

Conventional Versus Two Ports Plus One Puncture Laparoscopic Cholecystectomy: A Clinical Trial

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ABSTRACT

Background: The gold standard treatment for calculus cholecystitis is laparoscopic cholecystectomy (LC). In the conventional laparoscopic cholecystectomy (CLC), three instruments are most useful in ensuring the critical view of safety. The two ports plus one puncture laparoscopic cholecystectomy (TPPOP LC) assisted needle grasper approach upholds the laparoscopic triangulation principles and allows an accessible critical view of safety. This technique successfully reduces port numbers while maintaining equivalent surgical outcomes.

Method: The main objective is to compare clinical outcomes of conventional and two ports plus one puncture laparoscopic cholecystectomy. This is a single-center hospital based interventional double-blinded randomized controlled trial that included 98 patients undergoing laparoscopic cholecystectomy at No. (1) Military Hospital (700 bedded) from 01/12/2019 to 31/07/2021. The patients were randomized into group A (CLC) (n = 49) and group B (TPPOP LC) (n = 49). This trial was registered in the ISRCTN registry with the registration number ISRCTN50339464.

Results: Among total of 98 patients, 46.9% were male patients and 53.1% were female patients. Mean age in group A was 49.86 ± 7.77 years and in group B was 49.33 ± 7.69 years. Mean operation time in group A was 57.9 ± 6.7 minutes and in group B was 58.5 ± 7.1 minutes, with no significant difference ($p = 0.66$). Although 4.1% of patients in CLC group and 12.2% in TPPOP LC group experienced bile spillage, no other major intraoperative complications were noted. A significant difference was observed at 36 and 48 hours postoperatively (VAS: 2.69 ± 1.16 in group A and 1.94 ± 0.83 in group B at 36 hours; $p = 0.005$ and VAS: 1.69 ± 0.92 in group A and 1.33 ± 0.63 in group B at 48 hours; $p = 0.002$). Postoperative minor wound infection was detected 6.1% in group A and 4.1% in group B ($p = 0.64$). The mean duration of the postoperative hospital stay was 5.24 ± 1.01 days in group A and 4.98 ± 0.92 days in group B ($p = 0.17$).

Conclusion: This clinical trial concludes that two ports plus one puncture laparoscopic cholecystectomy is as effective and safe as conventional four-port laparoscopic cholecystectomy.

KEYWORDS: Gallstones, conventional, two ports, laparoscopic cholecystectomy, needle grasper, bile duct injury, bile spillage, operation time, postoperative pain, hospital stay.

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INTRODUCTION

Gallstones are a major cause of morbidity in Western countries, with an estimated incidence of symptomatic gallstones of 2.2 per 1,000 individuals, or an estimated 6.3 million men and 14.2 million women aged 20 to 74 years,

and approximately 700,000 cholecystectomies are performed each year to treat symptomatic gallstones in the United States. 98% of all gallbladder and biliary tract disorders are related to cholelithiasis, and gallstone-related complications are responsible for 3,000 deaths per year

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(0.12% of all deaths). Cholelithiasis is linked to gallbladder cancer, as chronic irritation of the gallbladder mucosa can lead to malignant transformation or the promotion of carcinogenic agents (1).

Open cholecystectomy was the first surgical procedure used to treat symptomatic gallstones, and it was first performed in the 1880s. Since its introduction by Philippe Mouret in France in 1987, laparoscopic cholecystectomy has become the most common and frequently performed laparoscopic operation globally (1). Since 1987, many investigators have conducted ongoing study using fewer and smaller ports in an effort to use fewer invasive procedures. By combining many ports into a single incision, fewer ports will be used overall, which will also result in fewer skin incisions overall (2).

Since the introduction of single incision laparoscopic cholecystectomy (SILC) in 1997 (3), there has been an increase in the risk of bile duct injury during this procedure due to the frequent conflict between laparoscopic instruments (4). Therefore, SILC is considered appropriate not for all patients with benign gallbladder diseases, but for selected patients without significant inflammation (5).

Bile duct injury is a serious complication that threatens the patient's safety. To minimize it, complete exposure and dissection of the critical view of safety is strongly recommended before clipping or dividing the cystic structures. In order to prevent inadvertent injury to the common bile duct or hepatic arteries, these techniques involve dynamically retracting the gallbladder fundus, dynamically retracting the gallbladder infundibulum, and locating and preserving the "critical view" of the cystic duct and artery (6).

Various studies have demonstrated that two ports LC can conveniently give a critical safety view while upholding laparoscopic triangulation principles (7). The insertion of two ports at the umbilical and epigastric regions, together with gallbladder anchorage with one or two percutaneous sutures or gallbladder suspension with a needle grasper, are the two most popular techniques for two ports LC, according to the systematic review (8).

