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Two-port needlescopic cholecystectomy: prospective study of 100 cases

一百宗兩孔針鏡膽囊切除手術的病例：前瞻性研究

Objective. To test the feasibility of needlescopic cholecystectomy using a two-port technique with 3-mm miniaturised instruments.

Design. Prospective study.

Setting. Regional hospital, Hong Kong.

Patients. One hundred consecutive patients undergoing elective cholecystectomy from September 2001 to August 2002.

Intervention. Two-port needlescopic cholecystectomy all performed or supervised by a single laparoscopic surgeon.

Main outcome measures. Conversion of the procedure, the operating time, postoperative analgesic requirement, pain score using the 10-cm visual analog scale, complications, and the postoperative stay. To determine the technical difficulty of this new technique, the data from the first 50 patients were compared with those of the latter 50. Outcome variables were also compared with a group of 58 patients operated on with the standard two-port laparoscopic cholecystectomy in a previous randomised trial.

Results. One conversion to open cholecystectomy was reported. Three patients required the enlargement of epigastric port to a size of 5 mm and six patients required an additional port to complete the operation. The median operating time was 62 minutes (range, 33-168 minutes). The median pain score was 3.5 (range, 0-9) and the median postoperative stay was 2 days (range, 1-14 days). Six patients had postoperative complications. When the first 50 patients were compared with the latter 50, there were no differences in the conversion rate, operating time, complication rate, and duration of hospital stay. However, the latter 50 patients had significantly lower pain scores (median, 3.5 vs 4.9; P=0.007) and faster resumption of diet (median, 5 vs 9 hours; P<0.001). The median operating time of needlescopic cholecystectomy was notably longer (62 vs 46 minutes; P<0.001) compared with that of the two-port laparoscopic cholecystectomy. Patients undergoing needlescopic cholecystectomy had a better resumption of diet (median, 5 vs 7 hours; P<0.001) and less postoperative pain (overall pain score, median, 3.5 vs 4.8; P=0.052) than the two-port laparoscopic cholecystectomy group. Pain scores at individual port sites were also lower in needlescopic cholecystectomy group (umbilical port: median, 3 vs 4.4, P=0.015; epigastric port: median, 2.0 vs 3.6, P=0.036).

Conclusion. Two-port needlescopic cholecystectomy is technically feasible and may further improve the surgical outcomes in terms of postoperative pain and cosmesis. It can be considered for routine practice by surgeons who are familiar with the two-port laparoscopic cholecystectomy technique.

Key words:
Cholecystectomy, laparoscopic;
Fiber optics;
Laparoscopes;
Miniaturization;
Needles

關鍵詞：
膽囊切除術，腹腔鏡的；
纖維光學；
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針

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目的：測試利用 3 毫米微型儀器進行兩孔針鏡膽囊切除手術的可行性。
設計：前瞻性研究。
安排：分區醫院，香港。
患者：2001 年 9 月至 2002 年 8 月期間，連續 100 位接受非緊急膽囊切除手術的病人。
療法：由一位腹腔鏡外科醫生進行或監督進行兩孔針鏡膽囊切除手術。
主要結果測量：手術方法的轉換、手術時間、術後止痛、以10厘米目測類比法檢定的疼痛指數、併發症，以及術後留院期。透過前50與後50位病人數據的比較，評估這項新技術的技術難度。此外，本研究亦把結果變數與前一次隨機測試中 58 位接受標準兩孔腹腔鏡膽囊切除手術的數據進行比較。
結果：1名病人須轉以開腹切除膽囊；3名病者須擴大上腹壁孔口至5毫米；6名病人則須多開一個孔口方能完成手術。手術時間的中位數為 62 分鐘（值域：33-168 分鐘），疼痛指數的中位數為 3.5（值域：0-9），而術後留院期的中位數則為 2 天（值域：1-14 天）。6 名病者出現術後併發症。根據前 50 位和後 50 位病人的數據顯示，手術方法轉換率、手術時間、併發症比率，以及術後留院期並無差異，但是後 50 名病人的疼痛指數明顯較低（中位數：3.5 比 4.9；P=0.007），術後亦可以較快重新進食（中位數：5 小時比 9 小時；P<0.001）。與兩孔腹腔鏡膽囊切除手術比較，針鏡膽囊切除手術明顯需要較長的時間（中位數：62 分鐘比 46 分鐘；P<0.001）；不過，病人在接受針鏡膽囊切除手術後重新進食的時間則較快（中位數：5 小時比 7 小時；P<0.001），而術後疼痛也較少（整體疼痛指數，中位數：3.5 比 4.8；P=0.052），個別孔口部位的疼痛指數亦較低（臍部孔口：中位數：3 比 4.4 ， P=0.015；上腹壁孔口：中位數：2.0 比 3.6 ， P=0.036）。
結論：兩孔針鏡膽囊切除手術在技術上是可行的，除了減輕術後疼痛，傷口的外觀也較好。掌握了兩孔腹腔鏡膽囊切除手術的外科醫生，可以考慮用這項新技術作為常規手術療法。

