นิพนธ์ต้นฉบับ . Original Article

การศึกษาเชิงสุ่มเปรียบเทียบการผ่าตัดถุงน้ำดีแบบส่องกล้องโดยใช้กล้องสามมิติกับสองมิติ: ประสิทธิภาพในการผ่าตัดและความปลอดภัย

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A Prospective Randomized Controlled Study Comparing Three-dimensional and Two-dimensional Laparoscopic Cholecystectomy: Operative Efficiency and Safety

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บทคัดย่อ

ภูมิหลังและวัตถุประสงค์: การผ่าตัดถุงน้ำดีด้วยวิธีส่องกล้อง เป็นการรักษามาตรฐานของโรคนิ่วในถุงน้ำดี อย่างไรก็ตาม ระบบส่องกล้องแบบสองมิติ (2D) ยังมีข้อจำกัดด้านการรับรู้ความลึก ซึ่งอาจส่งผลต่อความแม่นยำในการผ่าตัด ระบบส่องกล้องแบบสามมิติ (3D) ได้รับการพัฒนาขึ้นเพื่อเพิ่มประสิทธิภาพการมองเห็นและการรับรู้เชิงพื้นที่ การศึกษานี้มีวัตุประสงค์เพื่อเปรียบเทียบประสิทธิภาพและความปลอดภัย ของการผ่าตัดถุงน้ำดีแบบส่องกล้อง โดยใช้ระบบสามมิติและสองมิติ

วิธีการศึกษา: เป็นการศึกษาแบบสุ่มมีกลุ่มควบคุมเก็บข้อมูลไปข้างหน้า ในผู้ป่วยที่เข้ารับการผ่าตัดแบบ elective ณ โรงพยาบาลมหาสารคาม ช่วงเดือนตุลาคม 2568 ถึง กุมภาพันธ์ 2569 ผู้ป่วยถูกสุ่มเข้ากลุ่ม 3D หรือ 2D ประเมินระยะเวลาในการผ่าตัด ปริมาณการสูญเสียเลือดระหว่างผ่าตัด คะแนนความปวดหลังผ่าตัด คะแนนความยากในการผ่าตัด คะแนนคุณภาพของภาพและภาวะแทรกซ้อนหลังผ่าตัด

ผลการศึกษา: ผู้ป่วยจำนวน 70 ราย ถูกสุ่มเข้ากลุ่ม 3D และ 2D อย่างละเท่า ๆ กัน ลักษณะพื้นฐานของผู้ป่วย รวมถึงอายุและดัชนีมวลกาย ไม่แตกต่างกันระหว่างกลุ่ม ระยะเวลาเฉลี่ยในการผ่าตัดมีแนวโน้มสั้นกว่าเล็กน้อยในกลุ่ม 3D (41.83 เทียบกับ 43.94 นาที, p = 0.20) และมีปริมาณการสูญเสียเลือดน้อยกว่า (9.69 เทียบกับ 11.03 มิลลิลิตร p = 0.27) แต่ไม่แตกต่างอย่างมีนัยสำคัญทางสถิติ คะแนนคุณภาพของภาพสูงกว่าอย่างมีนัยสำคัญในกลุ่ม 3D (4.37 ± 0.49 เทียบกับ 4.09 ± 0.37, p = 0.008) คะแนนความปวดหลังผ่าตัดต่ำกว่าอย่างมีนัยสำคัญในกลุ่ม 3D ทั้งในวันที่ 1 (p = 0.017) และวันที่ 2 หลังผ่าตัด (p = 0.004) ไม่พบภาวะ

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แทรกซ้อนรุนแรง การเปลี่ยนเป็นผ่าตัดเปิด หรือการกลับมานอนโรงพยาบาลซ้ำในทั้งสองกลุ่ม
สรุป: การผ่าตัดถุงน้ำดีแบบส่องกล้องด้วยระบบสามมิติ ช่วยลดความปวดหลังผ่าตัด และให้การมองเห็นที่ดีขึ้น โดยไม่เพิ่มความเสี่ยงในการผ่าตัด

คำสำคัญ: การผ่าตัดถุงน้ำดีแบบส่องกล้อง, กล้องสามมิติ-สองมิติ, การทดลองแบบสุ่มมีกลุ่มควบคุม