Sutures are inserted into the abdominal cavity from a different location, the tissue is punctured, and the sutures are subsequently removed via the abdominal wall. Pulling the thread outside retracts the tissue. Although some surgeons advocate for this approach, laparoscopic cholecystectomy is time-consuming and can result in bile spillage. Gadgets measuring 1.6-3 mm in diameter, such as a pre-tied loop, a wire snare, and a needle grasper, can be inserted and employed for tissue retraction independently, just like in typical laparoscopic procedures (9).

Numerous changes have been made to the laparoscopic cholecystectomy procedure. Among these is a novel technique that involves the surgeon holding a needle

grasper in his left hand. The two-port LC assisted needle grasper technique successfully minimizes port numbers in comparison to conventional laparoscopic cholecystectomy, while maintaining comparable surgical outcomes in terms of operating time, open conversion rate, complication incidence, total analgesic requirement, and postoperative hospital stays. The difficult and technical challenges of SILC by itself were overcome by this technology. When it comes to benign gallbladder diseases, the two ports LC aided needle grasper improves cosmetic aspect while fulfilling safety and feasibility requirements. It can therefore replace conventional laparoscopic cholecystectomy (10). Our hypothesis was that two ports plus one puncture laparoscopic cholecystectomy is as safe and effective as conventional laparoscopic cholecystectomy.

MATERIALS AND METHOD

This is a single-center hospital based interventional double-blinded randomized controlled trial. This trial was registered in the ISRCTN registry (ISRCTN50339464), though registration occurred after participant recruitment had already begun due to an oversight. All study procedures adhered to ethical guidelines despite the delay in registration. This trial was conducted in the surgical unit of No. (1) Military Hospital (700 bedded) in Pyin Oo Lwin, Myanmar. The recruitment start date was 01/12/2019, and the end date was 31/07/2021. All patients with symptomatic gallstones who were treated by laparoscopic cholecystectomy were included in the trial. Patients with ASA III, IV & V, previous upper abdominal surgery, common bile duct pathology, clinical or USG suspected gall bladder cancer, and bleeding disorders were excluded from the trial.

Patients were evaluated using a detailed history, a thorough physical examination, and investigations such as liver function tests, a complete blood picture, urea, creatinine, viral serology, and abdominal sonography. An informed written consent explaining the research procedure was obtained at least one day before surgery. The required sample size for each group was 49, for a total of 98. A total of 98 patients were randomly allocated to group A (CLC) (n = 49) and group B (TPPOP LC) (n = 49) by the block randomization method (Figure 1).

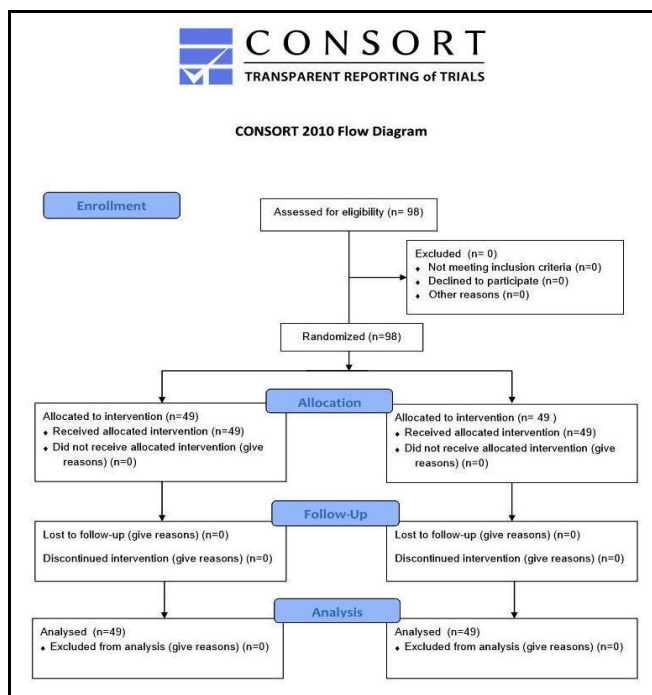


Figure 1. CONSORT Flow Diagram

For a total sample size of 98 patients, there were 10 blocks, each with 10 patients. In each block of 10 cases, two methods were allocated in random order. A random block design was generated by using Graphpad Prism Software. The first case was allocated into one block by the envelope method. Then the following 9 cases were in the same block in order. After completing one block, the same procedure was done for another block of 10 patients. A system of sequentially numbered, sealed, opaque envelopes containing treatment methods was used. The envelopes were opened in the operating theatre just before the operation. By using this randomization method, all patients were divided into two equal groups throughout the whole study period.

