REVIEW ARTICLE

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Needlescopic versus laparoscopic cholecystectomy: a meta-analysis

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Key words
needlescopic, laparoscopic, cholecystectomy, mini-laparoscopy, randomized trials.

Abbreviations
CI, confidence interval; d.f., degrees of freedom; LC, laparoscopic cholecystectomy; NC, needlescopic cholecystectomy; SMD, standardized mean difference; VAS, visual analogue scale.

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Abstract

Background: To systematically analyse clinical trials on needlescopic (NC) versus laparoscopic cholecystectomy (LC) that evaluated the effectiveness of both procedures for the management of cholelithiasis.
Methods: A systematic review of the literature was undertaken. Clinical trials on NC versus LC were selected according to specific criteria and analyzed to generate summative data expressed in standardized mean difference.
Results: Sixteen trials on NC versus LC encompassing 1549 patients were retrieved from electronic databases. Only six randomized controlled trials on 317 patients qualified for the meta-analysis according to inclusion criteria. NC was associated with longer operative time and higher conversion rate as compared with LC. There was statistically significant heterogeneity among trials. Intraoperative complications, post-operative complications and total stay in hospital were not significantly different. NC was superior to LC in terms of less post-operative pain and better cosmetic outcomes.
Conclusion: NC is a safe and effective procedure for the management of gallstone disease. NC is as effective as LC for perioperative complications and total stay in hospital. NC is superior to LC for less post-operative pain and better cosmetic results. NC is associated with longer operative time and higher conversion rate.

Introduction

Since the introduction of laparoscopic cholecystectomy (LC) by Muhe in 1985,[1] much debate has centred on which technique is the preferable mode of cholecystectomy. LC is popular among some surgeons, but others remain sceptical of replacing the relatively straightforward mini-cholecystectomy.[2] Main objections to the laparoscopic approach are increased operative cost (primarily due to disposable instruments[3] and increased operative time.[2] Proponents of LC claim the advantages of the procedure, including improved wound healing, shorter stay in hospital, and markedly reduced post-operative pain, lead to an early return to normal daily activities.[4] No other procedure has been as profoundly affected by the advent of laparoscopy as cholecystectomy. LC has become the procedure of choice for routine removal of the gallbladder. In recent years, many surgeons have attempted to further improve the established technique of LC. In general, the aim was to minimize tissue trauma and the invasiveness of the procedure by reducing the number of ports, or, more commonly, the size of the trocar and instruments. Many randomized[5–10] and non-randomized clinical trials from all over the world have provided sufficient evidence that needlescopic cholecystectomy (NC) is also a safe procedure. It further reduces traumatic stress and enhances full recovery. It has not been satisfactorily demonstrated that miniature instruments result in cogent benefit for patients undergoing NC in terms of compulsory length of hospital stay, quantity of analgesia required, and the start of intake of solid food after surgery.

The objective of this study was to use meta-analysis to compare the outcome of NC versus LC with regard to operation time, total stay in hospital, intraoperative complications, postoperative pain, cosmetic results and post-operative complications.

Methods

All studies on NC versus LC published between January 1992 and January 2007 were identified through the following databases: MEDLINE, EMBASE, CINAHL, Cochrane library and PUBMED. The terms 'trials on needlescopic cholecystectomy', 'minimal invasive cholecystectomy' and 'key hole surgery for cholecystitis', 'minilaparoscopic cholecystectomy for cholelithiasis' were used in combination with the medical subject headings 'needlescopic versus conventional laparoscopic cholecystectomy' and 'minimal versus conventional laparoscopic cholecystectomy'. Relevant articles referenced in these publications were obtained. The 'related article' function was also used to widen the search criteria.

