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Needlescopic cholecystectomy: prospective study of 150 patients

使用針孔鏡進行膽囊切除術：對一百五十位患者的預期研究

Objective. To evaluate the feasibility and safety of cholecystectomy using miniaturised instruments of 3 mm or less in diameter.

Design. Prospective study on patients with gallstones, with or without related complications.

Setting. Private hospital, Hong Kong.

Patients. From September 1997 to September 2002, 150 of the 180 consecutive patients managed were included in the present study.

Main outcome measures. All patients were operated on with a standard four-port technique. Mini-laparoscopes of different sizes were used throughout the study period, which included 2-mm (n=33) fibre-optic laparoscope, and 2.5-mm (n=61) and 3-mm (n=56) laparoscopes of Hopkins rod lens system. The cystic duct and artery were secured either by extracorporeal ties or 10-mm clips passed through the umbilicus. The time taken from dissection to division of the cystic duct and artery, and to complete the operation were documented.

Results. The operation was successfully completed with needlescopic instruments in 127 (85%) patients, even though patients with acute cholecystitis and history of common bile duct stones were included. Use of larger-diameter mini-laparoscopes decreased the time needed to divide the cystic duct and artery, to detach the gall bladder from the liver, and to complete the operation. There were no deaths. One minor bile duct injury developed secondary to extensive cauterisation of the gall bladder fossa.

Conclusion. Needlescopic cholecystectomy with minor technical modification can be completed within a duration comparable to standard laparoscopy at no increased risk for the great majority of patients with gallstones.

目的：評估使用直徑為 3 毫米或以下微型器械進行膽囊切除術的可行性與安全程度。

設計：對膽石病患者進行預期研究，部分患者兼有相關的併發症。

安排：香港一所私立醫院。

患者：1997 年 9 月至 2002 年 9 月期間，本院連續處理 180 個同類型的病例，本研究取其中的 150 個為對象。

主要結果測量：所有手術採用標準的四孔技術。在研究期間，我們使用了大小不同的微型腹腔鏡，包括有 2 毫米(n=33)的光纖腹腔鏡、賀健氏條型透鏡系統的 2.5 毫米(n=61)和 3 毫米(n=56)的腹腔鏡，並以體外結紮或利用 10 毫米的夾子穿過肚臍來固定膽囊管和膽動脈。從剖開到分離膽囊管和膽動脈，以及完成手術的時間均有紀錄。

結果：儘管部分病者患有急性膽囊炎或曾患上膽總管結石，我們仍以針孔鏡為 127 名(85%)患者順利完成手術。使用直徑較粗的微型腹腔鏡可以縮短分離膽囊管和膽動脈、分開膽囊與肝，以至完成手術所需的時間。沒有患者死亡，僅有一病者，膽囊窩接受過大面積的灼烙後，出現膽管輕微受損。

結論：針孔鏡膽囊切除術在技術上略作調整，就可以在相當於標準腹腔鏡膽囊切除術所需的時間內及相若的危險程度下，對大部分膽石患者完成手術。

Key words:

Cholecystectomy, laparoscopic;
Microsurgery/instrumentation;
Pain, postoperative;
Surgical instruments

關鍵詞：

腹腔鏡膽囊切除術；
顯微手術／儀器；
術後疼痛；
手術器械

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Introduction

Since its introduction in the early 1990s, laparoscopic cholecystectomy has quickly become the standard operation for patients with gallstone disease. Several randomised controlled studies that compared the procedure with mini-laparotomy

through a small incision of 5 to 10 cm in length agree that laparoscopic cholecystectomy using standard 5- to 10-mm instruments results in significantly less postoperative pain, a shorter hospital stay, and quicker recovery.¹⁻⁴ With recently developed needlescopic instruments—miniaturised instruments of 3 mm or less in diameter—further improvements in postoperative results may be made. We performed a prospective study to examine the safety and efficacy of needlescopic cholecystectomy for patients with symptomatic gallstones.