Introduction

The use of needlescopic instruments in cholecystectomy has been reported since 1998.[1] The use of miniaturised instruments has been associated with less postoperative pain and better cosmesis than the conventional four-port laparoscopic cholecystectomy (LC).[2,3] Since 1999, our unit has routinely performed LC using a modified two-port technique,[4] which has been shown to be safer and less painful at individual port sites than the conventional four-port LC.[5] With recent advances in technology, we postulated that we could further decrease the postoperative pain and improve cosmesis by using miniaturised instruments, which require smaller epigastric ports.

Methods

From September 2001 to August 2002, 100 consecutive patients who were referred for elective LC at our hospital were prospectively recruited in this study. All procedures were performed or supervised by a single laparoscopic surgeon who had previously performed more than 100 two-port laparoscopic cholecystectomies. The conversion of the LC procedure was the primary outcome measure that could be decided by the supervising surgeon and was either (1) the enlargement of epigastric port site to a standard 5-mm size; or (2) the requirement of additional port(s) to complete the procedure; or (3) the conversion to an open procedure. Other factors affecting the outcome included the operating time, the postoperative analgesic requirement, the pain score using a visual analog scale (VAS), complications, and the postoperative stay.

To determine the technical difficulty of this new technique, the data of the first 50 patients were compared with that of the second 50. The outcome variables were also compared with the data from 58 patients who were operated on with the standard two-port LC in a previous randomised trial.[5] The summary statistics were presented as the median together with the range. Categorical data were analysed with Pearson Chi squared test or Fisher exact test as appropriate. The Mann-Whitney *U* test was used to validate the equality of median. A P value of less than 0.05 was considered to be statistically significant. For statistical analysis, the Statistical Package for the Social Sciences (Windows version 9.0; SPSS Inc, Chicago, United States) was used.

Surgical technique

Two-port needlescopic cholecystectomy (NC) was performed by two surgeons who were both standing on the left side of the patient. After satisfactory general anaesthesia, an 11-mm supraumbilical port was inserted into peritoneum using the open technique, and a carbon dioxide pneumoperitoneum was then created (<12 mm Hg; 6 L/min). A 3.5-mm epigastric port was then inserted with direct visualisation. Apart from the use of the 3-mm needlescopic instruments,

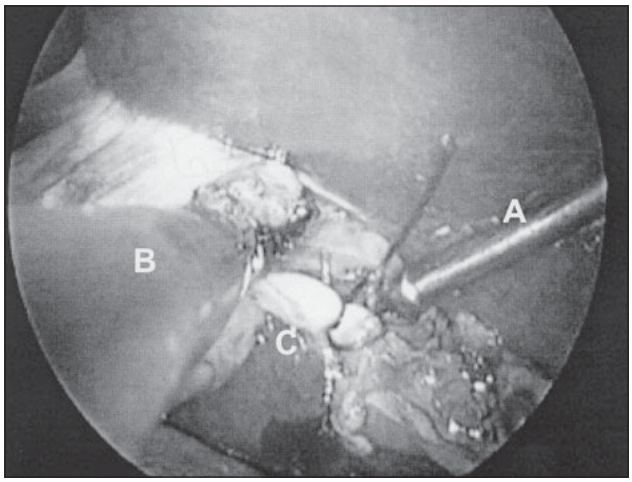

Fig 1. Extracorporeal knot to secure the cystic duct: (A) 3-mm knot pusher, (B) grasping forceps, and (C) cystic duct