Each article was critically reviewed by two authors to assess the eligibility for inclusion in this meta-analysis (Table 1). Authors agreed to analyse the five objective outcome variables (operation time, total stay in hospital, intraoperative complications and postoperative complications) and two subjective outcome variables (postoperative pain and cosmetic results) from qualified trials. Data were extracted by two authors independently, and it was matched and agreed by both. Name of the procedure 'NC' was agreed when surgeons used a 5–10-mm umbilical port, and at least two ports of 2 mm to carry out minimally invasive surgery to remove the gallbladder. The agreed cumulative port size for LC was 32 mm, and for NC, was 14–19 mm. We defined the term 'complication' as a condition that developed due to surgery and required re-operation, further medical treatment, or prolonged the length of stay in hospital. Wound infection (with evidence of cellulites and positive culture/sensitivity swab), wound abscess (which required incision and drainage), intra-abdominal abscess (which required surgical or radiological drainage), urinary tract infection (where urine culture was positive), chest infection (confirmed on chest radiography), prolonged ileus (no bowel sounds after 72 h), re-laparotomy for any reason, injury to the common bile duct, and intraoperative or postoperative destabilizing haemorrhage were recorded as a complication in our data. In trials where visual analogue scale (VAS) was not given in the standard format, outcome units were converted into units of VAS according to standard format (self-designed) to obtain homogenous results.

Statistical analysis was done by a senior statistician, using Statistics for Windows software at Microsoft Excel 2007 (Microsoft Corporation, Berkshire, UK). The methods used were Hedges G statistic for the calculation of standardized mean difference (SMD), the inverse variance method for the fixed effect model, and DerSimonian/Laired method for random effect model.[11] The estimate of the difference between both techniques was pooled depending upon the affect weights in results determined by each trial estimate variance. The Forest plot was used for the graphic display of results from the meta-analysis. The square around the estimate stands for the accuracy of the estimation (sample size), and the line represents the confidence interval (CI) of 95%.

Table 1 Inclusion criteria

- Prospective randomized controlled trials on needlescopic versus conventional laparoscopic cholecystectomy in all languages.
- Needlescopic technique where umbilical port is 5–10 mm and at least two ports of 2 mm were used to carry out minimally invasive surgery on the gallbladder.

Results

Sixteen trials on NC versus LC encompassing 1549 patients were retrieved from the electronic databases. Only six randomized controlled trails (RCT)[5–10] on 317 patients qualified for the meta-analysis according to inclusion criteria (Table 1). Ten trials[12–21] were excluded. Characteristics of each trial are given in Table 2. There were 161 patients in the NC group, and 156 patients in the LC group. The objective and subjective outcome variables extracted from these trials are given in Tables 3 and 4, respectively.

Methodologic quality of the included studies

The methodologic quality of the included trials is explained comprehensively in Table 5. The Mantel–Haenszel fixed effect model was used to compute robustness and susceptibility to an outlier among these trials. The allocation concealment and blinding of the investigator or assessor were not clearly reported; consequently, the methodologic quality of all the three trials was considered inadequate, and the results of our review may be considered biased. Heterogeneity (clinical and methodologic diversity) was seen among all these trials (Table 6). Limited availability of studies and lack of a major multi-centre double-blind RCT restricted the performance of sub-group analysis. We felt that carrying out sensitivity analysis was not relevant due to limited study numbers. We attempted to assess for publication bias using a funnel plot, but it was difficult to compute due to fewer patients in this review.

Operative time

In the fixed- and random-effect models, total operative time for NC was longer than LC (fixed-effect model SMD 0.41 (0.19–0.64) 95% CI, $P = 0.0003$, degrees of freedom (d.f.) = 5, $z = 3.62$, and random-effect model SMD 0.44 (0.01–0.8) 95% CI, $P = 0.042$, d.f. = 5, $z = 2.02$; Fig. 1). Significant heterogeneity among the trials ($Q = 17.24$, $P = 0.004$) was observed.

Total stay in hospital

Four trials[6–9] contributed to the combined analysis of total stay in hospital. In the fixed- and random-effect models, there was no

Table 2 Characteristics of included randomized controlled trials

Trials	Year	NC patients	LC patients	Ports used in NC
Bissgard *et al.*[13]	2000	13	13	10 mm and 3 × 2 mm
Schwenk *et al.*[14]	2000	25	25	2 × 5 mm, 2 × 2 mm
Cheah *et al.*[15]	2001	37	38	10 mm, 3 mm, 2 × 2 mm
Alponat *et al.*[16]	2002	22	22	10 mm, 3 × 2 mm
Huang *et al.*[17]	2003	30	25	10 mm and 3 × 2 mm
Novitsky *et al.*[18]	2005	34	33	10 mm, 5 mm, 2 × 2 mm

LC, laparoscopic cholecystectomy; NC, needlescopic cholecystectomy.