Patients underwent preoperative assessment by a consultant anaesthesiologist, and all operations were performed in the same theatre under general anesthesia. Fasting for 6 hours was required, and patients were asked to void urine before surgery. Prophylactic antibiotics were administered at induction of anesthesia, and the abdomen was cleaned and draped sterilely.

Operative Procedure

Carbon dioxide pneumoperitoneum was created and maintained at 12 mm Hg by making a 10 mm subumbilical incision and introducing a 10 mm port by the open Hasson technique. A video telescope was inserted from subumbilical port and assessed the pathological site and the visible intra-abdominal organs. The patient was placed in the reverse Trendelenburg position, and the operation table was tilted 15° left laterally.

Conventional LC

Three other working ports were inserted under vision via video scope. Another 10 mm trocar was placed in the

subxiphoid epigastric region, a 5 mm trocar was placed in the right subcostal midclavicular line, and another 5 mm trocar was placed in the right subcostal anterior axillary line location (Figure 2).



Figure 2. Trocars placement for conventional laparoscopic cholecystectomy (CLC)

The gallbladder was dissected using the conventional method, which involved first grasping and lifting the fundus before dissecting the cystic duct and artery. After obtaining the "critical view," these structures were clipped and divided. Using electrocautery, the gallbladder was removed from its bed and retrieved via the epigastric port (Figure 3).

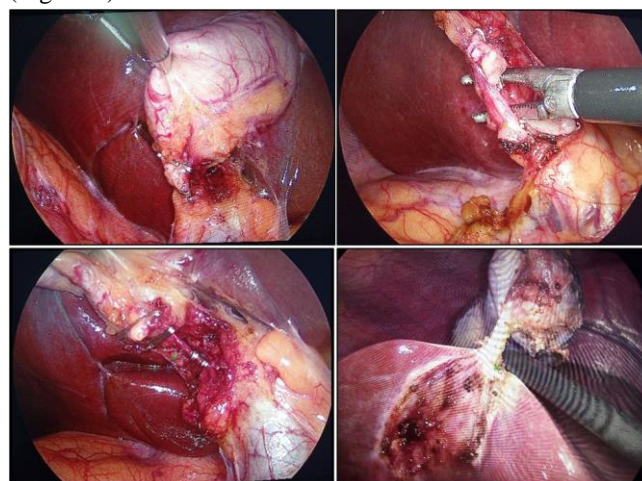


Figure 3. Laparoscopic views of operative procedure of conventional laparoscopic cholecystectomy (CLC).

Once the gallbladder was removed, the liver bed was examined to be sure there was no bleeding or bile leakage. Two 10 mm incisions were closed at the fascial level with non-absorbable sutures. All skin incisions were closed with non-absorbable sutures (Figure 4 and 5).

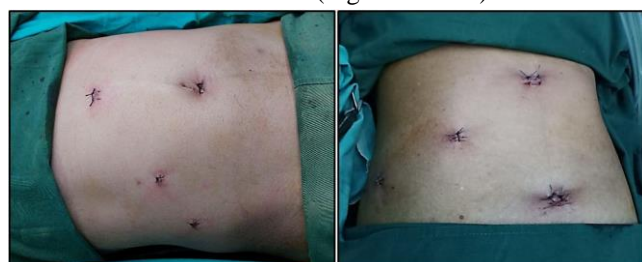


Figure 4. Closure of skin incisions in CLC.

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Figure 5. Postoperative condition of wound in CLC patient

Two ports plus one puncture LC

The working 5 mm port was inserted under vision via video scope and was placed in the subxiphoid epigastric region. A 2.3 mm alligator grasper (Teleflex MiniLap® Brand, Lacey Manufacturing Co., LLC., USA) (Figure 6) was punctured below the right costal margin under vision via video scope (Figure 7).



Figure 6. 2.3mm Alligator grasper (MiniLap®) for TPPOP LC.



Figure 7. Alligator grasper and trocars placement for two ports plus one puncture laparoscopic cholecystectomy (TPPOP LC).

The fundus or infundibulum of the gallbladder were grasped with a 2.3 mm alligator grasper to get good exposure (Figure 8). The cystic duct and artery were dissected with the standard Maryland laparoscopic instrument and clipped with a 5 mm clip applicator (Figure 9).

