

A Review of Randomized Controlled Trials comparing Single Port Laparoscopic Cholecystectomy with Conventional Laparoscopic Cholecystectomy

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ABSTRACT

Aim: To determine the safety and benefits of single port laparoscopic cholecystectomy.

Materials and methods: A search for randomized controlled trials comparing single port laparoscopic cholecystectomy with conventional laparoscopic cholecystectomy was conducted using Google scholar, HighPress and SCOPUS.

Results: Single port laparoscopic cholecystectomy has a longer operating time, with equivocal postoperative pain, and offers better cosmetic result with low morbidity.

Conclusion: Single port laparoscopic cholecystectomy is at least as safe as conventional laparoscopic cholecystectomy in carefully selected patients.

Keywords: Single incision laparoscopic cholecystectomy, Conventional laparoscopy, Randomized controlled trial.

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INTRODUCTION

Gallstone disease is a common surgical condition. Everhart et al in a national survey in the United States found that 6.3 million men and 14.2 million women who were within the age range of 20 to 74 years were afflicted with gallbladder disease. Gallstone disease is a least twice as common in females as in males.¹ In Europe, the prevalence was found to vary from 5.9% in Italy to 21.9% in Norway.² The incidence rate in Europe is about 0.63 to 0.93/100 persons/year^{3,4} which may reflect the increasing demand for cholecystectomy. In Taiwan, a lower prevalence of gallstone disease was noted 4.6% in men and 5.4% in women; however, there was no difference in sex prevalence.⁵ In Africa, a hospital prevalence of 747 cases in 4 years with a male to female ratio of 1:5 was also reported.⁶

Cholecystectomy is the proven treatment for symptomatic gallstone disease.⁶ Open cholecystectomy is the mainstay of surgical treatment of gallbladder disease; however, it has evolved in terms of the access to the gallbladder. Muhe in 1985 introduced laparoscopic cholecystectomy,⁷ which subsequently, became the gold standard of care⁸ because it offered better cosmetic outcome, reduced postoperative pain with early return to normal

physical activity⁹ as well as comparative levels of patient safety. During conventional, traditional, four-port laparoscopic cholecystectomy complementary procedures, such as laparoscopic intraoperative cholangiography using contrast may be performed¹⁰ to define the extrahepatic biliary anatomy and determine the presence of common bile duct stone. Some authors have also performed transcystic duct balloon dilatation of sphincter of Oddi during conventional laparoscopic cholecystectomy which is effective in flushing common bile duct stones into the duodenum in 85% of cases.¹¹

In 1997, Navarra performed the first single incision laparoscopic cholecystectomy.¹² Single incision laparoscopic cholecystectomy also goes by other terminologies, such as transumbilical laparoscopic cholecystectomy,¹³ single port laparoscopic cholecystectomy,¹⁴ natural orifice transumbilical surgery (NOTUS)¹⁵ cholecystectomy and laparoendoscopic single site (LESS) cholecystectomy.¹⁶ The popularity of single incision laparoscopic surgery is driven by reports of improved cosmesis,¹⁷ further reduction in postoperative pain alongside comparative safety.¹⁸ However, there are difficulties with swording of instruments and loss of triangulation¹⁹ as well as increased operating time, and port site hernia, and increased risk of conversion. The safety of single port laparoscopic cholecystectomy should be determined compared with the standard of care as recent reports suggest that advanced procedures, such as laparoscopic cholangiography is being undertaken during single port laparoscopic cholecystectomy with some success.^{20,21} Therefore, it is necessary to review randomized control trials that compared the single port laparoscopic cholecystectomy with the four-port laparoscopic cholecystectomy.

AIM

To compare safety of single incision laparoscopic cholecystectomy with conventional laparoscopic cholecystectomy with emphasis on the operating time, postoperative pain, and cosmesis (Table 1), and bile duct injuries as well as conversion rate.

MATERIALS AND METHODS

A search of published randomized controlled trials comparing single port laparoscopic cholecystectomy with

Table 1: Randomized controlled trials comparing single-port laparoscopic cholecystectomy with conventional laparoscopic cholecystectomy