Table 3 Objective outcome variables

Trial	Operative time	Stay	Conversions	Intraoperative complications	Postoperative complications
Bisgaard *et al.*					
Needlescopic	85 (45–155)		5	0	0
Laparoscopic	55 (30–180)	NA	0	0	0
Shwenk *et al.*					
Needlescopic	70 (60–87)	3	1	0	0
Laparoscopic	70 (60–87)	3	1	0	1
Cheah *et al.*					
Needlescopic	50 ± 5.4	1 ± 1	4	0	0
Laparoscopic	45 ± 4.3	1.5 ± 1	1	0	0
Alponat *et al.*					
Needlescopic	80.9 ± 18.4	1	5	0	0
Laparoscopic	72.05 ± 24.3	1	0	0	0
Huang *et al.*					
Needlescopic	64.8 ± 27.7	3.0 ± 0.8	5	0	3
Laparoscopic	47.3 ± 20.8	3.3 ± 2.3	0	2	6
Novisky *et al.*					
Needlescopic	50.5 ± 15.4	NA	8	0	1
Laparoscopic	54.9 ± 22.4		0	0	0

Time in minutes. Stay in days. NA, not available.

Table 4 Subjective outcome variables

Trial	Pain intensity (VAS 1–10)	Cosmetic outcome (VAS 1–10)
Bisgaard *et al.*		
Needlescopic	5 (3–9)	NA
Laparoscopic	10 (4–13)	
Shwenk *et al.*		
Needlescopic	2.9	10 (9–10)
Laparoscopic	3.4	9 (8–10)
Cheah *et al.*		
Needlescopic	2.2 ± 1.5	8
Laparoscopic	3.6 ± 1.9	10
Alponat *et al.*		
Needlescopic	NA	0.7 ± 0.82
Laparoscopic		1.93 ± 1.2
Huang *et al.*		
Needlescopic	5.4 ± 3.2	4.3 ± 0.5
Laparoscopic	4.7 ± 2.5	4.4 ± 0.6
Novisky *et al.*		
Needlescopic	3.9 ± 1.5	3.9 ± 2.1
Laparoscopic	4.9 ± 1.8	3.9 ± 2.5

NA, not available; VAS, visual analogue scale from 1–10.

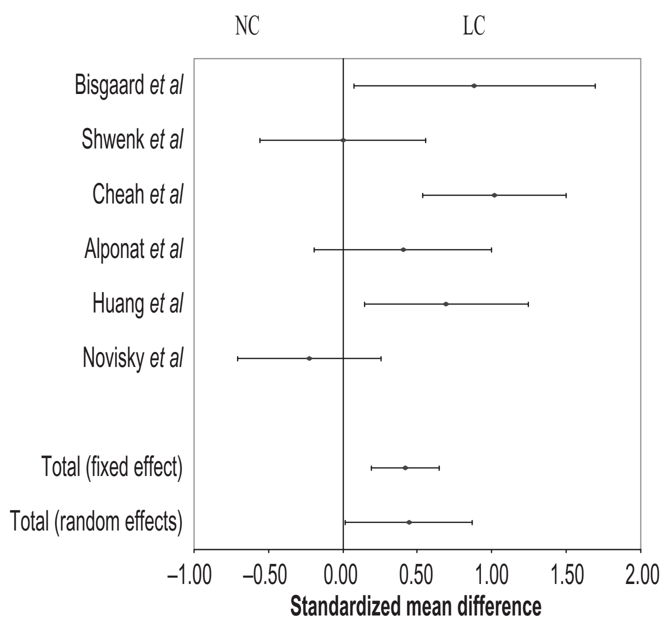

Fig. 1. Operative time. LC, laparoscopic cholecystectomy; NC, needlescopic cholecystectomy.

statistical difference in total stay in hospital between NC and LC (fixed-effect model SMD –0.2 (–0.4, 0.05) 95% CI, $P = 0.124$, d.f. = 3, $z = -1.5$ and random effect model SMD –0.2 (–0.4, 0.02) 95% CI, $P = 0.072$, d.f. = 3, $z = -1.7$). There was no heterogeneity among trials ($Q = 2.52$, $P = 0.47$).

