

# A Prospective Randomized Control Study Comparing Standard 4 Port Laparoscopic Cholecystectomy Versus Reduced Port Size Laparoscopic Cholecystectomy for Gall Stone (Cholelithiasis)

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**Abstract:** ***Background:** Gallstone disease (cholelithiasis) is a common health problem that often necessitates surgical removal of gallbladder (cholecystectomy). Laparoscopic cholecystectomy (LC) is gold standard for treating symptomatic gallstone disease, typically performed using a four-port technique. Recent advances in minimally invasive surgery have led to development of reduced port size laparoscopic cholecystectomy (RPLC), which aims to minimize the number and size of ports used, potentially offering benefits such as reduced postoperative pain, improved cosmetic outcomes, and faster recovery. **Objective:** This prospective randomized control study aims to compare the clinical outcomes of standard 4-port laparoscopic cholecystectomy (SLC) with reduced port size laparoscopic cholecystectomy (RPLC) for the treatment of gallstone disease. **Methods:** A total of 60 patients with cholelithiasis, fulfilling the inclusion criteria, were randomly assigned to either Group A (SLC) or Group B (RPLC), with 30 patients in each group. Both techniques involved laparoscopic removal of the gallbladder, with the only difference being the size of the epigastric and lateral ports. Intraoperative and postoperative outcomes were evaluated, including operative time, postoperative pain (measured using the Visual Analogue Scale), cosmetic outcomes (assessed using the Scar Cosmesis Assessment and Rating Scale), complication rates, patient satisfaction, and hospital stay. Data were analyzed using statistical methods, and significance was determined at a p-value < 0.05. **Results:** The RPLC group (Group B) had significantly longer operative times compared to the SLC group (32.27 ± 5.55 min vs. 26.90 ± 3.96 min, p = 0.0001). However, postoperative pain was consistently lower in Group B at 6, 12, and 24 hours postoperatively, with statistically significant differences. At the 7-day follow-up, all patients were pain-free. Cosmetic outcomes, particularly scar appearance, were significantly better in Group B, with lower scar scores at both the epigastric and lateral port sites (p < 0.0001). There were no significant differences in complication rates between the two groups. Hospital stay was shorter in Group B (mean 1.37 days vs. 1.80 days, p = 0.049). **Conclusion:** Reduced port size laparoscopic cholecystectomy (RPLC) offers significant advantages over standard 4-port laparoscopic cholecystectomy (SLC) in terms of reduced postoperative pain and improved cosmetic outcomes, without compromising safety. Although RPLC requires longer operative times, it is a feasible and patient-friendly option, particularly for those prioritizing cosmetic results and quicker recovery. These findings support the use of RPLC as a viable alternative to standard techniques in selected patients.*

**Keywords:** Cholelithiasis, laparoscopic cholecystectomy, reduced port size, postoperative pain, cosmetic outcomes, randomized controlled trial

## 1. Introduction

Cholelithiasis, commonly known as gallstone disease, is a significant and growing health problem that affects a substantial number of individuals globally. Gallstones, which are solid formations in the gallbladder made up of cholesterol, bilirubin, and other substances, can lead to various complications, including pain, inflammation (cholecystitis), poor digestion, and even life-threatening conditions such as

pancreatitis and jaundice. The condition is more common in females than males, especially in individuals over 40, and can severely affect the quality of life due to the pain and digestive disturbances it causes.

**Laparoscopic cholecystectomy (LC)** is the preferred treatment for symptomatic gallstone disease. This minimally invasive surgery involves the removal of the gallbladder through small incisions using a camera and specialized

instruments. Traditionally, LC is performed using a **four-port** technique, which consists of one 10 mm port for the camera and three working ports (10 mm and two 5 mm ports). This technique has become the gold standard due to its low complication rates, faster recovery times, and reduced postoperative pain compared to open surgery.

However, in recent years, there has been a push to make laparoscopic procedures even less invasive by reducing the size or number of ports used during surgery. This approach, known as **reduced port size laparoscopic cholecystectomy (RPLC)**, aims to minimize trauma to the abdominal wall, reduce postoperative pain, improve cosmetic outcomes, and shorten hospital stays without compromising the safety or efficacy of the procedure. This prospective randomized control study aims to compare the clinical outcomes of the standard four-port laparoscopic cholecystectomy and the reduced port size laparoscopic cholecystectomy for the treatment of cholelithiasis.

