Randomized clinical trial

Randomized trial of needlescopic *versus* laparoscopic cholecystectomy

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Background: Several studies have reported the feasibility of using 'needlescopic' instruments with a diameter less than 3 mm in minimally invasive surgery. This study reports a comparison of needlescopic cholecystectomy and laparoscopic cholecystectomy.
Methods: Seventy-five patients with symptomatic chronic cholelithiasis were randomized to needlescopic ($n = 37$) or laparoscopic ($n = 38$) cholecystectomy.
Results: The duration of surgery in the two groups was similar. Patients in the needlescopic group had less pain (mean visual analogue score 2·2 *versus* 3·6; $P < 0·003$) and had smaller scars (median length 17·0 *versus* 25·0 mm; $P < 0·001$). In addition, patients in the needlescopic group tended to require fewer intramuscular pethidine injections ($P = 0·05$). However, oral analgesic requirements in the two groups were similar. There were no complications in either group.
Conclusion: Needlescopic cholecystectomy resulted in less postoperative pain and a smaller surgical scar than laparoscopic cholecystectomy in patients with chronic cholecystitis.

Paper accepted 20 July 2000 British Journal of Surgery 2001, **88,** 45–47

Introduction

Since the early 1990s, laparoscopic cholecystectomy has overtaken open cholecystectomy as the procedure of choice for chronic cholecystitis, offering patients a shorter hospital stay, less postoperative pain and an early recovery[1].

Needlescopic surgery, using instruments with a diameter less than 3 mm, has been adapted to perform laparoscopic cholecystectomy[2]. The small-calibre instruments result in smaller scars. This paper reports a randomized trial of needlescopic *versus* laparoscopic cholecystectomy in which duration of operation, postoperative pain and complications were compared in patients with symptomatic cholelithiasis.

Patients and methods

Consecutive patients with symptomatic cholelithiasis were included in the study. Patients with acute cholecystitis, as determined from clinical findings of acute peritonitis and ultrasonographic features of a thickened gallbladder wall with pericholecystic fluid collection, and patients with previous upper abdominal surgery were excluded from the trial. Four surgeons with individual experiences of more than ten needlescopic cholecystectomies participated in the trial.

Patients were randomized to receive needlescopic or laparoscopic cholecystectomy using a blind envelope system. Informed consent was obtained from every patient. The patients were informed of the type of procedure only after postoperative pain scores had been obtained.

The laparoscopic technique has been described elsewhere[3], and included a 10-mm umbilical port and three 5-mm working ports. For the needlescopic procedure, the ports were 10 mm, 2 mm, 3 mm and 2 mm in the umbilicus, right lateral abdomen, right hypochondrium and epigastrium respectively. The gallbladder fundus was held with a 2-mm grasper (USSC, Norwalk, Connecticut, USA), Hartmann's pouch was held with a 3-mm grasper (Storz, Tuttlingen, Germany) and dissection was done using a 1·7-mm ball-tipped coagulator (MIST, Smithfield, North Carolina, USA). The camera was changed to a 3-mm needlescope (Storz) for clipping of the cystic artery and cystic duct, and subsequently changed back to the 10-mm instrument for division of the cystic structures using a pair of 2-mm scissors (USSC). All wounds were infiltrated with 0·5 per cent bupivacaine in both groups. The combined lengths of the incisions were measured and dressings were the same in all patients.

All patients received a standard analgesic protocol with oral naproxen 375 mg twice daily and intramuscular

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Table 1 Clinical details

	Needlescopic cholecystectomy ($n=37$)	Laparoscopic cholecystectomy ($n=38$)	P
Age (years)*	49	52	
Sex ratio (M : F)	14 : 23	17 : 21	
Duration of operation (min)*	50·0 (5·4)	45·0 (4·3)	0·29
Pain score†‡	2·2(1·5)	3·6(1·9)	< 0·003
Doses of naproxen*	2·0 (1·4)	2·0 (1·4)	0·45
Scar size (mm)*	17·0 (1·5)	25·0 (0·8)	< 0·001
Hospital stay (days)*	1 (1)	1·5 (1)	0·14

*Values are median (interquartile range); †values are mean(s.d.). ‡Visual analogue scale

pethidine 1 mg/kg every 6 h according to individual need. An independent observer, who was blinded to the type of operation, obtained a visual analogue score (range from 1 (minimal pain) to 10 (maximum pain)) the morning after surgery. All patients were reviewed after 2 weeks.