Conversion

Combined conversion (from NC into LC or open and from LC to open) rate was computable only by using the fixed-effect model. NC was associated with a statistically significant higher conversion rate (SMD 0.14 (0.05–0.41) 95% CI, $P = 0.0003$, d.f. = 5, $z = -3.6$; Fig. 2). There was no heterogeneity among the trials ($Q = 2.6$, $P = 0.62$).

Intraoperative complications

In the fixed- and random-effect models, there was no statistically significant difference in intraoperative complications between NC and LC (fixed-effect model SMD 1.5 (0.38–6.58) 95% CI, $P = 1.47$, d.f. = 5, $z = 0.63$ and random-effect model SMD 0.52 (0.19–1.3) 95% CI, $P = 0.19$, d.f. = 5, $z = -1.2$]. There was no heterogeneity among the trials ($Q = 0.77$, $P = 0.94$).

Postoperative complications

In the fixed- and random-effect models, there was no statistically significant difference in post-operative complications between NC

Table 5 Methodologic qualities of included trials

Quality variables	Bisgaard *et al.*	Shwenk *et al.*	Cheah *et al.*	Alponat *et al.*	Huang *et al.*	Novisky *et al.*
Inclusion criteria	Listed	Listed	Listed	Listed	Listed	Listed
Exclusion criteria	Listed	Listed	Listed	Listed	Listed	Listed
Randomization technique	Envelope based	Random selection	Envelope based	Envelope based	Envelope based	Computer based
Calculation of sample size	Stated	Stated	Not stated	Not stated	Not stated	Not stated
Baseline comparable	Listed	Listed	Listed	Listed	Listed	Listed
Masked/blinded	Yes	Not stated	Yes	Yes	Yes	Yes
Crossover	Not stated	Not stated	Not stated	Not stated	Yes	Yes
Lost to follow-up	No	No	Yes	No	No	No
Allocation concealment	Yes	Not stated	Yes	Not stated	Yes	Yes
Analysis by intention to treat	Yes	Yes	Not stated	Not stated	Yes	Yes

Table 6 Causes of heterogeneity

Methodological heterogeneity
- Different techniques of randomization.
- One trial was abandoned due to high conversion rate.
- No allocation concealment in all trials.
- Analysis by intention to treat was not stated in all trials.
- Variable inclusion and exclusion criteria.

Clinical heterogeneity
- Variable number and size of ports used among trials.
- Different outcome variables assessed (e.g. evaluation of pulmonary functions, level of stress hormones).
- Variable follow-up time among trials.
- Non-consistent results of trials.
- Pain score and cosmetic score assessed by patients in one trial and by investigators in other trials.

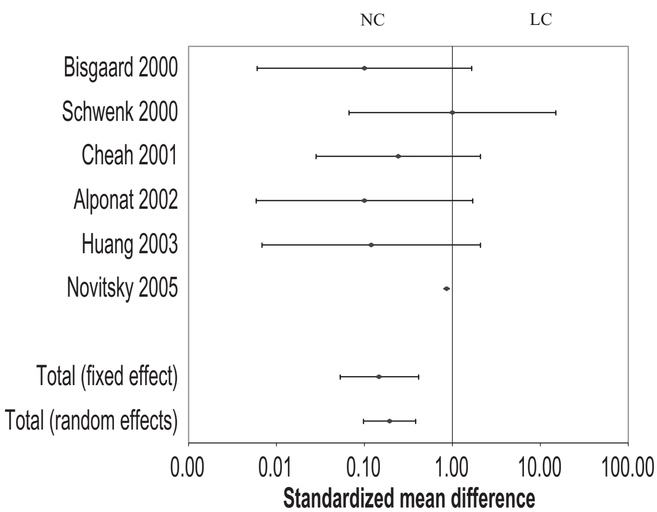

Fig. 2. Conversion. LC, laparoscopic cholecystectomy; NC, needlescopic cholecystectomy.

