



# Single-stage laparoscopic cholecystectomy and intraoperative endoscopic retrograde cholangiopancreatography: is this strategy feasible in Australia?

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## Abstract

Currently in Australasia, concomitant cholecystolithiasis and choledocholithiasis are usually managed with two procedures: laparoscopic cholecystectomy (LC) and pre or postoperative endoscopic retrograde cholangiopancreatography (ERCP). This approach exposes the patient to the risk of complications from the common bile duct stone(s) while awaiting ERCP, the risks of the ERCP itself (particularly pancreatitis) and the need for a second anaesthetic. This article explores the evidence for a newer hybrid approach, single stage LC and intraoperative ERCP (SSLCE) and compares this approach with the commonly used alternatives. SSLCE offers reduced rates of pancreatitis, reduced length of hospital stay and reduced cost compared with the two-stage approach and requires only one anaesthetic. There is a reduced risk of bile leak compared with procedures that involve a choledochotomy, and ductal clearance rates are superior to trans-cystic exploration and equivalent to the standard two-stage approach. Barriers to widespread implementation relate largely to operating theatre logistics and availability of appropriate endoscopic expertise, although when bile duct stones are anticipated these issues are manageable. There is compelling justification in the literature to gather prospective evidence surrounding SSLCE in the Australian Health-care system.

## Introduction

Over 19 000 cholecystectomies are performed in Australia each year,<sup>1</sup> more than 90% by laparoscopic cholecystectomy (LC). The prevalence of concomitant common bile duct (CBD) stones during this procedure has been estimated at 10–18%.<sup>2</sup> In one series, the intraoperative cholangiogram was the sole indicator of stones in 12% of procedures.<sup>3</sup> While up to a third of these will pass spontaneously by 6 weeks,<sup>4</sup> potentially serious complications like pancreatitis or cholangitis often mandates intervention for retained stones.<sup>5</sup>

There are a variety of options for the management of patients with combined cholecystolithiasis and choledocholithiasis, with equipoise regarding the ideal approach.<sup>6</sup> The historical gold standard was open CBD exploration at the time of cholecystectomy, now superseded by LC and endoscopic retrograde cholangiopancreatography (ERCP). The sequential combination of LC plus ERCP has the advantage of being less invasive, less painful and

lower morbidity than open common duct exploration.<sup>2</sup> However, logistically this approach has the disadvantage of requiring two separate procedures, with a small but significant risk of pancreatitis. If ERCP is performed preoperatively, there is a risk of further stone migration prior to surgery. In contrast, laparoscopic trans-cystic CBD exploration or laparoscopic choledochotomy are single-stage approaches that are practised. However, Medicare data suggest that the uptake of laparoscopic trans-cystic CBD exploration or choledochotomy has been limited, and two-stage LC + ERCP is currently the most common approach for stones discovered on operative cholangiography.<sup>7</sup> In the latest Surgical Variance Report from RACS and Medibank, only 3% of laparoscopic cholecystectomies billed to that health fund involved trans-cystic exploration.<sup>8</sup>

In keeping with the increasing acceptance of hybrid procedures, this article explores the evidence base for single-stage LC + intraoperative ERCP (SSLCE) compared with the two major alternatives: two-stage LC + ERCP and single-stage LC with trans-cystic CBD exploration +/-choledochotomy.

## Intraoperative ERCP: the procedure

Early pioneers of intraoperative ERCP performed the procedure semi-prone prior to LC or upon completion. It follows that this approach exposes the patient to the same risks during cannulation of the native papilla as the two-stage procedure, albeit with one anaesthetic. The addition of facilitated cannulation reduces the risk of post-ERCP pancreatitis.<sup>9,10</sup>

Facilitated cannulation facilitates visualization and cannulation of the papilla of Vater by antegrade trans-cystic insertion of a guidewire by the surgeon into the cystic duct and through into the duodenum via the papilla (an antegrade stent may be passed over this wire if a non-synchronous ERCP is being performed).<sup>11</sup> Using a duodenoscope, the guidewire is grasped by a snare or basket and a sphincterotome threaded over it for endoscopic sphincterotomy and stone retrieval.<sup>12</sup> This has been described as 'Rendezvous Technique' or the 'Laparo-endoscopic Rendezvous' (LERV). The endoscopic step is usually completed in the supine position. The main technical issue is passing the guidewire through the spiral valves of the cystic duct or past impacted stones. Multiple techniques have been used to avoid the wire curling, including the use of stent introducer sheaths or coated central venous cannulation devices to guide the wire into the duodenum. Other described but less well-established techniques include the use of a trans-cystic *Dormia* basket to grasp the sphincterotome from a duodenoscope and guide it through the ampulla,<sup>13</sup> and the use of antegrade sphincterotomy, passing an endoscopic sphincterotome through the cystic duct laparoscopically and division of the sphincter under direct vision from a duodenoscope.<sup>14</sup>