retraction and dissection of gallbladder was similar to the two-port technique using a 10-mm modified operating telescope (26036A; Karl Storz, Tuttlingen, Germany), which has been previously described.[4] Briefly, the 10-mm modified operating telescope together with an extra-long 43-cm grasping forceps were inserted through the supraumbilical port. Dissection of the Calot's triangle was accomplished with a 3-mm dissecting instrument inserted via the epigastric port. The cystic artery was coagulated by the bipolar diathermy coagulator, and the cystic duct was doubly ligated by the extracorporeal method using a 2-O polypropylene ligature (Polysorb; Auto Suture, Tyco Healthcare, Mansfield [MA], United States) [Fig 1]. The extracorporeal knot was secured by the Tayside method (Fig 2) and was then tightened using a 3-mm knot pusher. At the end of the surgery, the cystic duct was divided and the gallbladder was dissected from the liver bed and delivered using long grasping forceps through the operating channel of the telescope with direct visualisation. For difficult cases, the enlargement of the epigastric port to 5 mm to accommodate larger instrument(s) or insertion of additional ports were decided by the supervising surgeon.

All the patients received a standardised analgesic regimen of intramuscular pethidine (1 mg/kg every 4 hours) and a dologesic (one tablet 4 times daily as necessary) postoperatively. The overall pain and the pain at the umbilical and epigastric port sites were recorded by an independent assessor using a 0-10 unscaled VAS. Analgesic requirement, complications, and duration of hospital stay were also charted.

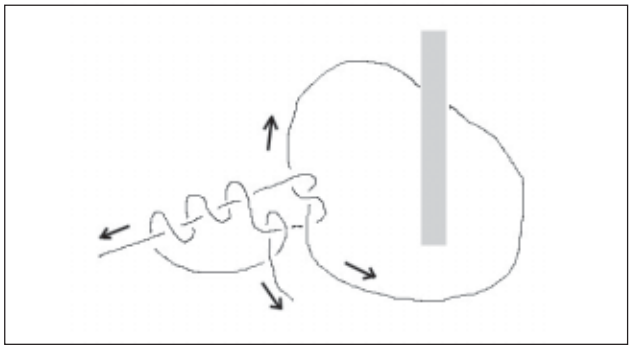

Fig 2. Tayside knot

Results

The median age of the patients was 54 years (range, 27-87 years), and the male to female ratio was 2:3. Indications for cholecystectomy included symptomatic gallstones (n=67), interval cholecystectomy for biliary pancreatitis or cholangitis (n=18), previous attack of acute cholecystitis (n=11), and gallbladder polyp (n=4). Ten (10%) of 100 patients required conversion of the LC procedure and are shown in Table 1. One patient with background history of acute cholecystitis was converted to open surgery, three patients required enlargement of epigastric port to 5 mm, and six patients were converted to either three-port (n=4) or four-port (n=2) surgery. The reasons for conversion included unclear anatomy due to adhesion (n=5), contracted gallbladder leading to a difficult retraction by the needlescopic instruments (n=4), and instrument failure (n=1). Patients with symptomatic gallstones had a lower conversion rate compared with those who had previous history of acute cholecystitis (4/67, 6.0% vs 5/11, 45.5%; P=0.002, Chi squared test).

The overall median operating time of all 100 patients receiving NC was 62 minutes (range, 33-168 minutes) and patients required a mean of 5 hours (range, 0.75-46 hours) to resume oral diet. The median overall VAS pain score was 3.5 (range, 0-9) and less pain was experienced at epigastric port (median, 2; range, 0-8.4) than at the umbilical port (median, 3; range, 0-9). Patients required zero median dose of intramuscular analgesia (range, 0-6) and only 2 median doses of oral analgesia (range, 0-28) were needed. The median postoperative stay was 2 days (range, 1-14 days). Six of the patients developed complications, and two of these patients had intra-abdominal collection which was treated successfully by conservative measures. Another patient developed a wound infection at the umbilical port site, and a further two patients experienced acute urine retention. One patient had postoperative deranged liver function and was

Table 1. List of patients with conversion of the laparoscopic cholecystectomy procedure