and LC (fixed-effect model SMD 1.66 (0.6–4.4) 95% CI, $P = 1.69$, d.f. = 5, $z = 1.03$ and random-effect model SMD 0.77 (0.2–2.7) 95% CI, $P = 0.69$, d.f. = 5, $z = -0.3$). There was no heterogeneity among the trials ($Q = 0.99$, $P = 0.90$).

Postoperative pain

Pain was evaluated generally rather than specifically to port site. It was not clearly mentioned in trials which port site was used to remove the gallbladder and if the port wound was extended. It was therefore difficult to evaluate the effect of port frequency and extension of port size on pain, cosmetic effect and combined stay in hospital. Five trials[5–7,9–10] contributed to the combined analysis of the intensity of postoperative pain between both procedures. In the random-effect model, NC was associated with statistically significant less postoperative pain (SMD–0.08 (–1.4, –0.18) 95% CI, $P = 0.0111$, d.f. = 4, $z = -2.5$; Fig. 3). There was significant heterogeneity among the trials (Q = 23.90, $P = 0.0001$).

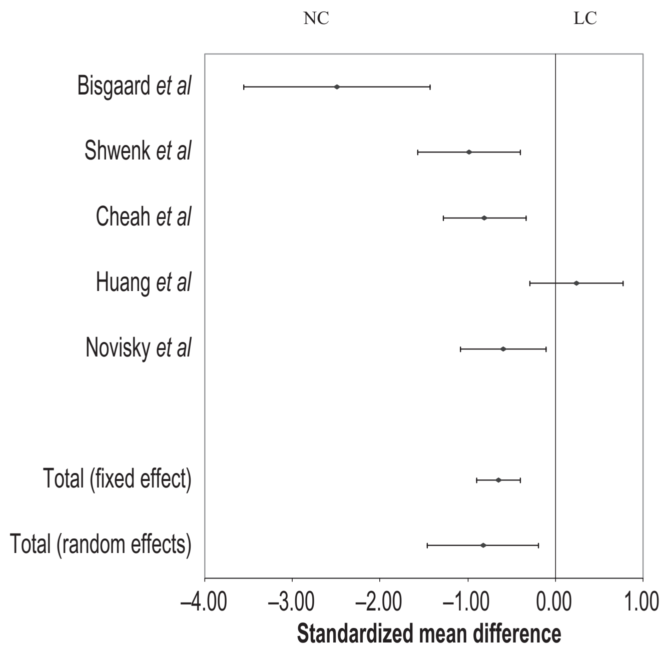

Fig. 3. Postoperative pain. LC, laparoscopic cholecystectomy; NC, needlescopic cholecystectomy.

Cosmetic outcome

Five trials[6–10] contributed to the combined analysis of cosmetic outcome after NC and LC. In the fixed-effect model, NC was cosmetically superior to LC (SMD –0.4 (–0.71, –0.15) 95% CI, $P = 0.0021$, d.f. = 4, $z = -3.07$; Figs. 4 and 5). There was significant heterogeneity among the trials ($Q = 162$, $P = 0.0000$).