Authors	Number of patients in single port laparoscopic cholecystectomy study arm	Number of patients in single port laparoscopic cholecystectomy controls	Operation time	Postoperative pain	Cosmesis	Difficult exposure and bile duct injuries	Conversion	Postoperative wound infection
1. Bucher P, Pugin F, Buchs N, Ostermann S et al ²³	75	75	Similar	SPLC; reduced postoperative pain (p < 0.001)	Better cosmetic outcome and body image scar scale (p < 0.001)	None	2 SPLC converted 1 LC converted to SPC due to adhesions	SPLC: CLC 3:4 for seroma/hematoma
2. Aprea G, Bottazz E, Guida F, Masone S et al ²⁹	25	25	Operation time was longer in SPLC (p < 0.04)	No difference in postoperative pain	Better cosmesis with SPLC (p = 0.05)	None	None	None
3. Marks J, Tacchino R, Roberts K, Onders R et al ²⁵	50	33	Longer in SPLC (p < 0.003)	No difference in pain	SPLC had better body image cosmesis from 1 week, p = 0.0002-0.0004) at 3 months	None	One SPLC to four-port LC	Incisional hernia at 3 months in SPLC
4. Lirici, M, Califano, A, Angelini, P, Corcione F ¹⁶	20	20	Double blinded longer operation time in SPLC (0.001)	CLC less painful first day postoperative pain p = 0.04	Better cosmesis (p = 0.025)	D + (0.004)	No conversion	None
5. Lai E, Yang G, Tang C, Yih P, Chan O, Li M ³⁰	24	27	Longer for SPLC	SPLC more painful on day 7 compared to LC	SPLC has better cosmesis	None	None	None
6. Ma J, Maria S, Georg O, Hammill C et al ²⁷	21	22	Significantly longer operation time in SPLC (p < 0.05)	No difference	No difference	—	—	No difference
7. Tsimoyiannis EC, Tsimogiannis KE, Pappas-Gogos G et al ¹⁸	20	20	Operation time is longer in SPLC	Two blinded independent less pain in SPLC	—	CBD leakage in one CLC and two SPLC had postoperative bile leakage	—	—
8. Chang S, Wang Y, Shen L, Iyer S, Shaik A, Lomanto D et al ²⁴	24	26	Similar operation time	SPLC lower pain at umbilical (0.002 at rest and during movement) and other sites (0.004)	Cosmesis better in SPLC but it is not statistically significant	—	—	—
9. Zheng M et al ²⁸	28	30	Operation time longer in SPLC (0.03)	SPLC less post-operative pain and mean pain index lower (p = 0.0003)	SPLC better satisfaction (0.012)	—	Two SPLC were converted	—
10. Phillips M, Marks J, Roberts K, Tacchino R et al ²⁶	117	80	Blinded multicenter RCT (10 centers) Operation time Longer in SPLC (p < 0.00001)	Postoperative pain less in CLC (p = 0.028)	Cosmesis better for SPLC (p = 0.002)	None	Conversion to CLC in one patient	Wound infection higher in SILS (p = 0.047) but hernia were equal in both arms

SPLC: Single port laparoscopic cholecystectomy; CLC: Conventional laparoscopic cholecystectomy; RCT: Randomized controlled trials

conventional cholecystectomy in databases such as Google Scholar, Highwire press, and PubMed, and SCOPUS between 1st January 2009 and 20th February 2013 was made using search terms, such as single incision laparoscopic cholecystectomy, single port cholecystectomy, and minimally invasive cholecystectomy. Other synonyms were included in the search, such as transumbilical laparoscopic cholecystectomy, nearly scarless cholecystectomy and laparoendoscopic single site cholecystectomy, NOTUS cholecystectomy. These studies must compare conventional laparoscopic cholecystectomy, or its synonyms, such as traditional laparoscopic cholecystectomy and Four-port laparoscopic cholecystectomy.

Inclusion Criteria

- Articles published in English.
- Publications between 1st January 2009 and 20th February 2013.
- Randomized controlled trials.
- The patients are adults aged 18 years up to 90 years old.
- The articles must evaluate any of the following criteria, operating time, postoperative pain and cosmesis, and bile duct injury and postoperative wound infection and conversion.

Exclusion Criteria

Randomization with bias or Quasi randomization. Eleven randomized controlled trials were found, but one study was excluded because the randomization was biased, hence, 10 studies were considered.

DISCUSSION

Operating Time

Operating time is an important consideration because it offers some idea about the difficulty of a surgical procedure. Single incision cholecystectomy is associated with crossing of instrument intracorporeally as well as the ends of trocars and handles of the hand instruments impeding the extracorporeal instrumentation. It depicts the time from the first incision on the patient to the closure of the last incision on the patient. There were no differences in the mean operation time in two studies (Figs 1 and 2),^{23,24} similarity in the operating time noted in these results may be as a result of the similarity in the instruments used which are the chip on tip flexible telescope and the articulated instruments. While the mean operating time for conventional laparoscopic cholecystectomy was shorter and statistically significant ($p = 0.003$,²⁵ $p = 0.001$ ¹⁶ and $p = 0.00001$).²⁶ These variations may be partly explained by the differences in the level of skill of different surgeons' involved in the

trials as well as the learning curve within each trial group. A decline in operating time of about 21 minutes was observed between the first five single port laparoscopy procedures and the last five procedures, more so, two surgeons with more than 15 years experience in advanced laparoscopic surgery and transanal endoscopic microsurgery performed all the procedures.¹⁶ Other studies showed mean operating times for conventional laparoscopic cholecystectomy that were marginally statistically significant ($p = 0.03$),²⁷ $p = 0.05$.²⁶ Phillips et al demonstrated a highly statistically significant difference in the mean operating time in a multicenter study involving 10 centers which enrolled a large number of participating patients.