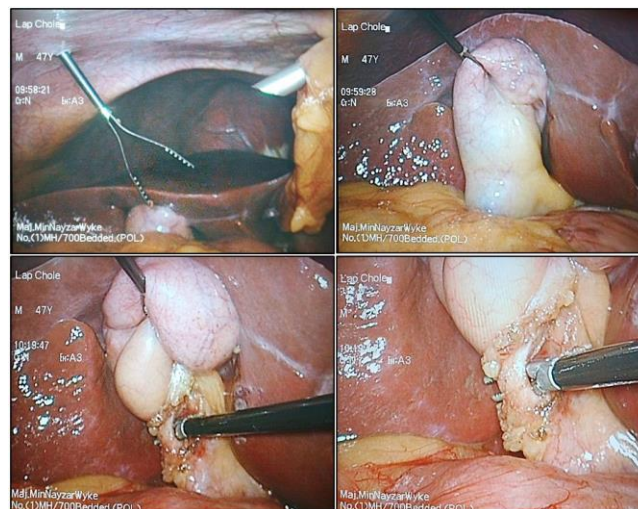


Figure 8. Laparoscopic views of operative procedure of TPPOP laparoscopic cholecystectomy.

The gallbladder was removed from the liver bed using cautery, then placed in a specimen retrieval bag and removed through a 10 mm subumbilical port under vision via video telescope from the 5 mm port. The 2.3 mm alligator grasper was removed, and this punctured site was covered with adhesive plaster only. The 10mm subumbilical incision was closed at the fascial level with non-absorbable sutures. All skin incisions were closed with non-absorbable sutures (Figure 10 and 11).

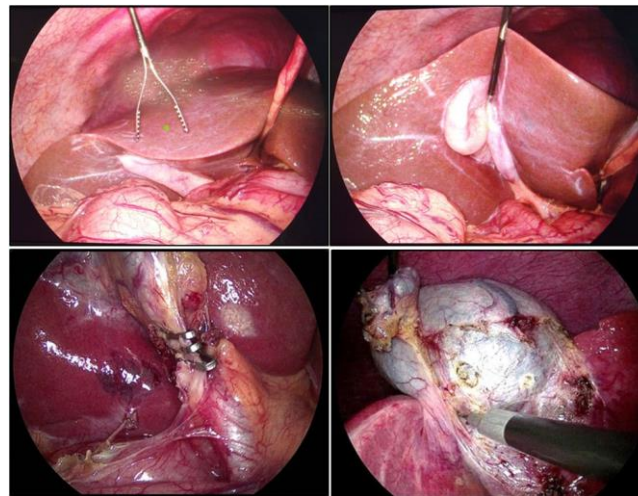


Figure 9. Laparoscopic views of operative procedure of TPPOP laparoscopic cholecystectomy.



Figure 10. Closure of skin incisions in TPPOP LC.



Figure 11. Postoperative condition of wound in patient with TPPOP LC

After surgery, antibiotics were administered in a single dose, with three doses for gallbladder perforation with bile spillage. Postoperative pain control was achieved with paracetamol suppository, with daily doses up to 72 hours. Patients were assessed using a visual analogue scale (VAS) and added intravenous tramadol 1mg/kg if VAS was higher than 4 or if pain occurred between assessments. Early postoperative complications like prolonged ileus and wound infection were monitored daily until patients were discharged. Patients were given oral cefixime 200 mg twice a day and paracetamol 500 mg if pain arose. Postoperative hospital stays were calculated and recorded in proforma for each patient.

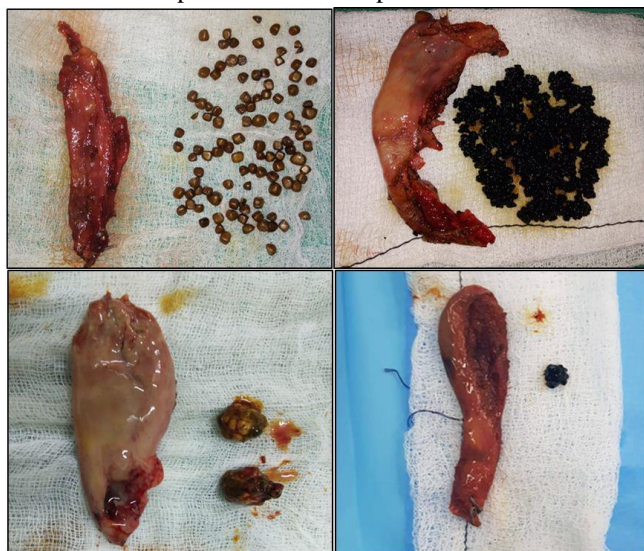


Figure 12. Gallbladder specimens with gallstones

In this clinical trial, age and sex distribution, operation time (from the time of skin incision to the last stitch of skin closure), intraoperative complications (bile duct injury, bowel injury, vascular injury, injury to nearby structures, and others), conversion rate, postoperative pain assessment by VAS, rescue analgesic injection tramadol requirement, postoperative complications (wound infection, prolonged ileus, and others), and duration of

postoperative hospital stay of both groups were reviewed and compared.

