. Statistical significance was set at P<0.05. All statistical analyses were conducted using SAS version 9.2 (SAS Institute Inc., Cary, NC).

Results

From May 2013 to December 2014, 245 patients who were to receive LC in our department were enrolled in the study and randomized to either the three-port LC group (group A) or the conventional four-port group (group B). **Figure 1** shows the follow-up situation of the 245 patients enrolled in the trial. Twelve subjects were excluded after surgery because drainage was used, and the trial retained 216 of the remaining 233 patients because of patients lost to follow-up.

Patient characteristics

The baseline characteristics of the two groups are shown in **Table 1**. There were 129 (59.7%) female and 87 (40.3%) male subjects with a mean age of 52.8 years. There were no significant differences between the two groups in terms of age, sex, body mass index and visual analogue score (VAS).

Surgical outcomes

Table 2 shows a comparison of the two groups with respect to operative and postoperative parameters. There were no significant differences in the mean operating time (P= 0.2030) and bleeding volume (P=0.3320) between the two groups. Out of all 216 subjects, none of their surgeries were converted to open cholecystectomy, and there were no major intra-operative complications. One subject suffered from a wound infection three days after surgery in group B, and this patient was discharged from the hospital safely after a corresponding 5-day treatment. The postoperative pain score was significantly lower 24 hours after surgery in group A (2.3±2.1 versus 4.3±2.6; P<0.01). A significant difference was also observed in the length of the hospital stay between the two groups, as the mean length of the hospital stay in group A was 2.2±1.5 days, while in group B it was 3.6±1.7 days (P<0.05). The hospitalization cost was evidently lower in group A (13587±1053 versus 15678±993 RMB; P<0.05). The time to discharge was significantly shorter in group A (17±7.5 versus 22±8.8 hours; P<0.05). The time that was required to return to normal activity was significantly shorter in group A (12±3.8 versus 20±4.3 hours; P<0.01), as well as the time required to return to work (5.3±2.7 versus 7.8±2.5 days; P<0.05). The short-term mortality of these subjects was 0.

Cosmesis

As is shown in **Figure 2**, the Patient Scar Questionnaire is divided into five categories: appearance, symptoms, scar consciousness,