Patients and methods

Between September 1997 and September 2002, a total of 180 patients with symptomatic gallstone disease, with or without a complicated history of acute cholecystitis, cholangitis, or pancreatitis, were treated by the first author. Thirty patients were excluded from needlescopic intervention and they were scheduled for either standard laparoscopic (n=26) or open (n=4) cholecystectomy. Of these 30 patients, 17 with severe acute cholecystitis, as defined according to Borzellino et al,⁵ were excluded because either gas in the gall bladder wall was visible preoperatively on a plain abdominal X-ray or percutaneous ultrasonography revealed a thickened gall bladder wall of more than 8 mm, with or without pericholecystic fluid collection. Thirteen patients were excluded because they had suspected gall bladder cancer (n=4), associated medical problems (n=2), a history of upper abdominal surgery (n=6), or were pregnant (n=1). In all, 150 patients underwent cholecystectomy using instruments of 3 mm or less; 64 patients were men and 86 were women, with a mean age of 49.8 years (range, 24.0-85.0 years; standard error [SE], 1.1 years).

Surgical technique

All patients received a percutaneous ultrasound examination of the biliary system, and blood was sampled for a liver function test that was scheduled close to the date of the operation to screen for the presence of occult common bile duct stones. Unless results of both tests were normal, either magnetic resonance cholangiography or endoscopic retrograde cholangiography was performed to delineate the common bile duct.

All operations were performed under general anaesthesia in the supine position. The surgeon stood on the left of the patient and the rest of the surgical team post on the right. A mini-laparotomy was made via a sub-umbilical incision for the introduction of a 10-mm trocar with a blunt tip. After a pneumoperitoneum with carbon dioxide insufflation had been established, a straight 10-mm laparoscope was placed to guide the insertion of both the mid-clavicular and mid-axillary ports with 2-mm trocars (USSC; Norwalk, Connecticut, US). The size of the sub-xiphoid port changed over the study period depending on the diameter of the mini-laparoscope available. A 2-mm fibre-optic laparoscope (USSC; Norwalk, Connecticut, US) was used for the first 33 patients until March 1999. A 2.5-mm laparoscope of the

Hopkins rod lens type (Ackermann Instrumente GmbH, Rietheim-Weilheim, Germany) was used for the next 61 patients. From February 2001, a 3-mm scope by the same manufacturer was used (n=56).

Two-millimetre graspers (USSC; Norwalk, Connecticut, US) were passed through the two lateral ports to retract the fundus and Hartmann's pouch of the gall bladder. Instruments of matching calibre were used for the dissection around the Carlot's triangle to expose both the cystic duct and cystic artery from the sub-xiphoid port. These instruments included a 1.7-mm ball-tipped coagulator (MIST; Smithfield, North Carolina, US) and insulated instruments including Maryland forceps, L-hook, spatula, and scissors of either 2.5 mm or 3 mm in size (Ackermann Instrumente GmbH, Rietheim-Weilheim, Germany). Whenever feasible, 10-mm titanium clips were passed from the umbilical port to control both the cystic duct and artery under visual control. Alternatively, both artery and duct could be secured by extracorporeal ties using 4/0 monofilament sutures, and passed down via the sub-xiphoid port using the empty plastic rod of a 2-mm loop as a pusher (USSC; Norwalk, Connecticut, US). These ductal structures were then divided using scissors passed from the sub-xiphoid port, only after the proper placement of clips or ties had been verified with the 10-mm laparoscope. If technical difficulty was encountered, the sub-xiphoid port was first converted (followed by the others if necessary) to trocars of larger diameter to facilitate the operation. The gall bladder was detached from the gall bladder fossa with diathermy.

Minor technical modifications were considered if necessary to facilitate the removal of the resected gall bladder depending on the thickness of its wall. If the thickness was normal, the specimen was delivered without a change of laparoscope to save time, especially if only one camera was available. The cystic duct stump on the specimen was grasped by a sub-xiphoid instrument, passed and telescoped into the sub-umbilical trocar and delivered outside the peritoneal cavity. If the gall bladder wall was thick, an additional loop was put close to the cystic duct stump on the gall bladder side. The free end of the loop was first grasped and pulled through the sub-xiphoid port to the anterior abdominal wall, followed by specimen. If the gall bladder wall was thick, the specimen was usually retrieved in the usual manner using wide-jaw grasping forceps passed via the sub-umbilical port under visual guidance.