Postoperative Pain

The reduction in postoperative pain is a one of the benefits of single incision laparoscopic cholecystectomy. Conventional laparoscopic cholecystectomy involves about three to four multiple incision, rather than one umbilical incision used in single port laparoscopic cholecystectomy. Other factors that may cause postoperative pain include irritation of the peritoneum under the diaphragm by the carbon dioxide used in creating the pneumoperitoneum, and

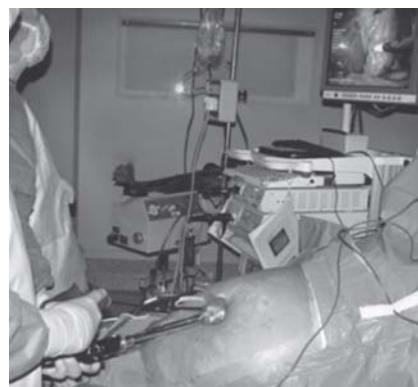


Fig. 1: Laparoendoscopic single-site cholecystectomy²³



Fig. 2: Conventional laparoscopic cholecystectomy²³

pressure at the port sites. Postoperative pain parameter was accessed in all the randomized controlled trials. There was no difference in the severity of postoperative pain experienced by the study group and controls.^{24,26,28} Other authors noted that postoperative pain was lower in patients who underwent conventional laparoscopic cholecystectomy ($p = 0.04$,¹⁶ $p = 0.028$).²⁵ Some results noted that single port laparoscopic cholecystectomy resulted in less postoperative pain as ($p = 0.001$,²² $p = 0.002$).²³ These conflicting results may arise from the difference in the timing used in assessing the postoperative pain.

Cosmesis and Body Image

Cosmetic appearance of the abdominal wound after surgery was assessed using the scar satisfaction scale. Cosmesis was assessed in all the studies reviewed except for Tsimoyiannis et al.¹⁸ The cosmetic outcome was in favor of single port laparoscopic cholecystectomy except for one study that reported that there was no difference.²⁶ Another study noted that the reported difference was not statistically significant.²³ However, seven of the studies reviewed reported a better cosmetic appearance outcome^{16,22,24,25,27-29} which were statistically significant. The study that detected the highest statistically significant difference in cosmesis ($p = 0.0002$) had assessed cosmesis after single port laparoscopic cholecystectomy at 2 weeks.²⁴ All the cosmetic evaluations in clinical trials reviewed were done within the first 3 months of surgery. The cosmetic appearance of conventional laparoscopic cholecystectomy after 4 years was judged to be excellent by a retrospective study.^{31,32} This may be considered in choosing the between single port cholecystectomy and conventional laparoscopic cholecystectomy.

Bile Duct Injuries and Conversion

Bile duct injuries were uncommon in the studies reviewed. Two cases of postoperative bile duct leaks were reported following single port laparoscopic cholecystectomy while one bile duct injury occurred following conventional laparoscopic cholecystectomy. This is similar to the finding of bile duct leaks in (0.6%) of procedures performed as single port laparoscopic cholecystectomy.³⁰ These bile leaks resolved spontaneously following closed drainage.¹⁸ These leaks may arise from the accessory hepatic duct, from the cystic duct stump or from the common bile duct as a result of use of energy devices. There were seven conversions from single incision laparoscopic cholecystectomy to conventional laparoscopic cholecystectomy in very few procedures^{22,24,25,27} while one conventional laparoscopic cholecystectomy was converted to single port chole-

cystectomy due to upper abdominal adhesions obscuring port placement.²² This is an unusual conversion which should be borne in mind as an advantage of single port laparoscopic cholecystectomy.

Postoperative Wound Infections and Other Wound Complications

Wound hematoma was noted in three cases of single incision laparoscopic surgery compared to four cases observed following conventional laparoscopic cholecystectomy²⁴ this is similar to about 17 cases observed in a review of 1,180 cases.³⁰ Wound infections were uncommon, and occurred more frequently in the single port laparoscopic cholecystectomy, and was statistically significant ($p = 0.04$).²⁵ This may be due to the pressure necrosis from the snugly fit port as well as extraction of the inflamed gallbladder through the umbilicus. Umbilical hernia occurred more frequently following single port laparoscopic cholecystectomy. Other studies found that these were evenly distributed between the two arms;²⁵ however, umbilical incisional hernia may be related more to technical failure in the repair of the umbilical port.

CONCLUSION

The randomized controlled trial that were available were relatively few, and the sample sizes were small, this may explain the failure to detect statistically significant differences in many of the safety criteria evaluated. However, improved cosmesis is the most consistent benefit derived from the trials, it is also noteworthy that bile duct leaks were low and no mortality was reported. These remarkably good outcomes may be spurious considering the meticulous criteria adopted in selecting the patients that participated in this study. Large scale multicenter trials are needed to challenge the findings in this review.

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