Statistical analysis

Statistics were analyzed on a total of 98 patients by using SPSS® Statistic software package version 28.0. The categorical data was calculated by the statistical method Chi-square. For continuous variables, the statistical significance of patients was analyzed by two independent Student's t tests.

RESULTS

Among a total of 98 patients, 46.9% were male patients and 53.1% were female patients (Figure 13). The mean age in group A was 49.86 ± 7.77 years and in group B was 49.33 ± 7.69 years (Table 1).

Table 1. Patient Demographics in both groups

	Group A (CLC)	Group B (TPPOP LC)	P value
Mean age	49.86 ± 7.77	49.33 ± 7.69	0.56
Male	21	25	0.42
Female	28	24	

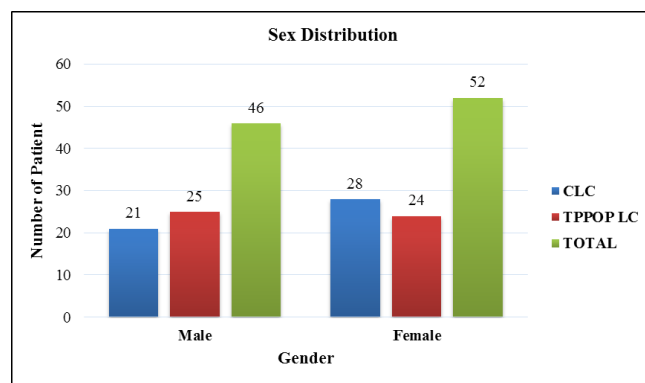


Figure 13. Sex distribution in both study groups

Mean operation time in group A was 57.9 ± 6.7 minutes and in group B was 58.5 ± 7.1 minutes, with no significant difference ($p = 0.66$) (Table 2 and Figure 14). The mean duration of the postoperative hospital stay was 5.24 ± 1.01 days in group A and 4.98 ± 0.92 days in group B ($p = 0.17$) (Table 2 and Figure 15).

Table 2. Comparison of parameters in both groups

	Group A (CLC)	Group B (TPPOP LC)	P value
Operation time	57.9 ± 6.7	58.5 ± 7.1	0.66
Postoperative hospital stays	5.24 ± 1.01	4.98 ± 0.92	0.17

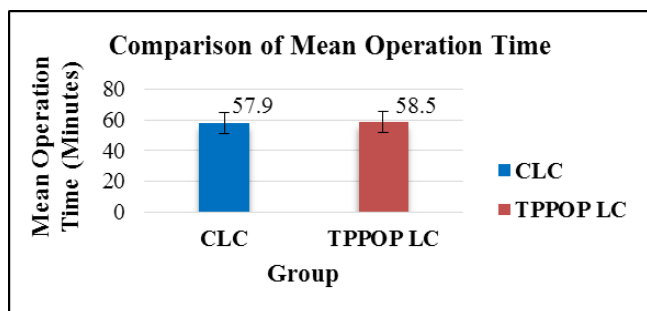


Figure 14. Comparison of mean operation time in both groups

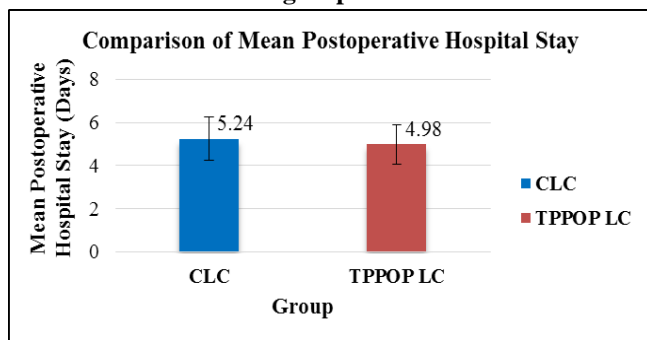


Figure 15. Comparison of mean postoperative hospital stay in both groups

Although 4.1% of patients in the CLC group and 12.2% in the TPPOP LC group experienced bile spillage as a result of gallbladder perforation during the operation, no other major intraoperative complications were noted (Table 3). Postoperative minor wound infection was detected 6.1% in group A and 4.1% in group B ($p = 0.64$) (Table 3).