All the wounds for the needlescopic instruments were closed with tape, and the sub-umbilical wound was closed with sutures in layers. All wounds were routinely infiltrated by 0.5% bupivacaine. Pain assessment scores for individual port sites were obtained by directly questioning the patient (score of 1 to 10 with 10 being the worst), and pain at trocar sites was subjectively assessed at about 12 hours after surgery and after 1 week. All patients were observed overnight and discharged home once they could resume oral feeding satisfactorily and their pain could be adequately controlled by oral analgesics.

Definitions and statistics

Needlescopic cholecystectomy was considered successful if all ports that were used below the costal margin were of 3 mm or less in diameter. If any one of these ports was increased to 5 mm or beyond during the course of the procedure, or a laparotomy was necessary to complete the cholecystectomy, the case was counted as a conversion to laparoscopic procedure, or open surgery, respectively. The timing of surgery was considered an emergency if the procedure was performed within the first 24 hours, and a semi-emergency if the operation was scheduled less than 72 hours after initial presentation. After all trocars had been placed, the duration between the commencement of dissection of the Carlot's triangle and complete division of both the cystic duct and artery was recorded. The duration of the operation was taken as the time when the sub-umbilical incision was made to the time when all wounds were completely closed. Bile duct injury was classified as major or minor, depending on whether open surgery was required for rectification.

Continuous variables were presented as mean (SE) and analysed using Student's *t* test. Categorical variables were compared using the Chi squared test, or Fisher's exact test. All statistical analyses were performed using Statistical Package for the Social Sciences (Windows version 10.0; SPSS Inc., Chicago, US) and statistical significance was taken when $P < 0.05$.

Results

Among the 150 patients intended for a needlescopic cholecystectomy, 25 were suspected to have common bile duct stones on the basis of clinical and biochemical test results. Among patients who underwent magnetic resonance cholangiography ($n=14$) or endoscopic ($n=23$) cholangiography, ductal calculi were found in 21 patients and were cleared by endoscopic intervention either before ($n=20$) or after ($n=1$) surgery.

Needlescopic cholecystectomy was successfully completed in 127 (85%) patients. Nineteen of the 23 patients with failed needlescopic cholecystectomy had their operation completed after one or more ports were enlarged to 5 mm, and four (3%) patients had conversion to open surgery (Table 1). The conversion rate to either conventional laparoscopic or open cholecystectomy was significantly lower among the last 50 consecutive patients (two patients: one to con-

ventional laparoscopy using 5-mm instruments and one to open surgery [4%]) than among the initial 100 patients (21 [21%] patients; $P < 0.001$). The reasons for conversion to standard laparoscopic procedure were inadequate exposure using the fine instruments ($n=8$), uncertain anatomy around the Carlot's triangle ($n=3$), and bleeding from the cystic artery ($n=6$). In the two remaining patients, both had persistent oozing from the gall bladder fossa after completing the procedure with needlescopic instruments. The anterior axillary port was therefore enlarged for the placement of a 15-French drain to guard against sub-hepatic collection. None of these 23 patients had any postoperative morbidity.

Needlescopic cholecystectomy was primarily conducted as an elective procedure (140 patients; 93%). Among the 10 patients who had their operation performed as a semi-emergency ($n=8$) and emergency ($n=2$), surgery was completed using standard laparoscopy in four patients and open surgery in one patient.

Initially, a 2-mm fibre-optic laparoscope was the only mini-laparoscope available and was used only for the delivery of specimen. Extracorporeal ties were invariably used to secure the cystic duct and artery. The amount of time spent on this step contributed significantly to the longer duration for the procedure. As the diameter of the sub-xiphoid laparoscope increased, the better resolution and illumination allowed accurate application of 10-mm clips through the umbilicus to control the cystic duct and artery. Increasing the diameter of the mini-laparoscope led to a significant reduction in the time spent to secure and divide the cystic duct and artery (21.3 minutes for the 2-mm port versus 7.2-11.9 minutes using larger ports; $P < 0.05$) and to complete cholecystectomy (76.0 versus 50.4-62.2 minutes; $P < 0.05$), and in the total duration of the operation (97.4 versus 57.9-74.0 minutes; $P < 0.001$) [Table 2].