Abstract

Background and objective: Laparoscopic cholecystectomy is the standard treatment for symptomatic gallstone disease. However, conventional two-dimensional (2D) laparoscopic systems have limitations in depth perception, which may affect surgical precision. Three-dimensional (3D) laparoscopic systems have been developed to improve visualization and spatial perception during surgery. This study aimed to compare the operative efficiency and safety of three-dimensional and conventional two-dimensional laparoscopic cholecystectomy.
Methods: A prospective randomized controlled trial was conducted in patients undergoing elective laparoscopic cholecystectomy at Mahasarakham Hospital between October 2068 - Feburay 2026. Patients were randomized into either the 3D or 2D laparoscopic group. Operative time, intraoperative blood loss, postoperative pain scores, surgeon difficulty score, image quality score, and postoperative complications were evaluated.
Results: Seventy patients were equally randomized into the 3D and 2D groups. Baseline characteristics, including age and body mass index (BMI), were comparable between groups. The mean operative time tended to be slightly shorter in the 3D group (41.83 vs. 43.94 minutes, p = 0.20), and intraoperative blood loss was lower (9.69 vs. 11.03 mL, p = 0.27), although these differences were not statistically significant. The image quality score was significantly higher in the 3D group (4.37 ± 0.49 vs. 4.09 ± 0.37, p = 0.008). Postoperative pain scores were significantly lower in the 3D group on postoperative day 1 (p = 0.017) and postoperative day 2 (p = 0.004). No major complications, conversion to open surgery, or readmissions were observed in either group.
Conclusion: Three-dimensional laparoscopic cholecystectomy may improve visualization and reduce postoperative pain without increasing operative risk. Further multicenter studies with larger sample sizes are required to confirm these findings.

Keywords: laparoscopic cholecystectomy, three-dimensional laparoscopy, two-dimensional laparoscopy, randomized controlled trial

Introduction

Laparoscopic cholecystectomy (LC) is the standard surgical treatment for symptomatic gallbladder disease [1-5]. However, conventional two-dimensional (2D) laparoscopic systems lack stereoscopic depth perception, requiring surgeons to rely on visual cues and operative experience during dissection. This limitation may increase technical difficulty during critical operative steps, particularly during dissection of Calot's triangle, where precise anatomical identification is essential to prevent bile duct injury, one of the most serious complications of laparoscopic cholecystectomy [6-10].

Three-dimensional (3D) laparoscopic imaging systems were developed to improve stereoscopic visualization and spatial orientation during minimally invasive surgery. Previous studies have suggested that 3D laparoscopy may enhance hand–eye coordination, depth perception, and surgical precision compared with conventional 2D systems [8,9,11,12]. Randomized controlled trials and meta-analyses have also demonstrated improved visualization and surgeon performance with 3D imaging. However, the effects on operative outcomes, including operative time, blood loss, postoperative pain, and complication rates, remain inconsistent across studies [10-15].

Although the adoption of 3D laparoscopic systems has increased in many surgical centers, evidence regarding their clinical benefits in routine laparoscopic cholecystectomy remains inconclusive, particularly in regional hospitals and resource-limited healthcare settings. Most previous studies were conducted in high-volume academic centers in developed countries, whereas data from regional hospitals remain limited. Furthermore, evidence regarding the effectiveness of 3D laparoscopy in routine clinical practice in Thailand remains scarce.

Mahasarakham Hospital is a tertiary referral center in northeastern Thailand where laparoscopic cholecystectomy is routinely performed. Evaluating the potential advantages of 3D laparoscopy in routine clinical practice may help optimize surgical performance and improve patient outcomes. Therefore, this study aimed to compare operative efficiency and safety between three-dimensional and conventional two-dimensional laparoscopic cholecystectomy in patients undergoing elective surgery at Mahasarakham Hospital.

Methods

Study design

A single-blind, randomized controlled trial comparing three-dimensional laparoscopic cholecystectomy (3D LC) with conventional two-dimensional laparoscopic cholecystectomy (2D LC) was conducted at Mahasarakham Hospital, Thailand. The study protocol was approved by the Ethics Committee of Mahasarakham Hospital (COA No.68/110, MSKH_REC 68-01-110) on date December 1, 2025. and written informed consent was obtained from all participants prior to enrollment. The trial was conducted in accordance with the principles of the Declaration of Helsinki and reported following the CONSORT guidelines.