The evidence suggests that intraoperative ERCP ductal clearance rates of 96.3% are essentially equivalent to preoperative ERCP (96.9%).<sup>15</sup> The LERV technique was first described nearly 20 years ago and has gained increasing popularity in Europe with a multidisciplinary team approach, consisting of gastroenterologists and surgeons whom perform the procedure in the same operating suite.<sup>16,17</sup> In contrast, American literature describes surgical endoscopists performing both laparoscopic and endoscopic components.<sup>18</sup>

Barriers to single-stage management of CBD stones at the time of LC are twofold. Firstly, timely access is required to a trained endoscopist during LC. The logistics of combining modalities in an efficient timeframe are challenging even for the largest hospitals. Except in situations where the surgeon is trained in ERCP, strong collaboration between surgeon and endoscopist is required, as well as adequate training of theatre staff or scheduling available endoscopy staff. This is a major barrier in Australia where many cholecystectomies are performed outside tertiary referral centres with surgical endoscopists. Transferring all regional patients with known stones to surgical endoscopists may be impractical. Secondly and probably less importantly, the supine position may increase the difficulty of positioning the duodenoscope. However, anecdotal data support safety and efficacy of ERCP on a supine, intubated patient compared with a prone, sedated one.<sup>18–20</sup>

## Comparison: two-stage approach

Optimal timing of the ERCP in relation to the cholecystectomy for patients with suspected CBD stones has been controversial.

Preoperative ERCP followed by LC is plagued by a high rate of negative explorations (40–70%),<sup>21</sup> potentially exposing the patient to unnecessary complications of ERCP. The landmark 1999 multi-centre randomized controlled trial by Cuschieri *et al.*<sup>22</sup> demonstrated no difference in ductal clearance rates between preoperative ERCP and single-stage laparoscopic exploration (84 versus 80%). However, 23% in the preoperative group had an unnecessary ERCP with no stones found. The use of decision algorithms including pre-operative liver function tests and magnetic resonance cholangiopancreatography reduces but does not eliminate this problem.

An early study from 2006 comparing the preoperative ERCP with SSLCE (with LERV technique) observed a decrease in morbidity in the group that received the SSLCE, due to lower rates of post-ERCP pancreatitis and cholecystitis.<sup>23</sup> A case-control study from Sweden (12 718 procedures) suggests that LERV technique reduces post-ERCP pancreatitis (3.6–2.2%) due to facilitated cannulation.<sup>24</sup>

Lella *et al.*<sup>20</sup> randomized 120 high-risk patients out of 256 to preoperative ERCP and subsequent LC or SSLCE using LERV technique. There was strong evidence of a difference in pancreatitis rates, with no incidence of pancreatitis in the facilitated cannulation group as opposed to six patients in the conventional group. In a study of 91 patients, Morino *et al.*<sup>25</sup> found reduced cost and hospital stay in the intraoperative group, but the study was insufficiently powered to determine a difference in morbidity. Similarly, in the randomized controlled trial by Tzovaras *et al.*<sup>17</sup> in 2012, shorter hospital stay but no difference in morbidity was found. The authors comment on a reduced post-procedural amylase in the LERV group, but this is clinically insignificant. Enochsson *et al.* had no cases of pancreatitis in 34 patients undergoing intraoperative ERCP.<sup>12</sup>

A meta-analysis by Wang *et al.*<sup>26</sup> in 2013 concluded that preoperative ERCP was associated with a risk 2.27 times higher than intraoperative ERCP with regards to post-ERCP complications. Not all five trials utilized the LERV technique. A 2014 European review of 21 scientific papers found that intraoperative ERCP was associated with an average saving of 2.8 inpatient days, with an associated reduction in costs.<sup>15</sup> This Italian review found no difference in regards to overall morbidity.<sup>18,25,27</sup>

In the context of stones unsuitable for trans-cystic clearance where intraoperative ERCP was not available, Martin *et al.*<sup>11</sup> described trans-cystic ampullary stenting and then *facilitated* post-operative ERCP. The selective CBD cannulation rate was 98% following placement of a trans-cystic ampullary (*Nepean*) stent. There were no cases of pancreatitis in 56 patients. A larger multi-centre trial was planned over 10 years to complete in December 2015, but was terminated prior to publication. Fanelli's case series of trans-cystic ampullary stenting in 48 patients also resulted in complete stone clearance at postoperative ERCP without any episodes of pancreatitis or perforation.<sup>28</sup>

In conclusion, there is good evidence from both European and American studies to indicate that performing a LC and ERCP under the same anaesthetic reduces both the length of hospital stay and overall hospital costs.<sup>2,6,7</sup> Complications for facilitated ERCP are lower than postoperative cannulation of the native duodenal papilla. Furthermore, if intraoperative ERCP is unsuccessful, then common

duct exploration can be performed under the same anaesthetic. Finally, if stone retrieval is incomplete, then subsequent postoperative ERCP is facilitated by the intraoperative sphincterotomy,<sup>3</sup> and therefore less likely to result in pancreatitis.

## Comparison: single-stage laparoscopic approach

The single-stage alternatives for CBD stones are trans-cystic bile duct exploration or laparoscopic choledochotomy (laparoscopic CBD exploration (LCBDE)). There is no prospective data comparing these approaches with intraoperative ERCP using LERV technique.