Table 3. Comparison of intra-operative and post-operative complications in both groups

	Group A (CLC)	Group B (TPPOP LC)	P value
<i>Intra-operative complications</i>			
Bile duct injury	0	0	
Bowel injury	0	0	
Vascular injury	0	0	
Injury to nearby structures	0	0	
Bile spillage	2 (4.1%)	6 (12.2%)	0.14
<i>Post-operative complications</i>			
Wound infection	3 (6.1%)	2 (4.1%)	0.64
Prolonged ileus	0	0	
Others	0	0	

In both groups, there was no conversion to open cholecystectomy, and in group B, there was no conversion to the conventional method.

Postoperative pain among patients was assessed by the Visual Analogue Scale (VAS). Sodhi and Fernando (2002) categorized the severity of pain as mild pain (VAS 1 to 4), moderate pain (VAS 5 to 7) and severe pain (VAS 8 to 10). Postoperative pain assessment with VAS was evaluated at different time points: 12 hours, 24 hours, 36 hours, and 48 hours after the operation.

Regarding the distribution of pain with VAS at 12 hours after operation, the majority of patients (57.1%) expressed mild pain, while about 42.9% of them felt moderate pain in group A (CLC). Similarly, in group B (TPPOP LC), mild pain accounted for 67.3% and the rest (32.7%) for moderate pain. Severe pain was not detected among patients in either group. This distribution was not significantly different between the two study groups ($p = 0.3$).

More than 70% of patients experienced mild pain at 24 hours after surgery, with moderate pain decreasing to 28.6% from 42.9% in group A (CLC). Patients with mild and moderate pain were 87.8% and 12.2%, respectively, in group B (TPPOP LC). This severity of pain distribution was significantly different between the two study groups ($p = 0.04$).

According to pain assessment with VAS at 36 hours after operation, in the CLC group, 91.8% of patients stated mild pain and about 8.2% expressed moderate pain. Among the patients in the TPPOP LC group, all of them felt mild pain only. This severity of pain distribution was significantly different between the two study groups ($p = 0.04$).

The distribution of pain with VAS at 48 hours after the operation revealed that all patients in group A (CLC) expressed mild pain only as similar as in group B (TPPOP LC). Nevertheless, the distribution of pain with VAS at 48 hours after the operation was not different between the two study groups (Table 4).

Table 4. Postoperative pain assessment by VAS at regular intervals

VAS at hour	Group	Mild (VAS 1-4)	Moderate (VAS 5-7)	Severe (VAS 8-10)	P value
12 hr	A	28 (57.1%)	21 (42.9%)	0	0.3
	B	33 (67.3%)	16 (32.7%)	0	
24 hr	A	35 (71.4%)	14 (28.6%)	0	0.04
	B	43 (87.8%)	6 (12.2%)	0	
36 hr	A	45 (91.8%)	4 (8.2%)	0	0.04
	B	49 (100%)	0	0	
48 hr	A	49 (100%)	0	0	-
	B	49 (100%)	0	0	

VAS, visual analogue scale

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Up to 24 hours after surgery, the mean VAS values for group B did not differ significantly from those of group A. A significant difference was observed at 36 and 48 hours postoperatively (VAS: 2.69 ± 1.16 in group A and 1.94 ± 0.83 in group B at 36 hours; $p = 0.005$ and VAS: 1.69 ± 0.92 in group A and 1.33 ± 0.63 in group B at 48 hours; $p = 0.002$) (Table 5 and Figure 16).

Table 5. Comparison of postoperative pain scores in both groups

Postoperative period	Group A (CLC)	Group B (TPPOP LC)	P value
At 12 hours	4.71 ± 1.08	4.20 ± 0.99	0.13
At 24 hours	3.86 ± 1.17	3.08 ± 1.04	0.44
At 36 hours	2.69 ± 1.16	1.94 ± 0.83	0.005
At 48 hours	1.69 ± 0.92	1.33 ± 0.63	0.002

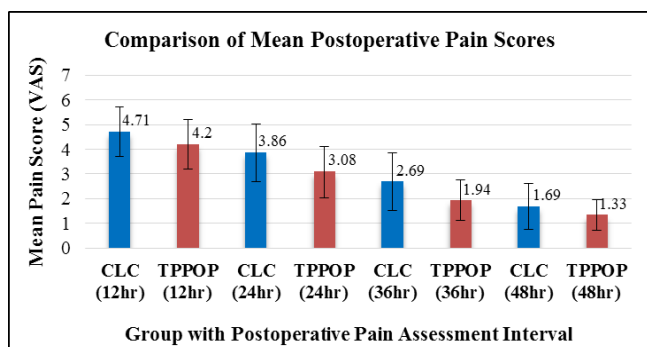


Figure 16. Comparison of mean postoperative pain scores in both groups

Regarding analgesic requirements, injection Tramadol was given to a total of 21 patients in group A (CLC) and 16 patients in group B (TPPOP LC), although 57.1% in group A and 67.3% in group B had no rescue analgesic requirement (Figure 17). There was a lower rescue analgesic requirement in group B after 24 hours but there was no significant difference in both study groups ($p = 0.11$).