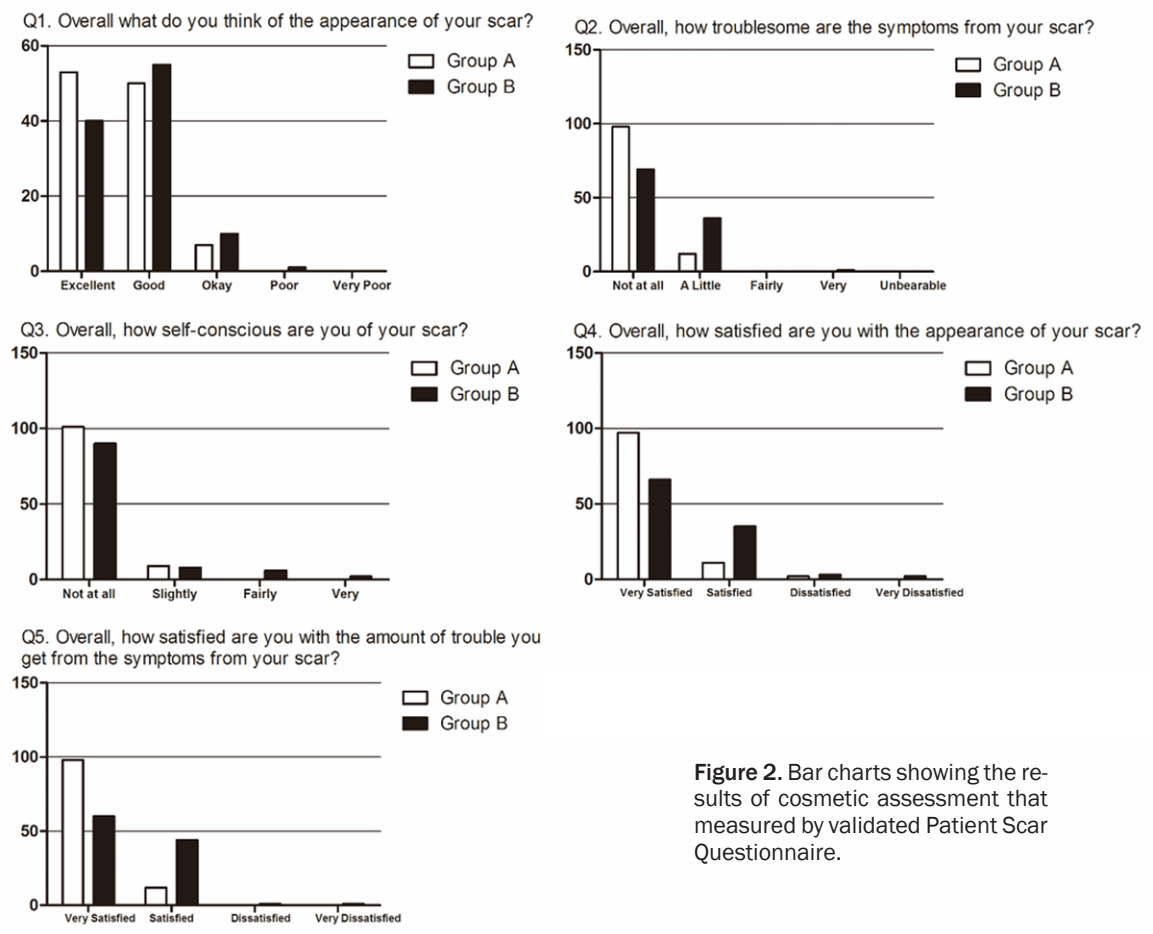

Figure 2. Bar charts showing the results of cosmetic assessment that measured by validated Patient Scar Questionnaire.

satisfaction with appearance and satisfaction with symptoms. The median score in group A was significantly better in all categories. It is worth noting that we observed a difference in symptoms, satisfaction with appearance and satisfaction with symptoms between the two groups. In group A, 89% of the patients expressed that they experienced no difficulties from symptoms of the scar, while in group B, only 65% of the patients expressed that they experienced no difficulties from symptoms of the scar. With regard to satisfaction with the appearance and symptoms of the scar, approximately 90% of the patients in group A were "very satisfied". In contrast, in group B, only 62% of the patients were very satisfied with the appearance of the scar, and 57% of the patients were very satisfied with the symptoms of the scar. All of these results indicate that the three-port LC resulted in better cosmesis.

Quality of life

Figure 3 shows the results of the MOS-24 questionnaire 3 months after treatment. No significant differences were observed in physical functioning (P=0.4958), role functioning (P=0.4053) and social functioning (P=0.3574) between the two groups. However, patients in group A showed better outcomes in mental health (P=0.0001) and health perception (P=0.0037) than patients in group B.

Discussion

In the era of laparoscopic surgery, modifications regarding port number and size have been tried since the advent of the conventional four-port LC to improve cosmetic outcome and quality of life of patients [2, 7, 9, 14]. Although research has found that three-port LC has a variety of advantages compared to four-port LC [7, 9, 11, 15, 16], here we confirmed this conclusion with more detailed data.

This study showed that the three-port LC technique had a variety of advantages compared to conventional four-port LC. We found that the mean operating time and bleeding volume were not significantly different between the two