## 2. Aim and Objectives

The primary aim of the study is to compare the outcomes of standard 4-port laparoscopic cholecystectomy (SLC) and reduced port size laparoscopic cholecystectomy (RPLC) in patients with gallstone disease. The specific objectives include:

- 1) **Operative Time:** To evaluate the duration of surgery for both techniques.
- 2) **Postoperative Pain:** To compare postoperative pain levels using the Visual Analogue Scale (VAS) at different intervals (6 hours, 12 hours, 24 hours, and 7 days).
- 3) **Cosmetic Outcomes:** To assess cosmetic outcomes using the Scar Cosmesis Assessment and Rating (SCAR) scale at 1 month post-surgery.
- 4) **Complication Rates:** To monitor and compare any intraoperative and postoperative complications between the two groups.
- 5) **Patient Satisfaction and Quality of Life:** To measure patient satisfaction with the procedure, focusing on recovery time, pain management, and cosmetic results.
- 6) **Hospital Stay:** To compare the duration of hospital stay postoperatively between the two techniques.

## 3. Materials and Methods

**Study Design:** This study is designed as a prospective randomized control trial (RCT). It will be conducted over a period of 6 months, from January 1, 2024, to June 30, 2024, at the Department of Surgery, S.P. Medical College, Bikaner.

**Study Population:** The study will include patients diagnosed with gallstone disease (cholelithiasis) and referred for elective laparoscopic cholecystectomy at PBM Hospital, Bikaner. All participants will be from both the outpatient (OPD) and inpatient (IPD) departments.

**Sample Size:** The sample size will consist of 60 patients who meet the inclusion and exclusion criteria and who consent to participate. They will be randomly divided into two groups of 30 patients each:

- **Group A:** Standard 4-port laparoscopic cholecystectomy (SLC).
- **Group B:** Reduced port size laparoscopic cholecystectomy (RPLC).

### Sampling Method

A **convenience sampling** technique will be used to recruit all patients presenting with gallstone disease who meet the inclusion criteria during the study period. Patients will then be randomized into one of the two surgical groups.

### Inclusion Criteria

- Patients diagnosed with **gallstone disease** (cholelithiasis).
- **Adult patients (≥18 years).**
- Patients willing to give informed consent for surgery and participation in the study.

### Exclusion Criteria

- Patients with **common bile duct (CBD) stones.**
- Patients who have undergone an **Endoscopic Retrograde Cholangiopancreatography (ERCP).**
- Patients with **acute cholecystitis with empyema or perforation.**
- Patients with gallstone disease complicated by **cirrhosis or portal hypertension.**
- Patients with a history of **previous abdominal surgeries.**

### Preoperative Preparation and Investigation

- a) **Thorough history** taking and clinical examination.
- b) **Baseline investigations** including:
  - Complete blood count (CBC)
  - Liver function tests (LFT)
  - Renal function tests (RFT)
  - Random blood sugar (RBS)
  - Coagulation profile (BT, CT)
  - Imaging: **Ultrasound** for assessing gallstones, gallbladder wall thickness, and bile duct status. **Magnetic Resonance Cholangiopancreatography (MRCP)** will be done if liver function tests are deranged or if CBD stones are suspected.

### Operative Techniques

- 1) **Standard 4-Port Laparoscopic Cholecystectomy (Group A)**
  - a) Four ports will be used:
    - One **10 mm** port at the **umbilicus** for the camera.
    - One **10 mm** port at the **epigastrium** for dissection and gallbladder removal.
    - Two **5 mm** ports on the lateral side for retracting the gallbladder and assisting in dissection.
- 2) **Reduced Port Size Laparoscopic Cholecystectomy (Group B)**
  - a) Similar technique as the standard 4-port method, but with **reduced port sizes:**
    - **10 mm** umbilical port for the camera.
    - **5 mm** epigastric port and **3 mm** lateral ports for dissection and retraction, respectively.

### Postoperative Care

- Postoperative **pain will be assessed** using the Visual Analogue Scale (VAS) at 6 hours, 12 hours, 24 hours, and 7 days.

- Patients will be followed up at **1 month** and **6 months** postoperatively for scar assessment and overall recovery.
- Photographs of the surgical scars will be taken for cosmetic evaluation using the **SCAR scale**.

**Follow-up and Data Collection**

- A structured **questionnaire** and **proforma** will be used to collect detailed information regarding patient demographics, clinical history, intraoperative findings, and postoperative outcomes.
- **Patient satisfaction** and **quality of life** post-surgery will be assessed during follow-up visits and telephonic interviews.

**Data Analysis**

**Epi-info software** will be used for data analysis. Statistical significance will be determined using the appropriate statistical tests (Student’s t-test for continuous variables and Chi-square test for categorical data). A **p-value < 0.05** will be considered statistically significant.