Patient No.	Sex	Age (years)	Indication	Conversion	Cause of conversion
1	F	55	Symptomatic gallstones	3-port	Adhesion
2	M	69	Symptomatic gallstones	5-mm epigastric port, 3-port	Adhesion
3	F	59	Symptomatic gallstones	4-port	Adhesion
4	M	70	Symptomatic gallstones	10-mm epigastric port, 4-port	Adhesion
5	F	81	History of acute cholecystitis	5-mm epigastric port	Adhesion with contracted gallbladder
6	M	54	History of acute cholecystitis	5-mm epigastric port	Adhesion
7	F	61	History of acute cholecystitis	Open	Adhesion with contracted gallbladder
8	F	76	History of acute cholecystitis	3-port	Adhesion with contracted gallbladder
9	M	69	History of acute cholecystitis	10-mm epigastric port, 3-port	Adhesion with contracted gallbladder
10	M	60	History of cholangitis	5-mm epigastric port	Instrument failure

Table 2. Outcome variables of first 50 patients and latter 50 patients

Outcome variable	First 50 patients*	Latter 50 patients*	P value
Procedure performed by the laparoscopic surgeon	20	9	0.035†
Operating time (minutes)	60 (37-105)	65 (33-168)	0.303
No. of patients having conversion	4	6	0.464
Epigastric port-site enlargement or additional subcostal ports	3	6	
Open conversion	1	0	
Time required to resume diet (hours)	9 (2-24)	5 (0.75-46)	0.001‡
Overall pain score (0-10 unscaled visual analog scale)	4.9 (0-9)	3.5 (0-9)	<0.007‡
No. of doses of intramuscular analgesia	0 (0-6)	0 (0-1)	0.148
No. of doses of oral analgesia	1 (0-18)	2 (0-28)	0.171
Postoperative stay (days)	2 (1-10)	2 (1-14)	0.610
No. of complications	2	4	0.686

* Data are shown in median (range) unless otherwise stated
† Chi squared test
‡ Mann-Whitney *U* test

found to have common bile duct stones, which were removed by endoscopic retrograde cholangiopancreatography. No bile duct injuries occurred in our series.

Comparison between the outcomes of the first 50 patients and that of the latter 50 are shown in Table 2. There were no differences in the operating time (median, 60 vs 65 minutes), the numbers of conversion (4 vs 6) and complications (2 vs 4), the analgesic requirement, and the duration of postoperative stay. In contrast, the latter 50 patients had a significantly lower overall pain score (median, 4.9 vs 3.5; P=0.007, Mann-Whitney *U* test) and faster resumption of diet (median, 9 vs 5 hours; P<0.001, Mann-Whitney *U* test). The single laparoscopic surgeon performed more operations in the first 50 patients than the latter 50 (20 vs 9; P=0.035, Chi squared test).

Demographic data were well matched between the NC patients from this study and LC patients from the previous study[5] (Table 3). A significant difference was found in the indicating pathologies, for example, more patients with history of acute cholecystitis were operated in NC group (11 vs 0; P=0.02, Chi squared test) than the LC group. The operating time in the NC group was significantly longer than the LC group (median, 62 vs 46 minutes; P<0.001, Mann-Whitney *U* test). In contrast, the NC group had significantly lower pain scores at both the umbilical port (median, 3.0 vs 4.4; P=0.015, Mann-Whitney *U* test) and the epigastric port (median, 2.0 vs 3.6; P= 0.036, Mann-Whitney *U* test) than LC group. Although the overall pain scores were lower in NC group, they were not statistically significant (median, 3.5 vs 4.8; P=0.052, Mann-Whitney *U* test). Patients in the NC group had faster resumption of diet (median, 5 vs 7 hours; P<0.001, Mann-Whitney *U* test). No statistical differences could be detected between the two groups in the conversion rate, the number of complications, and the length of postoperative stay (Table 4).

Discussion

Two-port LC has become the routine procedure of

Table 3. Demographic data comparison between needlescopic and laparoscopic cholecystectomy groups

Outcome variable	Needlescopic cholecystectomy, n=100	Laparoscopic cholecystectomy, n=58	P value
Median age (range) [years]	62 (23-87)	50 (23-79)	0.104
Sex ratio (female:male)	41:59	24:34	0.904
Indications of surgery			0.02*
Symptomatic gallstones	64	39	
Pancreatitis or cholangitis	22	12	
Acute cholecystitis	11	0	
Gallbladder polyp	4	5	
Others	0	2	

* Overall P value for all pathologies using the Chi squared test

Table 4. Outcome variables comparison between needlescopic and laparoscopic cholecystectomy groups

