

Single-incision laparoscopic cholecystectomy

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg508

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG346.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of single-incision laparoscopic cholecystectomy is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 Single-incision laparoscopic cholecystectomy is technically challenging and should only be carried out by experienced laparoscopic surgeons who have had specific training in the procedure.

2 Indications and current treatments

- 2.1 Gallstones form in the gallbladder from cholesterol or bile pigments: they may be small and multiple, or large and sometimes single. They are more common in women and in people who are obese. Most people with gallstones are asymptomatic but some may develop recurrent symptoms, typically abdominal pain after eating a meal. In some people, gallstones may lead to episodes of acute inflammation of the gallbladder (acute cholecystitis) that can cause pain, fever, nausea and vomiting. Other presentations (resulting from displacement of gallbladder stones into the common bile duct) include biliary colic, obstructive jaundice and acute pancreatitis.
- 2.2 The usual treatment option for symptomatic gallstones is cholecystectomy. This is typically done laparoscopically, using several

small incisions in the abdomen, although open surgery through a larger incision is sometimes necessary.

3 The procedure

- 3.1 Single-incision laparoscopic cholecystectomy aims to remove the gallbladder through a single incision, which is usually made near the umbilicus. The claimed benefits of this procedure over standard laparoscopic cholecystectomy include less pain, shorter recovery time, fewer wound complications and improved cosmesis.
- 3.2 Single-incision laparoscopic cholecystectomy is done with the patient under general anaesthesia. There are 2 surgical approaches. One uses a single umbilical skin incision with skin flaps to insert ports through multiple fascial punctures. The other uses a specifically designed device that allows multiple instruments to be passed through a single port placed in or near the umbilicus. A pneumoperitoneum is established and the gallbladder is retracted with a laparoscopic instrument ('grasper') or by a transabdominal suture. The hilum of the gallbladder is dissected using endoscopic instruments. The cystic artery and cystic duct are clipped and divided and the gallbladder is separated from the liver. At least 1 additional port in the epigastrium may be needed if a cholangiogram is performed or if the common bile duct is explored. The gallbladder is removed through the umbilical incision.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. Much of the evidence considered by the Committee was presented in meta-analyses from 2 systematic reviews, which reported relative risks in the form of pooled mean differences for continuous outcome variables, and odds ratios for dichotomous variables. Pooled measures of absolute risk were not reported. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 4.1 In a systematic review of 25 randomised controlled trials that included 1841 patients treated by single-incision laparoscopic cholecystectomy

(SILC) or conventional multiport laparoscopic cholecystectomy (CMLC), meta-analysis of the proportion of procedures that were converted to open surgery revealed no significant difference between groups (odds ratio of 0.69; 95% confidence interval [CI] 0.13 to 3.58, $p=0.655$).

- 4.2 In the systematic review of 25 randomised controlled trials that included 1841 patients treated by SILC or CMLC, meta-analysis of the proportion of procedures that needed an additional surgical instrument revealed an odds ratio of 7.45 in favour of CMLC (95% CI 3.82 to 14.52). The proportion of procedures that needed additional surgical instruments was significantly lower in the CMLC group ($p<0.001$).
- 4.3 In a systematic review of 40 studies that included 3711 patients treated by SILC or CMLC, meta-analysis of intraoperative blood loss revealed no significant difference between groups (pooled mean difference of 0.44; 95% CI -0.96 to 1.85, $p=0.54$).
- 4.4 In the systematic review of 25 randomised controlled trials that included 1841 patients treated by SILC or CMLC, meta-analysis of postoperative pain scores revealed a pooled mean difference of -0.70 in favour of SILC at 3 to 4 hours (95% CI -1.32 to -0.09). Pain scores were significantly better in the SILC group ($p=0.026$). At 6 to 8 hours, the pooled mean difference was -0.613 in favour of SILC (95% CI -1.077 to -0.149, $p=0.01$).
- 4.5 In the systematic review of 25 randomised controlled trials that included 1841 patients treated by SILC or CMLC, meta-analysis of cosmesis scores at final follow-up revealed a pooled mean difference of 1.16 in favour of SILC (95% CI 0.61 to 1.70). Cosmesis scores were significantly better in the SILC group ($p<0.001$).
- 4.6 In a randomised controlled trial of 200 patients treated by SILC ($n=119$) or CMLC ($n=81$), postoperative SF-12 scores (ranging from 0 to 100 with higher scores indicating better outcomes) were 51.1 ± 8.9 in the SILC group and 54.1 ± 6.7 in the CMLC group at 1-month follow-up (no preoperative SF-12 scores were reported, $p=0.03$).
- 4.7 Specialist advisers listed key efficacy outcomes as cosmesis, patient satisfaction and pain scores.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. Much of the evidence considered by the Committee was presented in meta-analyses from 2 systematic reviews, which reported relative risks in the form of pooled mean differences for continuous outcome variables, and odds ratios for dichotomous variables. Pooled measures of absolute risk were not reported. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 In a systematic review of 25 randomised controlled trials that included 1841 patients treated by single-incision laparoscopic cholecystectomy (SILC) or conventional multiport laparoscopic cholecystectomy (CMLC), meta-analysis of the incidence of bile duct injuries revealed no significant difference between groups (odds ratio of 1.00; 95% confidence interval [CI] 0.165 to 6.066, $p=1.0$).
- 5.2 Gallbladder perforation was reported in 12% (9/75) of patients in the SILC group and 8% (6/75) of patients in the CMLC group in a randomised controlled trial of 150 patients (no p values reported).
- 5.3 In a systematic review of 40 studies that included 3711 patients treated by SILC or CMLC, meta-analysis of the incidence of wound haematomas revealed no significant difference between groups (odds ratio of 2.07; 95% CI 0.90 to 4.74, $p=0.09$).
- 5.4 In the systematic review of 40 studies that included 3711 patients treated by SILC or CMLC, meta-analysis of the incidence of wound infections revealed no significant difference between groups (odds ratio of 1.03; 95% CI 0.53 to 2.0, $p=0.92$).
- 5.5 In the systematic review of 40 studies that included 3711 patients treated by SILC or CMLC, meta-analysis of the incidence of incisional hernias revealed no significant difference between groups (odds ratio of 1.67; 95% CI 0.65 to 4.27, $p=0.29$).
- 5.6 In the systematic review of 25 randomised controlled trials that included 1841 patients treated by SILC or CMLC, meta-analysis of the incidence of

retained gallstones revealed no significant difference between groups (odds ratio of 2.15; 95% CI 0.55 to 8.33, $p=0.269$).

- 5.7 Erythema was reported in 4% (5/119) of patients in the SILC group and 0% of patients in the CMLC group in a randomised controlled trial of 200 patients (no p values reported). In the same study, ecchymosis was reported in 1% (1/119) of patients in the SILC group and 0% of patients in the CMLC group (no p values reported).
- 5.8 A non-systematic review of safety events that included 38 studies (1180 patients treated by SILC) reported seroma in 1% (17/1180) of patients, renal failure in 0.08% (1/1180) of patients and ileus in 0.17% (2/1180) of patients.
- 5.9 Specialist advisers did not highlight any additional adverse events reported in the literature. Retained gallstones, incisional hernias, and visceral and vascular injuries (such as bile duct injuries) were identified as theoretical adverse events.

6 Committee comments

- 6.1 The Committee noted that there have been recent developments in the instruments used to perform the procedure.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).

Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).