Sample size

Sample size calculation was performed based on the comparison of postoperative pain scores between the 3D and 2D laparoscopic groups from previous studies. Assuming a moderate effect size, a two-sided alpha error of 0.05, and 80% statistical power, the minimum required sample size was estimated to be 31 patients per group. To compensate for possible incomplete data or dropout, 35 patients were included in each group, resulting in a total sample size of 70 patients.

Participants

The study population consisted of patients diagnosed with symptomatic gallstone disease who were scheduled to undergo elective laparoscopic cholecystectomy at Mahasarakham Hospital between October 2025- Feburay 2026.

Inclusion criteria included patients aged 18 years or older who were diagnosed with symptomatic

gallstone disease and scheduled for elective laparoscopic cholecystectomy. Patients with gallbladder polyps or biliary colic requiring surgical treatment were also eligible for participation.

Exclusion criteria were patients who were unfit for surgery, had acute cholecystitis requiring emergency surgery, had a history of previous upper abdominal surgery, had suspected gallbladder malignancy, or could not tolerate general anesthesia.

A total of 70 patients were randomized equally into two groups: 35 in the two-dimensional laparoscopic cholecystectomy (2D LC) group and 35 in the three-dimensional laparoscopic cholecystectomy (3D LC) group.

Randomization and allocation concealment

Patients who met the eligibility criteria were randomly assigned in a 1:1 ratio to either the 2D or 3D laparoscopic cholecystectomy group using a computer-generated randomization sequence. Allocation concealment was ensured using sequentially numbered, sealed opaque envelopes that were opened immediately before surgery (Figure 1).

Consort flow diagram

A total of 70 patients were assessed for eligibility. All eligible patients were randomized into two groups: 35 patients were allocated to the two-dimensional laparoscopic cholecystectomy group and 35 patients to the three-dimensional laparoscopic cholecystectomy group. All patients received the allocated intervention, and no patients were lost to follow-up. All randomized patients were included in the final analysis (Figure 1).

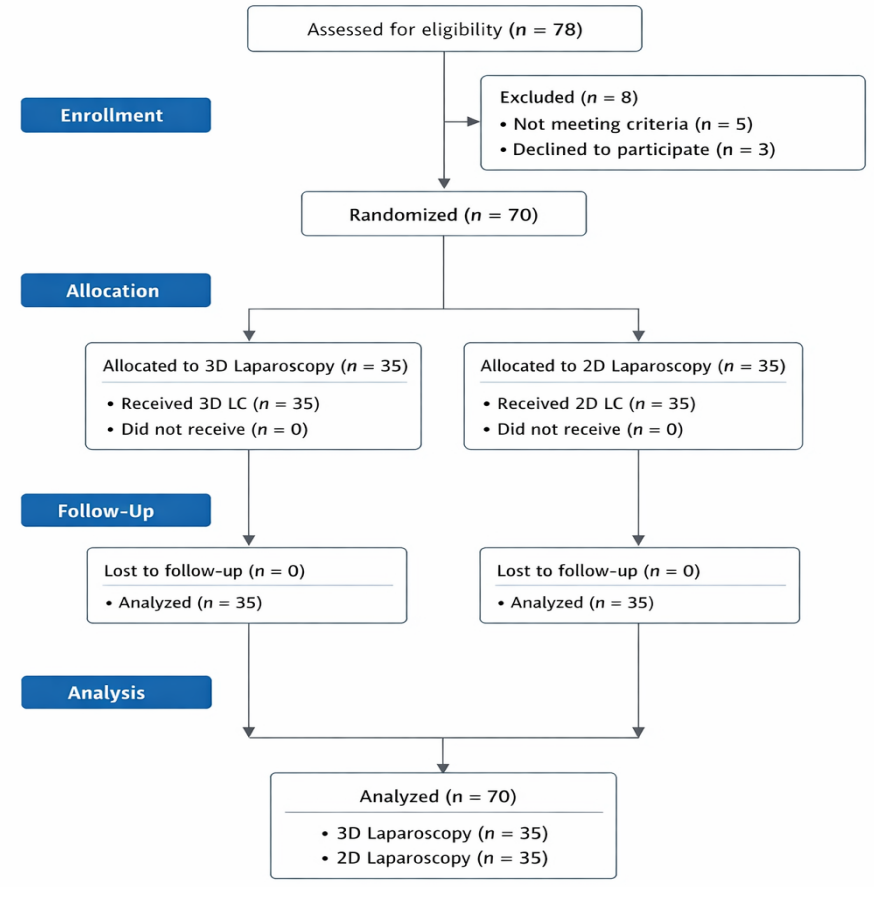


Figure 1 CONSORT flow diagram

Blinding

This study was conducted as a single-blind randomized controlled trial. Patients were blinded to group allocation, as they were not informed whether a three-dimensional or two-dimensional laparoscopic system was used during surgery. Postoperative outcome assessors, including ward nurses responsible for recording postoperative pain scores, were also blinded to group allocation. In addition, data analysts were blinded during statistical analysis to minimize potential bias.