A mixed effects linear model was used to compare the two groups. Data were analysed using the SPSS 9.0 statistical software (SPSS, Chicago, Illinois, USA). The observed differences were assumed to be statistically significant if the probability of chance occurrence was $P < 0·05$.

Results

A total of 75 patients entered the trial, 37 patients in the needlescopic group and 38 in the laparoscopic group. The results are summarized in *Table 1*. All patients were under the care of one of the four surgeons. During the study interval, 12 patients declined to be involved and five patients who had acute cholecystitis were excluded.

Four patients in the needlescopic group required conversion of the procedure, three to laparoscopic cholecystectomy and one to an open operation, because of adhesions or a thick-walled gallbladder. The conversion rate was 11 per cent. All four patients were included in the needlescopic group. There was one conversion to open surgery in the laparoscopic group. There was no difference in the median duration of surgery between the two groups (50 *versus* 45 min). There was also no difference in duration between the surgeons.

Patients who had needlescopic cholecystectomy had less postoperative pain according to mean visual analogue scores (2·2 *versus* 3·6; $P < 0·003$). Although intramuscular pethidine requirement only reached borderline significance, the needlescopic group tended to require fewer injections than the laparoscopic group (total seven *versus* 12 injections; $P = 0·05$).

The scars after needlescopic surgery were 32 per cent smaller than those after laparoscopy (median 17 *versus* 25 mm; $P < 0·001$). There was no difference in duration of hospital stay and most patients were discharged within 2 days of surgery.

Clinical follow-up in outpatients was achieved in 96 per cent of patients and averaged 6 months (mean). There were no complications in either group.

Discussion

This randomized trial compared needlescopic with laparoscopic cholecystectomy. Two other retrospective studies have compared the two procedures[4,5]. One study showed a reduction in scar size for the needlescopic group while the other showed a decrease in the need for postoperative analgesia despite a longer operating time. Needlescopic instruments have been used to perform other operations such as appendicectomy, splenectomy, fundoplication, adrenalectomy, inguinal herniorrhaphy and thoracic sympathectomy[5–8].

A randomized trial comparing the use of 5- and 10-mm epigastric ports for laparoscopic cholecystectomy showed no reduction in pain scores and postoperative analgesic use[9]. The present study showed a lower pain score even with a reduction from 5-mm to 2- and 3-mm ports. Comparing 10-mm ports and 'needleports' could make a bigger difference to pain scores.

The reduction in postoperative pain in the needlescopic group may have resulted from the smaller wounds. The median scar length was used because a mean value would have skewed the results because of the inclusion of single conversions to open surgery in both groups.

The benefits to the patient have to be weighed against the additional expense involved in the use of needlescopic instruments. The needlescopic equipment, although purchased at additional cost, was reused at subsequent surgery. The thinner 2-mm graspers are more flexible than the 3-mm instruments and are liable to bend with rough handling, so retraction and dissection of the gallbladder was performed with the 3-mm grasper. In addition, non-thickened or non-inflammed gallbladders were selected for the study because needlescopic instruments are not as effective as larger instruments in handling a thickened gallbladder. The four patients in the needlescopic group whose operation was converted to laparoscopic cholecystectomy or open surgery remained in the original group for the purpose of analysis by intention to treat. The longer operating times in these patients did not affect the results of the needlescopic group.

Similar to a previous report[5], this study showed that the needlescopic procedure was no more difficult than the

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standard laparoscopic cholecystectomy. There was no difference in the duration of surgery and complications between the two groups. The dissection to identify the cystic structures was done safely using a 10-mm laparoscope. The view was changed to the 3-mm needlescope only for clipping, and not division, of the cystic artery and duct. Alternatively, the structures could be ligated with intracorporeal suturing without the need to change the laparoscope.

Needlescopic cholecystectomy resulted in less postoperative pain and a smaller scar than laparoscopic cholecystectomy. Needlescopic cholecystectomy appears to be as safe as laparoscopic cholecystectomy in patients with chronic cholecystitis.

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