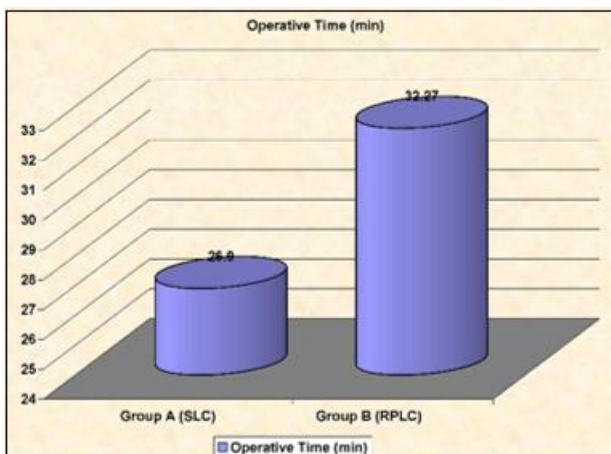
**4. Results**

This prospective randomized control study aimed to compare the outcomes of standard 4-port laparoscopic cholecystectomy (SLC) and reduced port size laparoscopic cholecystectomy (RPLC) for the treatment of gallstone disease. The results were analyzed based on several key parameters, including operative time, postoperative pain, cosmetic outcomes, complication rates, and duration of hospital stay. A total of 60 patients, 30 in each group, were included in the study.

**Table 1: Operative Time Comparison**

Parameter	Group A (SLC)	Group B (RPLC)	P-value
Operative Time (min)	26.90 ± 3.96	32.27 ± 5.55	0.0001

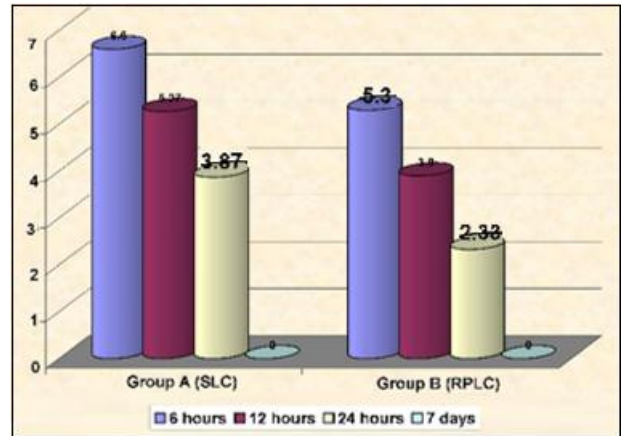
RPLC required more operative time compared to SLC, and the difference was highly statistically significant.



**Table 2: Postoperative Pain (VAS Score)**

Time Interval	Group A (SLC)	Group B (RPLC)	P-value
6 hours	6.60 ± 1.67	5.30 ± 1.34	0.002
12 hours	5.27 ± 1.55	3.90 ± 1.30	0.0001
24 hours	3.87 ± 1.74	2.33 ± 1.42	0.0001
7 days	0	0	—

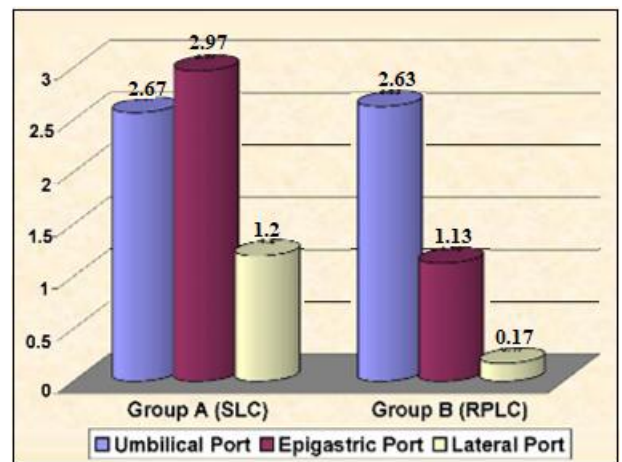
RPLC showed significantly lower postoperative pain at all early time intervals, but both groups had complete pain relief by day 7.



**Table 3: Cosmetic Outcomes (SCAR Score)**

Port Site	Group A (SLC)	Group B (RPLC)	P-value
Umbilical Port	2.57 ± 0.68	2.63 ± 0.56	0.710
Epigastric Port	2.97 ± 0.49	1.13 ± 0.35	0.0001
Lateral Port	1.20 ± 0.41	0.17 ± 0.38	0.0001

RPLC showed significantly better cosmetic outcomes at epigastric and lateral ports, while no difference was observed at the umbilical port.



**Table 4: Complications and Hospital Stay**

Parameter	Group A (SLC)	Group B (RPLC)	P-value	Observation
Biliary Spillage (%)	16.67%	23.33%	0.747	No significant difference
Other Complications	Minimal	Minimal	—	Similar in both groups
Hospital Stay (days)	1.80 ± 0.96	1.37 ± 0.67	0.049	Shorter stay in RPLC

Both techniques had similar complication rates, but RPLC resulted in a significantly shorter hospital stay.