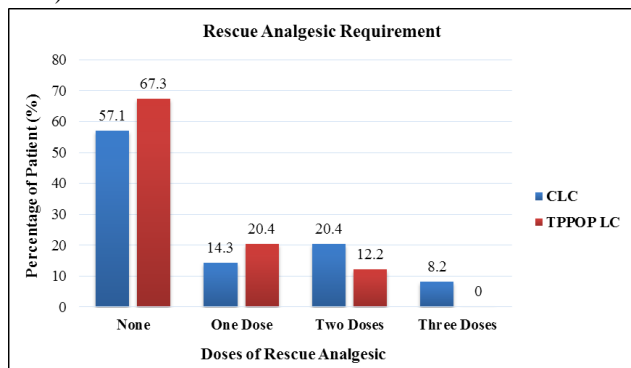


Figure 17. Rescue analgesic requirement in both groups

DISCUSSION

A single-center hospital based interventional double-blinded randomized controlled trial was conducted in No.

(1) Military Hospital (700 Bedded) to study and compare the clinical outcomes of conventional laparoscopic cholecystectomy (CLC) and two ports plus one puncture laparoscopic cholecystectomy (TPPOP LC) patients. 98 patients who satisfied the selection and exclusion criteria were included in the trial. Of these, randomly, 49 patients underwent conventional laparoscopic cholecystectomy (10mm, 10mm, 5mm, 5mm), and 49 patients underwent two ports plus one needle puncture laparoscopic cholecystectomy (10mm, 5mm, 2.3mm).

All included patients in two groups were evaluated and compared by means of age and sex distribution, male to female ratio, operation time, intraoperative complications (such as bile duct injury, bowel injury, vascular injury, injury to nearby structures, and others), conversion rate, postoperative pain assessment with VAS at 12, 24, 36, and 48 hours after operation, rescue analgesic requirement, postoperative complications (such as prolonged ileus, wound infection, and others), and postoperative hospital stay.

The majority of the female and male patients were between the ages of 41 and 60. In this trial, the youngest patient was 24 years old, and the oldest was 62 years old. The mean age in group A was 49.86 ± 7.77 years, while the mean age in group B was 49.33 ± 7.69 years. The age distribution in both study groups was similar, with no statistical difference ($p = 0.56$). In this trial, the majority of patients were females (53.1%), as compared to males (46.9%). Gallstones are also more common in women than in men, according to the findings of this trial. The occurrence of gall stones in the male population has also become common and noticeable. This is most probably because the study population is mainly based on the military population. But there was no significant distribution of sex in the two groups ($p = 0.42$).

In terms of operation time, the mean operation time of TPPOP LC was 58.5 ± 7.1 minutes, with no significant difference when compared to the CLC operation time of 57.9 ± 6.7 minutes. Because the operation time of TPPOP LC was nearly identical to the conventional method, anesthetic complications were not different between the two groups. The operation time was determined by the experience of the surgeon and the disease situation. In the future, more experience with laparoscopic instruments and better visualization cameras will shorten the operation time.

Between the two patient groups in this trial, there was not a significant distinction in intraoperative complications ($p = 0.14$). Except for bile spillage due to gallbladder perforation (4.1%), there were no intraoperative complications in the CLC group, such as bile duct injury, bowel injury, or injury to nearby structures. Similarly, in the TPPOP LC group, there were no intraoperative complications such as bile duct injury, bowel injury, or injury to nearby structures, with the exception of bile

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spillage (12.2%), making it comparable to the conventional method in terms of intraoperative complication rate.

All cases of bile spillage in both groups occurred during mobilization of the gallbladder from the liver and again during gallbladder traction with a grasper because of the thickening of the gallbladder wall. When bile was observed escaping from a torn gallbladder, the contents were aspirated and the torn gallbladder was clamped with a grasper clamp or clips. In my trial, all gallbladder perforations were tiny and were controlled using a grasper clamp or clips. The subhepatic and subphrenic areas were then thoroughly irrigated. These patients received up to three doses of intravenous antibiotics.



Figure 18. Positioning and handling of alligator needle grasper and laparoscopic instruments (TPPOP LC).