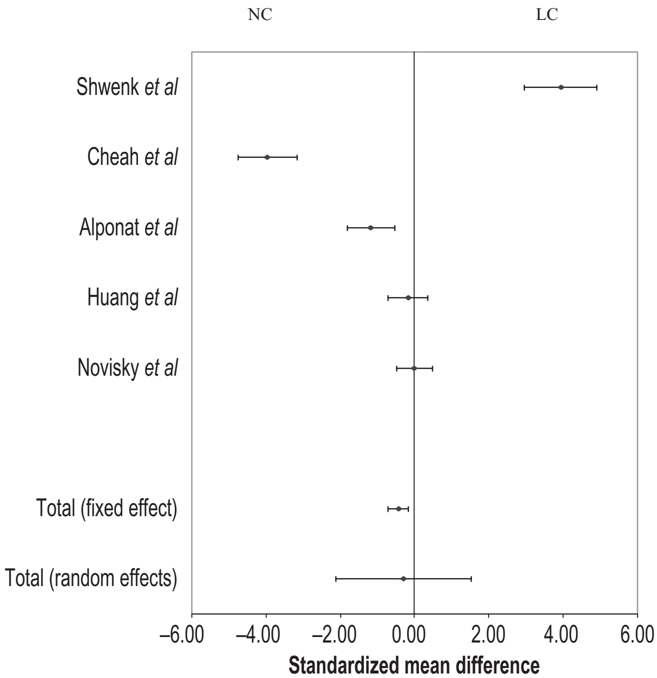

Fig. 4. Cosmetic outcome. LC, laparoscopic cholecystectomy; NC, needlescopic cholecystectomy.

Fig. 5. Cosmetic outcome after needlescopic cholecystectomy.

Discussion

NC is an evolving technique in gallstone surgery that is being practised by general surgeons with great caution due to lack of sufficient evidence. It is the hope of those pioneering this field that it will extend the benefits already proven for LC to NC versus open cholecystectomy. Several studies have demonstrated that NC holds the advantage of eliciting a reduced level of wound pain, a reduced requirement of postoperative analgesia compared with LC,[8,15] with better cosmetic results and good acceptance among different patient groups.[5,15,22–24] These apparent advantages of NC are achieved only when the technical difficulties of using finer instruments are circumvented, and better hand–eye–tissue coordination is ensured. Smaller incisions have resulted in minimal scarring and better cosmetic results, but evaluation of cosmetic results is challenged by the absence of a reliable objective scale. The combination of multiple contributing factors, potential observer bias and variations in patient expectations contribute to difficulties in assessing cosmetic results. Prolonged operative time (as concluded in this article) often limit implementation of new technologies. Many investigators[5,6,14,22–24] have reported no significant increase in operative time after adopting the NC technique. There was no difference between intraoperative and postoperative complications between these two techniques, emphasizing further the safety of NC. Higher conversion rate in the NC group is indicative of the technical difficulties surgeons face using finer instruments. With current instrumentation and skill level of general surgeons, NC understandably will take longer than more traditional laparoscopic procedures. After an initial steep learning curve, improved and high-quality results may be achieved.

There was significant heterogeneity amongst these trials (Table 6). The first possible cause of heterogeneity is researcher bias and patient bias because these trials were not carried out in double-blind conditions. Patients and researchers may have been biased in result reporting, particularly for postoperative pain and cosmetic effect. The second possible cause of heterogeneity was confounding variables among different patients, for example, use of pre-operative antibiotics or different analgesic regimens in different doses and patients of American Society of Anaesthesiology (ASA) I and ASA II categories. The results of the included trials in this meta-analysis were not consistent. In one trial, the operative time for NC was 113 min, whereas it was 50 min in another trial. There was no major multi-centre RCT on NC in the literature, which made it more difficult to find high-quality unbiased data for meta-analysis.

Advocates of NC believe that an element of surgical trauma is due to the skin wound and tissue handling. A better outcome is anticipated if we can operate with a smaller skin wound and more gentle tissue handling without compromising access. Surgeons must therefore strike a balance between trauma and adequate access. This meta-analysis paves the path for NC, a less invasive procedure for definitive management of gallstones, but further exploration and investigations are required. This study shows that NC has some significant proven benefits over LC and no significant disadvantages, but recommending all gallbladder surgery by NC would be inappropriate. This contribution is the only reported review on NC, which highlights the need for a major multi-centre, double-blind, prospective, RCT on NC to produce level-I evidence in this area. Based on this review, NC can be recommended as a routine procedure for gallbladder removal, but it may be considered an alternative while waiting for stronger evidence.

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