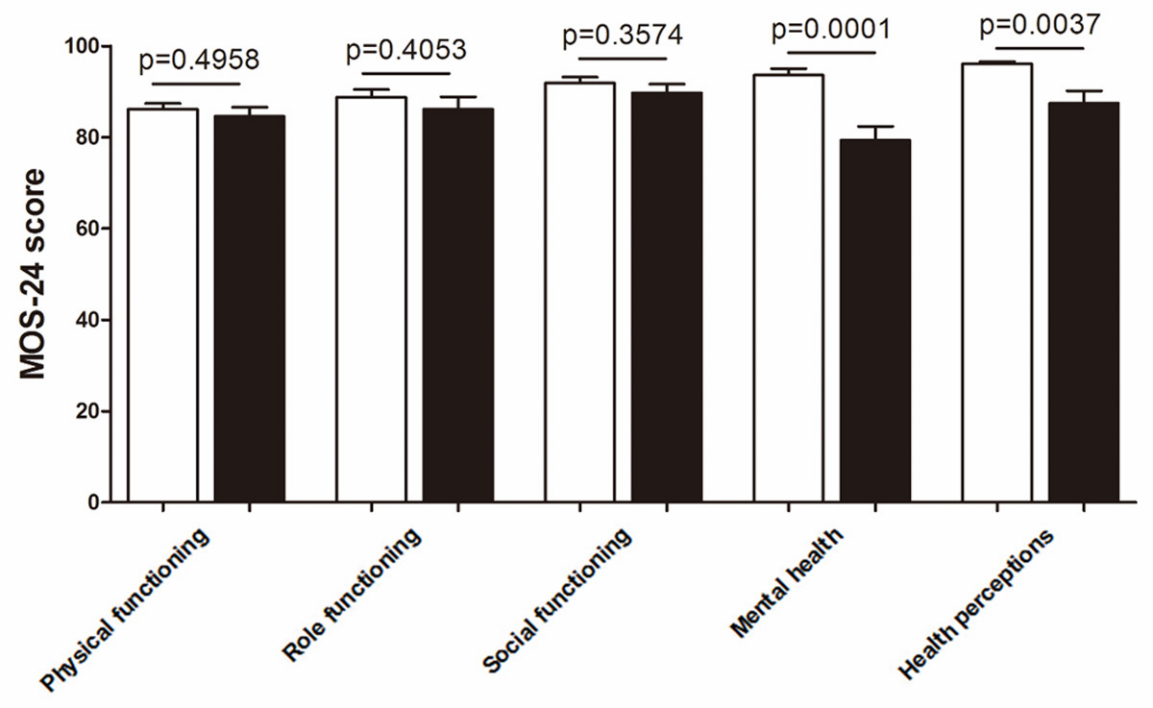

Figure 3. Life quality assessed by MOS-24 questionnaire 3 month after surgery.

groups. In addition, no patient was converted to open surgery, and no complications such as postoperative bleeding and bile leakage occurred. These results indicate that three-port LC is as effective as conventional four-port LC. Moreover, the three-port LC was more effective in relieving pain, shortening discharge time and length of hospital stay, reducing hospitalization cost and returning patients to normal activity and normal work than the conventional four-port LC. Moreover, the three-port technique resulted in a better cosmetic outcome as assessed by the validated Patient Scar Questionnaire; mental health and health perceptions were significantly better as well. A single-blind study was used to assess pain scores after surgery and 24 hours was long enough for the anesthetics to be metabolized, which eliminated the analgesic effect. All of these results suggest that three-port LC is a safe and effective procedure that has a better effect on cosmesis and quality of life, and therefore should be used as a the standard surgical procedure.

A strength of this study was the randomized controlled study design. Most importantly, for the first time, we introduced the MOS-24 questionnaire into the research protocol in order to assess the improvement in quality of life after LC, which revealed that three-port LC had a better effect on quality of life.

Several details of this study should be considered. Patients who underwent acute cholecystitis were excluded because the acute inflammation makes the gall bladder easy to tear when grasped, which may result in the leakage of infected bile. Routine prophylactic drainage after LC in acute inflammatory cholecystitis is commonly performed [17]. Some details of the operation itself should also be emphasized. For instance, we clamped all of the ductules that were suspected to be blood vessels or bile ductules to prevent postoperative bleeding and bile leakage. After removing the gallbladder, we splayed the gallbladder bed with an electric scalpel (80-90 volts) to make it more secure. Irrigating the abdominal cavity with 250-500 ml of sterilized normal saline was necessary, and we suctioned the abdominal fluid as cleanly as possible. All of these points were the basis of the no-drainage protocol. In addition, during the operation the three-port LC could be changed to a four-port LC if needed, which offered options for the surgery. It also reduced the number of surgeons, which facilitated surgical manipulation.