Due to the nature of the intervention, blinding of the operating surgeon was not feasible. Blinding procedures were implemented to reduce performance and detection bias.

Study protocol

All patients underwent preoperative evaluation including physical examination, abdominal ultrasonography, and routine laboratory investigations. Prophylactic antibiotics were administered approximately 30 minutes before surgery. All procedures were performed under general anesthesia. Postoperative pain was evaluated using the visual analog scale (VAS). Patients received intravenous analgesics when the VAS score was ≥4. Oral intake was initiated on the first postoperative day, and patients were discharged when they were clinically stable and able to tolerate oral intake. Patients were followed during the postoperative hospital stay to evaluate early complications such as bleeding, bile leakage, wound infection, or conversion to open surgery. Clinical data were prospectively recorded to assess operative outcomes and postoperative complications.

Operation technique

All patients underwent laparoscopic cholecystectomy using the standard four-port technique under general anesthesia. Patients were placed in the supine reverse Trendelenburg position with slight left tilt to facilitate exposure of the gallbladder. Pneumoperitoneum was established using carbon dioxide insufflation to a pressure of approximately 12–14 mmHg. A 10-mm camera port was inserted at the umbilicus for a 30° laparoscope. Additional ports were placed in the epigastric region and right subcostal area according to the standard laparoscopic cholecystectomy configuration (Figure 2). The gallbladder was retracted superiorly to expose Calot's triangle. Careful dissection was performed to identify the cystic duct and cystic artery. The critical view of safety was achieved before clipping and dividing the cystic duct and cystic artery (Figure 3). In the 2D LC group, surgery was performed using a conventional two-dimensional laparoscopic imaging system (Olympus, Storz (Karl Storz), Medtronic). In the 3D LC group, surgery was performed using a three-dimensional laparoscopic imaging system (storz, Mindray), which provided stereoscopic visualization and improved depth perception. The gallbladder was dissected from the liver bed using electrocautery or an ultrasonic surgical device. After complete dissection, the gallbladder specimen was retrieved using a specimen retrieval bag through the umbilical port (Figure 4). Hemostasis was confirmed before completion of the procedure.

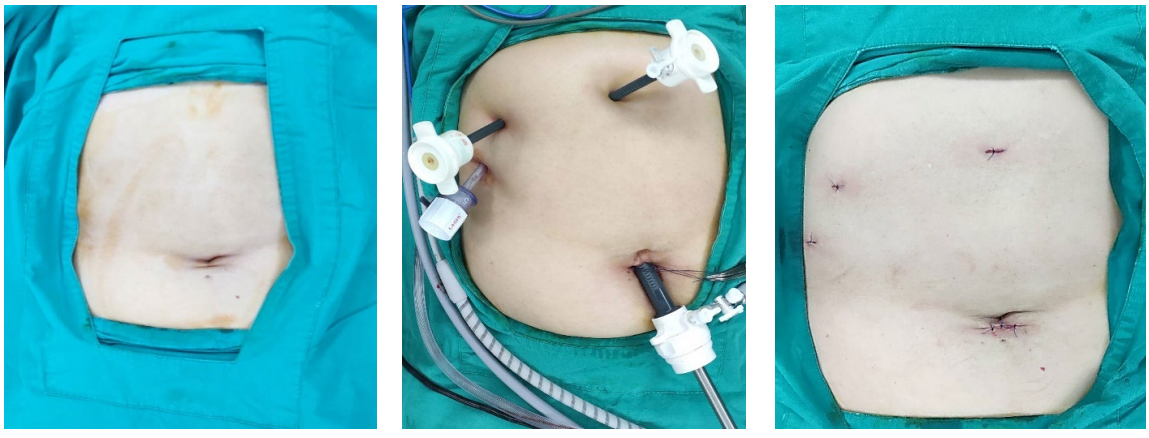


Figure 2 Standard four-port placement for laparoscopic cholecystectomy using a 10-mm umbilical camera port, a 10-mm epigastric working port, and two 5-mm right subcostal ports
(illustrated by the authors).