In the TPPOP LC group, the 2.3mm alligator needle grasper, which was inserted through a direct puncture on the right upper abdomen, allowed for the preservation of triangulation between instruments and the reduction of frequent conflict between instruments (Figure 18). With the addition of a needle grasper to the two-port LC, visualization of the operation site improved significantly, achieving a critical view of safety. There was also no blind dissection or blind clipping. The use of a needle grasper through the abdominal wall without the use of a trocar for Hartman's pouch retraction or for fundal retraction was also acceptable and did not change the nomenclature. The ergonomics were excellent, and the technique was just as comfortable as the four-port conventional laparoscopic cholecystectomy. The use of two ports and a needle grasper did not increase operative difficulties in this study, as the mean duration of procedures was nearly identical in both groups.

In this trial, there was no conversion to open cholecystectomy in either the CLC or TPPOP LC groups. There was also no conversion to the conventional method in the TPPOP LC group. The conversion rate in laparoscopic cholecystectomy depends on operative difficulties and instrument failure. The operative difficulty is based on the status of the gallbladder, anatomical

variations, and adhesions around the gallbladder fossa and elsewhere in the abdomen. Calot's triangle and cystic duct anatomy was similar in both groups, and there was no episode of instrument failure in this trial.

When the VAS score of pain at postoperative 12, 24, 36, and 48 hours was compared, postoperative pain was similar in both groups at the first 12 hours, but at 24 and 36 hours, postoperative pain was significantly less in the TPPOP LC group as compared to the CLC group, and therefore, postoperative rescue analgesic requirement was also less in the TPPOP LC group with no statistically significant difference.

In terms of postoperative complications, there were no cases of prolonged ileus, but wound infection occurred in both groups. Minor wound infection occurred in 3 cases (6.1%) in the CLC group and 2 cases (4.1%) in the TPPOP LC group during the postoperative period, but it was not statistically significant ($p = 0.64$). In this trial, the most wound infection occurred at the umbilical port sites, which were usually 10 mm incisions where the gallbladder was removed. Smaller port sites had a lower chance of becoming infected. Three patients in group A experienced moderate postoperative pain for up to 36 hours and required an additional three doses of rescue analgesic, while two patients in group B experienced moderate postoperative pain for up to 24 hours and required two doses of rescue analgesic. All five patients were given conservative treatment and wound dressings were changed on a daily basis.

The mean duration of postoperative hospital stay in the CLC group was 5.24 ± 1.01 days and 4.98 ± 0.92 days in the TPPOP LC group ($p = 0.17$). That is, the total duration of postoperative hospital stay was remarkably similar in both study groups, with no statistically significant difference. Even though these procedures were not performed as outpatient procedures, but rather with well-defined, well-established protocols, they can, in my opinion, be performed in the future as day-care procedures if there are no major intraoperative complications.

In this clinical trial, all procedures were completed, and none required conversion to CLC or open cholecystectomy. All laparoscopic cholecystectomy procedures in both study groups were completed successfully without any mortality or major morbidity. The learning curve in TPPOP LC is similar and not very long compared to CLC because the orientation and ergonomics are similar to the conventional method.

CONCLUSION

In conclusion from this clinical trial, in properly selected cases, laparoscopic cholecystectomy can be performed with a two-port technique using a 10mm umbilical port, a 5mm epigastric port, and a single 2.3mm needle grasper, maximizing the benefits of minimal access surgeries. As a result, this clinical trial concludes that two ports plus one

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puncture laparoscopic cholecystectomy is as effective and safe as conventional laparoscopic cholecystectomy.

RECOMMENDATION

Two ports plus one puncture laparoscopic cholecystectomy (TPPOP LC) is a safe and feasible alternative method for laparoscopic cholecystectomy, and it is an applicable form of minimally invasive surgery for patients with calculus cholecystitis, as it does not cause harmful effects in both the intraoperative and postoperative period. Thus, this technique can be recommended in selected patients and may still be beneficial for patients with symptomatic gallstone disease.

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We acknowledge that the ISRCTN registration (ISRCTN50339464) occurred after the start of participant recruitment, and we have implemented measures to ensure that future studies comply with pre-recruitment registration requirements.

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Without the contributions of all those mentioned, the successful publication of this clinical trial would not have been possible.

CONFLICTS OF INTEREST

The authors declared no potential conflict of interests with respect to authorship and publication of this article.

ETHICAL APPROVAL

This clinical trial was approved by Ethical Review Committee from Defence Services Medical Academy, Yangon, Myanmar. The approval number was 11/Ethics 2018 (14-11-2019) and the period allowed by Ethical Review Committee was from 01.12.2019 to 31.12.2021.

The informed consent from human participants was obtained by written form.

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