The main limitation of this surgical procedure is that experienced surgeons are needed for the three-port operation. Generally, surgeons with more than 1 year of LC experience could perform this operation [10]. The mean operating time seemed to be longer but not significantly different. In terms of cosmesis, it is necessary to mention single-port laparoscopic surgery (SPLS) and natural orifice transluminal endoscopic surgery (NOTES), as both of these claim better cosmesis and studies have shown a quicker recovery and reduced pain [12, 13], which is consistent with our previously published work [18]. Therefore, future studies that compare three-port LC with SPLS and NOTES are needed.

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Disclosure of conflict of interest

None.

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References

[1] Litynski GS. Endoscopic surgery: the history, the pioneers. World J Surg 1999; 23: 745-753.
[2] Bignell M, Lewis MP, Cheong EC and Rhodes M. A prospective, randomized, single-blind trial of 5-mm versus 3-mm ports for laparoscopic cholecystectomy: is smaller better? Surg Endosc 2013; 27: 3616-3621.
[3] Welbourn RB. Highlights from endocrine surgical history. World J Surg 1996; 20: 603-612.
[4] Olsen DO. Laparoscopic cholecystectomy. Am J Surg 1991; 161: 339-344.
[5] Litwin DE and Cahan MA. Laparoscopic cholecystectomy. Surg Clin North Am 2008; 88: 1295-1313, ix.
[6] Bawahab MA, Abd El Maksoud WM, Alsareii SA, Al Amri FS, Ali HF, Nimeri AR, Al Amri AR, Assiri AA and Abdul Aziz MI. Drainage vs. non-drainage after cholecystectomy for acute cholecystitis: a retrospective study. J Biomed Res 2014; 28: 240-245.
[7] Chalkoo M, Ahangar S and Durrani AM. Is fourth port really required in laparoscopic cholecystectomy? Indian J Surg 2010; 72: 373-376.
[8] Monson JR, Guillou PJ, Keane FB, Tanner WA and Brennan TG. Cholecystectomy is safer without drainage: the results of a prospective, randomized clinical trial. Surgery 1991; 109: 740-746.
[9] Kumar M, Agrawal CS and Gupta RK. Three-port versus standard four-port laparoscopic cholecystectomy: a randomized controlled clinical trial in a community-based teaching hospital in eastern Nepal. JSLS 2007; 11: 358-362.
[10] Tagaya N, Kita J, Takagi K, Imada T, Ishikawa K, Kogure H and Ohyama O. Experience with three-port laparoscopic cholecystectomy. J Hepatobiliary Pancreat Surg 1998; 5: 309-311.
[11] Trichak S. Three-port vs standard four-port laparoscopic cholecystectomy. Surg Endosc 2003; 17: 1434-1436.
[12] Ersin S, Firat O and Sozbilen M. Single-incision laparoscopic cholecystectomy: is it more than a challenge? Surg Endosc 2010; 24: 68-71.
[13] Tacchino R, Greco F and Matera D. Single-incision laparoscopic cholecystectomy: surgery without a visible scar. Surg Endosc 2009; 23: 896-899.
[14] Mayir B, Dogan U, Koc U, Aslaner A, Bilecik T, Ensari CO, Cakir T and Oruc MT. Safety and effectiveness of three-port laparoscopic cholecystectomy. Int J Clin Exp Med 2014; 7: 2339-2342.
[15] Leggett PL, Bissell CD, Churchman-Winn R and Ahn C. Three-port microlaparoscopic cholecystectomy in 159 patients. Surg Endosc 2001; 15: 293-296.
[16] Leggett PL, Churchman-Winn R and Miller G. Minimizing ports to improve laparoscopic cholecystectomy. Surg Endosc 2000; 14: 32-36.
[17] Park JS, Kim JH, Kim JK and Yoon DS. The role of abdominal drainage to prevent of intra-abdominal complications after laparoscopic cholecystectomy for acute cholecystitis: prospective randomized trial. Surg Endosc 2014; 29: 453-7.
[18] Niu J, Song W, Yan M, Fan W, Niu W, Liu E, Peng C, Lin P, Li P and Khan AQ. Transvaginal laparoscopically assisted endoscopic cholecystectomy: preliminary clinical results for a series of 43 cases in China. Surg Endosc 2011; 25: 1281-1286.