#### 1) Operative Time:

- a) The mean operative time for Group A (SLC) was  $26.90 \pm 3.96$  minutes, while for Group B (RPLC), it was significantly longer at  $32.27 \pm 5.55$  minutes.
- b) **P-value:** 0.0001, indicating a highly significant difference between the two groups. Group B (RPLC) required more time due to the reduced size and complexity of the ports used.

#### 2) Postoperative Pain:

- a) Pain levels were assessed using the Visual Analogue Scale (VAS) at 6, 12, and 24 hours postoperatively, and then again at 7 days.
- b) At 6 hours, the mean pain score for Group A was  $6.60 \pm 1.67$ , compared to  $5.30 \pm 1.34$  in Group B.
  - **P-value:** 0.002, showing significantly less pain in Group B (RPLC).
- c) At 12 hours, the mean pain score for Group A was  $5.27 \pm 1.55$ , while Group B had a score of  $3.90 \pm 1.30$ .
  - **P-value:** 0.0001, again showing a significant reduction in pain for Group B.
- d) At 24 hours, Group A had a mean pain score of  $3.87 \pm 1.74$ , and Group B had  $2.33 \pm 1.42$ .
  - **P-value:** 0.0001, indicating significant pain reduction in Group B.
- e) By Day 7, all patients in both groups reported no pain (VAS score of 0), indicating full recovery in terms of pain management for both techniques.

#### 3) Cosmetic Outcomes:

- a) Cosmetic outcomes were assessed using the Scar Cosmesis Assessment and Rating (SCAR) Scale. Scars were evaluated at the umbilical, epigastric, and lateral port sites.
- b) At the umbilical port (10 mm), the mean scar score for Group A was  $2.57 \pm 0.68$ , while Group B had a mean score of  $2.63 \pm 0.56$ .
  - **P-value:** 0.710, indicating no significant difference between the groups at the umbilical port site.
- c) At the epigastric port, Group A had a mean scar score of  $2.97 \pm 0.49$ , compared to  $1.13 \pm 0.35$  in Group B.
  - **P-value:** 0.0001, indicating a highly significant difference, with Group B showing better cosmetic results.
- d) At the lateral port, Group A had a mean scar score of  $1.20 \pm 0.41$ , while Group B had  $0.17 \pm 0.38$ .
  - **P-value:** 0.0001, again showing significantly better cosmetic outcomes in Group B.

#### 4) Complication Rates:

- a) Biliary spillage occurred in 16.67% of cases in Group A and 23.33% of cases in Group B.
  - **P-value:** 0.747, indicating no significant difference in complication rates between the two groups.
- b) Other postoperative complications, such as bile leakage, bleeding, and infection, were minimal and similar in both groups.

#### 5) Hospital Stay:

- a) The mean duration of hospital stay for Group A was  $1.80 \pm 0.96$  days, while Group B had a shorter stay of  $1.37 \pm 0.67$  days.

- **P-value:** 0.049, indicating a statistically significant difference, with Group B having a shorter hospital stay, likely due to reduced postoperative pain and quicker recovery.

#### Expected Outcomes

The study will provide valuable insights into the efficacy and safety of reduced port size laparoscopic cholecystectomy (RPLC) compared to the standard 4-port approach. Expected outcomes include:

- 1) **Operative time:** RPLC may result in longer operative times due to the smaller working space and increased technical complexity.
- 2) **Postoperative pain:** RPLC is anticipated to result in **lower postoperative pain**, particularly in the early recovery phase.
- 3) **Cosmetic outcomes:** RPLC may provide **superior cosmetic outcomes** due to smaller incisions, which are likely to result in less noticeable scarring.
- 4) **Complications:** Both techniques are expected to have **similar complication rates**, with no significant increase in risks associated with the reduced port size approach.
- 5) **Patient satisfaction:** Patients undergoing RPLC are expected to report **higher satisfaction** with their recovery and cosmetic results.
- 6) **Hospital stay:** The duration of hospital stay is anticipated to be **shorter** in patients undergoing RPLC due to reduced postoperative discomfort and faster recovery times.

#### 5. Conclusion

This randomized controlled trial will compare the outcomes of standard 4-port laparoscopic cholecystectomy and reduced port size laparoscopic cholecystectomy for the treatment of gallstone disease. Reduced port size techniques offer potential advantages, such as less postoperative pain and better cosmetic outcomes, which may improve overall patient satisfaction. However, these benefits may come at the cost of **increased operative time**. The study will provide important evidence on the feasibility, safety, and clinical benefits of reduced port size laparoscopic cholecystectomy, helping to guide surgical decision-making and improve patient outcomes in the treatment of gallstone disease.

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