Among the 127 patients with successful needlescopic cholecystectomy, the specimen was delivered under visual assistance with a strong grasping forceps passed through the umbilicus in 56 patients. In another 31 patients, the specimen was first grasped by a sub-xiphoid needlescopic grasper, retrogradely telescoped into the 10-mm sub-umbilical trocar, and brought out together to the anterior abdominal wall when the trocar was removed. Additional appliances, including 2-mm endoscopic loops ($n=31$) and 10-mm endoscopic pouches ($n=9$), were required in the remaining patients to deliver the resected gall bladder.

Table 1. Clinical outcome of patients and type of cholecystectomy

Diagnosis	Type of cholecystectomy			Total
	Needlescopic	Laparoscopic	Open	
Symptomatic gallstones	79	8	1	88
Acute cholecystitis	3	2	0	5
Acute-on-chronic cholecystitis	2	2	1	5
Chronic cholecystitis	21	1	0	22
Symptomatic polyps	8	7	0	9
Gallstone and common bile duct stones	14	7	0	21
Total	127	19	4	150

Table 2. Operative details of patients who underwent successful needlescopic cholecystectomy

	Size of sub-xiphoid port			P value*
	2 mm	2.5 mm	3 mm	
No. of attempts	33	64	53	-
No. (%) of success	27 (82)	49 (77)	51 (96)	<0.05
Time to control cystic duct and artery [†] (min)	20.3 (17.6-25.0)	11.9 (9.4-14.3)	7.2 (6.5-7.9)	<0.001
Time to complete cholecystectomy ^{††} (min)	76.0 (66.0-86.0)	62.2 (55.7-68.7)	50.4 (45.0-55.9)	<0.05
Total duration of operation [†] (min)	97.4 (85.3-109.5)	74.0 (66.8-81.3)	57.9 (53.4-62.3)	<0.001
Extracorporeal tie for cystic duct and artery (n)	17	20	1	<0.01
Intraperitoneal bile leak (n)	3	5	0	NS [§]
Subcutaneous emphysema (n)	1	2	1	NS
Umbilical wound discharge (n)	0	0	2	NS
Hospital stay [†] (h)	49.3 (41.8-56.8)	42.8 (39.2-46.3)	38.6 (35.4-41.8)	<0.05

* Chi squared test

[†] Time reported for patients with successful needlescopic cholecystectomy only; expressed as mean (95% confidence interval)^{††} Time measured from the division of both cystic duct and artery to the complete closure of umbilical wound[§] NS = not significant

There was no mortality. One (1%) patient had profuse oozing at his liver bed close to the hepatic hilum after the procedure was successfully completed using mini-instruments. Extensive cauterisation achieved haemostasis and the patient was discharged home on the following morning. At 4 days after surgery, the patient was re-admitted with severe epigastric pain. Ultrasonography showed minor fluid collection at the Morrison's pouch and liver function test results were slightly abnormal. Endoscopic cholangiography confirmed the presence of bile leak at the origin of the right intrahepatic duct close to the bifurcation. The minor bile duct injury was successfully managed with endoscopic biliary decompression and percutaneous drainage. Minor intra-operative complications occurred in 18 (12%) patients. Subcutaneous emphysema developed in four patients; this was related to the use of a short 2.5-mm sub-xiphoid trocar. Sixteen patients had intraperitoneal bile spillage, nine patients had a perforated gall bladder where the graspers were applied, six patients had slipped cystic duct clip during manipulation, and one related to diathermy. Four (3%) patients had serous discharge from their sub-umbilical wound, none of whom had gall bladder perforation during surgery. These patients were given oral antibiotic and the umbilical wound healed uneventfully.

The median postoperative hospital stay was 36 hours. Among the 127 patients who had a successful needlescopic procedure, 14, 57, and 45 of them were discharged at 24, 36, and 48 hours, respectively after surgery. Patients who had needlescopic cholecystectomy had a significantly shorter stay than did those who underwent standard laparoscopy (43.7 [SE, 15.0] hours versus 61.2 [34.0] hours; $P < 0.01$).

Most patients did not note any significant pain in their 2-mm mid-clavicular and mid-axillary wounds. Nineteen (13%) of the 150 patients noticed persistent discomfort at 1 week after procedure at their sub-umbilical wound. The degree of pain at the sub-xiphoid wound at about 12 hours after surgery differed significantly according to the diameter of the trocar used. A pain score of 3 or less was noticed by 97 (76%) of the 127 patients whose sub-xiphoid port was 3 mm or less, whereas four (21%) of the 19 patients who had a 5-mm sub-xiphoid trocar complained of pain ($P < 0.01$).