Outcome variable	Needlescopic* cholecystectomy	Laparoscopic* cholecystectomy	P value
Operating time (minutes)	62 (33-168)	46 (22-140)	<0.001†
No. of patients having conversion	10	5	0.125
Epigastric port-site enlargement or additional subcostal ports	9	2	
Open conversion	1	3	
Time required to resume diet (hours)	5.0 (0.75-46)	7.0 (2-99)	<0.001†
Overall pain score (0-10 unscaled VAS‡)	3.5 (0-9)	4.8 (0.4-10)	0.052†
Pain score at umbilical port site (0-10 unscaled VAS)	3.0 (0-9)	4.4 (0-10)	0.015†
Pain score at epigastric port site (0-10 unscaled VAS)	2.0 (0-8.4)	3.6 (0-10)	0.036†
Postoperative stay (days)	2 (1-14)	2 (1-11)	0.118
No. of complications	6	3	0.875

* Data are shown in median (range) unless otherwise stated
† Mann-Whitney *U* test
‡ VAS visual analog scale

elective cholecystectomy in our unit since 1999. Our previous randomised trial demonstrated that two-port LC was safe and efficient compared with conventional LC.[5] To further improve the clinical outcome, the two-port technique using needlescopic instruments was a reasonable option. Since the development of miniaturised instruments, four randomised trials comparing the benefits of mini-LC versus standard LC have successfully demonstrated the reduction in postoperative pain.[2,3,6,7] Bisgaard et al[6] reported the first randomised trial comparing micro-LC (2 mm) with conventional LC. The postoperative pain was considerably reduced, but 38% of patients required conversion to conventional LC. The same group of surgeons repeated the trial using 3.5-mm instruments which achieved a lower conversion rate (3.3%).[3] The successful surgery, hence, indicated that the lower conversion rate was related to the strength of the instrument, which was reflected in the larger 3.5-mm size. A recent prospective study on NC showed that the use of a larger-diameter mini-laparoscopic instrument also decreased operating time.[8] Thus, we chose 3-mm instruments for the cholecystectomy via the epigastric port. The operation was successfully completed in 90% of patients, and this result was comparable to the conversion rate in other studies.[2,3,8] Previous history of acute cholecystitis was a major factor contributing to conversion from NC procedure, because adhesion around the Calot's triangle and the presence of contracted gallbladder required stronger instruments to perform the dissection and retraction.

In the comparison of the first and second half of patients, there were no differences detected in operating time, conversion rate, and complications, despite a higher proportion of operations by a single surgeon on the first 50 patients. Learning curve virtually did not exist in two-port NC. The faster resumption of diet and lower pain score in the latter 50 patients reflected further maturity of this new technique, although it was not shown in analgesia consumption and hospital stay. Two-port NC did not differ much from the standard two-port technique apart from the use of extracorporeal knot to secure cystic duct. We tried different types of suture material for extracorporeal knot in the first few cases. 2-O polypropylene was selected for its smooth knotting property which could facilitate pushing the extracorporeal knot down to

cystic duct. Nevertheless, there was no difficulty for the same group of surgeons to move from two-port LC to two-port NC. The operating time of first 10 cases were compared with the rest of the procedures, and no difference could be detected (median, 67 vs 60 minutes; P=0.36, Mann-Whitney *U* test).

The comparison between our NC group and a previously reported LC group showed interesting results. With increasing experience in two-port technique, there was no exclusion criterion in NC group. Even patients with previous attack of acute cholecystitis were recruited in this study. Despite the absence of exclusion criteria, clinical outcomes of NC group were better than that of LC group in terms of pain control as well as diet resumption. The lower pain score at epigastric port site in NC group supported the fact that small-port incision led to less postoperative pain. The overall pain score was also marginally less in NC group. Such benefits were achieved using miniaturised instruments, but at the expense of a longer operating time in NC group. This was likely related to the use of an extracorporeal knot and more time-consuming dissection using the miniaturised instruments. Nevertheless, a median operating time of 62 minutes was still acceptable for elective cholecystectomy. With the similar conversion and complication rate to LC, two-port NC should be regarded as a safe routine procedure.

Conclusion

Two-port NC was found to be feasible and safe in elective cholecystectomy with better outcomes compared with the conventional two-port LC and could even replace this standard technique. Experienced NC surgeons seem to be the key to a successful outcome with less postoperative pain, but at the expense of longer operating time. Surgeons who are experienced with the two-port LC technique should have no difficulty adapting to two-port NC using 3-mm miniaturised instruments. In view of the advancements in this technique, our unit will be using two-port NC in routine elective cases.

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