The trans-cystic exploration approach benefits the patient by avoiding sphincterotomy altogether. Compared with the preoperative ERCP two-stage approach, unnecessary sphincterotomy is avoided and the patient is subjected to only one anaesthetic. However, this approach is only suitable for small stones and is technically demanding. Despite the benefits, most surgeons in Australia performing LC have not adopted the procedure.

In a large case-control series (253 in exploration group), no additional complications with trans-cystic exploration occurred above those encountered during LC alone.<sup>29</sup> An older case series from 2003 performed trans-cystic exploration in 34 patients, with success in 32. However, their median operative time was 120 min with 8.8% morbidity. Hospital stay remained below 48 h.<sup>30</sup> This suggests that the complication rate for trans-cystic exploration is acceptable, with comparable short hospital stays to those for SSLCE.

Unfortunately, trans-cystic clearance of stones is not possible for all patients with CBD stones. Nathanson *et al.*<sup>31</sup> describe a 66% overall success rate of trans-cystic clearance, with significantly reduced morbidity compared with either choledochotomy or postoperative ERCP. Darrien's (2015) series showed a 68% trans-cystic ductal clearance rate, increased to 87% with choledochotomy.<sup>32</sup> Other series have described much higher rates of stone clearance but were much more selective in choice of patients for this technique.<sup>31</sup> Bove *et al.*<sup>32</sup> recommends that ideal candidates for trans-cystic clearance have less than three CBD stones, a CBD diameter less than 8 mm, without the co-presence of biliary sludge. Clearly, the trans-cystic approach is not universally applicable, and it is clear that this approach has not been widely adopted by Australian surgeons.<sup>8</sup>

LCBDE appears no safer than postoperative ERCP. In Nathanson's<sup>31</sup> trial above of 86 patients who failed trans-cystic exploration, laparoscopic choledochotomy was associated with similar risks of pancreatitis (7.3 versus 8.8%) and re-operation (7.3 versus 8.8%) as postoperative ERCP, however there was a bile leak rate of 14.6%. Their conclusions were that LCBDE should be reserved for those patients in whom ERCP was not anatomically feasible or in whom access to endoscopy is limited.

Hong *et al.*<sup>33</sup> compared LCBDE with SSLCE, finding no differences between the two in regards to duration of surgery, success rate, complications, retained stones, hospital stay and costs. This Chinese study performed standard sphincterotomy and did not utilize LERV technique. ElGeidie *et al.*<sup>34</sup> compared SSLCE (once again only 5 out of 111 using LERV technique) with LCBDE in 211 patients with almost identical results; no significant differences

existed between success/failure rates, surgical time and postoperative length of stay. In this Egyptian study, they found gaseous distension interfered with the remainder of the LC and abandoned the technique. The only significant difference observed was the rate of retained stones, which was higher in the LCBDE group.

The latest Cochrane systematic review concluded that there is no significant difference in mortality and morbidity between LCBDE and ERCP.<sup>2</sup> The only two studies comparing SSLCE with LCBDE found that the rates of bile leak in the latter group were equivalent to the rates of pancreatitis in the ERCP group. It is important, however, to recognize that standard SSLCE without LERV technique was used<sup>33</sup> and that SSLCE using LERV has the potential to reduce overall morbidity by virtue of reducing post-ERCP pancreatitis rates.

## Conclusion

Our review of the literature indicates that facilitated ERCP (either using LERV technique as a single-stage procedure or trans-cystic ampullary stent plus ERCP as a two-stage procedure) has the highest successful CBD clearance rate and the lowest complication rate compared with staged LC + standard ERCP or laparoscopic choledochotomy. Facilitated ERCP has lower rates of pancreatitis than standard ERCP, and no risk of bile leak compared with LCBDE. SSLCE combines the advantages of low morbidity associated with facilitated ERCP and the advantages of a single-stage procedure. Practically the SSLCE approach is most likely to be useful when CBD stones are anticipated preoperatively; the trans-cystic ampullary stent followed by postoperative ERCP is most practical for the unexpected CBD stone found on operative cholangiography or when ERCP is not immediately available.

Trans-cystic CBD exploration is safe but frequently fails to clear the CBD. There are no studies comparing laparoscopic trans-cystic exploration and SSLCE, so a difference in outcome can only be surmised. It is likely that ductal clearance rates are higher in the SSLCE group and length of stay similar although there may be some significant differences in operative times. When comparing single- and two-stage procedures, an increased morbidity from multiple anaesthetics is assumed but has not been well established in the above literature.

Availability and coordination of laparoscopic and endoscopic resources may remain a barrier to the universal implementation of SSLCE in Australia. This is less of an issue when stones are anticipated than when stones are discovered unexpectedly on operative cholangiography. However, we feel that the evidence suggests that a study to compare single-stage LC and intraoperative ERCP and other routinely practiced techniques in the management of CBD stones in the Australian healthcare system is appropriate.

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