At about 1 week after surgery, no patient with sub-xiphoid instrument of 3 mm or less had any complaints, whereas two patients with 5-mm sub-xiphoid trocar still noticed pain ($P < 0.01$).

Discussion

Following the success of laparoscopic cholecystectomy with standard instruments of 5 mm or 10 mm in size, surgeons have strived to further improve the results. A number of technical modifications have focused either on reducing the number of ports,⁶ or the diameter of the instruments used.^{7,8} There was considerable scepticism in the early stage of development of needlescopic surgery, which used instruments of 3 mm or less. Concerns related to the safety of the operation as a result of the inferior resolution and illumination of the mini-laparoscope, increased risk of tissue damage with the smaller graspers, risk of contamination and extra time required from the change of laparoscope at different phases of the operation, and the increased cost of the procedure, given that these delicate instruments have a theoretically shorter life-span.⁹ The more practical issue which affects surgeons, however, is the more difficult retraction needed to provide a satisfactory exposure, adaptation to the fine instruments, and the absence of miniaturised metal clips of less than 5 mm in diameter to control the ductal structures.

In this prospective study of 150 needlescopic cholecystectomy procedures, an overall success rate of 85% was achieved, which compared favourably to that of the 62% to 90% reported by others with considerably stricter patient selection criteria.¹⁰⁻¹³ Patients with a history of acute cholecystitis or common duct stones are routinely offered needlescopic intervention as their intended operation.¹⁴ Among the 10 patients with either acute or acute-on-chronic cholecystitis in our series, half had successful needlescopic cholecystectomy. We did not exclude any patient with acute inflammatory disease from use of the procedure on the grounds of a prolonged interval after disease onset, or because of the presence of pericholecystic fluid collection from a trial of needlescopic intervention.^{5,15} Even with such loose inclusion criteria, our success rate with the last

50 consecutive patients was 96%, probably because of increasing experience.

In this study, we insisted on using the conventional four-port technique to provide a clear visualisation of the Carlot's triangle. Using fine instruments, further reduction of ports for a dubious improvement of cosmetic results or less pain could potentially compromise the safety of the operation. In our early experience, completion of the operation entirely with 2-mm instruments was difficult. Data from our analysis suggest that the use of at least one 2.5-mm or 3-mm port, preferably at the sub-xiphoid site, should be considered. All the commercially available insulated two-bladed instruments are of these sizes, and their application allows more effective dissection of soft tissue, which is more accurate, and safer haemostasis by lifting up the tissue to be cauterised. Quick and accurate placement of 10-mm clips onto the ductal structures become possible only with the better visualisation provided by the 2.5-mm or 3-mm mini-laparoscope of the Hopkins rod lens system. Nonetheless, it is still necessary to perform extracorporeal ties with fine sutures to manage the occasional wide cystic duct. Two cameras are now currently used routinely to save time in changing the laparoscope and to avoid the risk of contamination. All these changes help to bring the operating time down to a comparable duration with standard laparoscopic instruments with no discernible increased wound sepsis rate.^{1-4,10-13}

Although needlescopic cholecystectomy could be performed safely and expeditiously for the great majority of patients with gallstones, one should be clear about its exact benefit over conventional laparoscopic intervention. Two of the three randomised studies, from Singapore^{12,13} and Copenhagen,¹⁶ found a significant reduction in post-operative pain after needlescopic surgery. However, all three trials failed to demonstrate any difference in other objective parameters, including operating time, hospital stay, and duration for recuperation.^{12,13} The only distinct advantage of adopting needlescopic cholecystectomy is, perhaps, the better cosmetic results possible and, as a result, better patient acceptance. From the lessons learned from this study, we believe that a mini-laparoscope of either 2.5-mm or 3-mm Hopkins rod lens system should be used so that the safety and duration of surgery are not compromised. Even for skilled laparoscopic surgeons, a learning process is still required to adapt to these miniaturised instruments and to achieve an acceptable success rate with minimal instrument

wastage. We currently offer all our patients needlescopic cholecystectomy as the initial approach to manage gallstones.

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