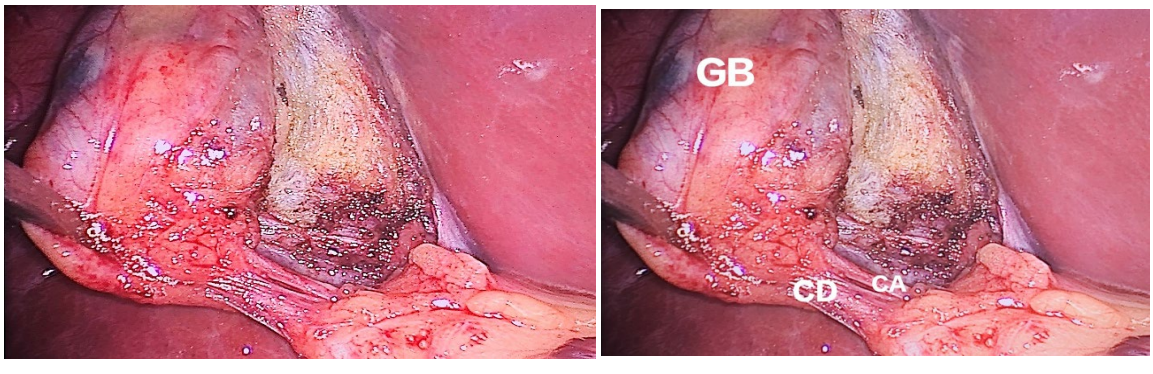


Figure 3 Critical view of safety demonstrating clear identification of the cystic duct (CD) and cystic artery (CA) after dissection of the lower gallbladder from the liver bed.

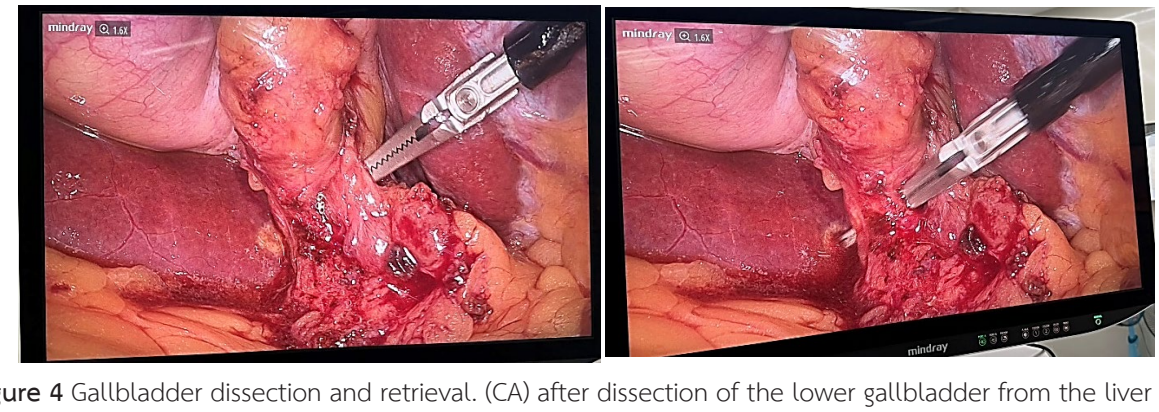


Figure 4 Gallbladder dissection and retrieval. (CA) after dissection of the lower gallbladder from the liver bed.

Outcomes

Data recorded for each patient included age, sex, body mass index (BMI), operative time, intraoperative blood loss, postoperative pain scores, length of hospital stay, and postoperative complications.

The primary outcomes were operative time and intraoperative blood loss. Operative time was defined as the time interval from skin incision to skin closure, measured in minutes. Intraoperative blood loss was estimated based on the volume of blood collected

in the suction canister after subtraction of irrigation fluid, combined with visual estimation of blood loss from surgical gauze and sponges.

The secondary outcomes included postoperative pain scores, length of hospital stay, surgeon difficulty score, image quality score, and postoperative complications.

Postoperative pain was assessed using the visual analog scale (VAS; 0–10), with higher scores indicating greater pain intensity. Postoperative pain scores were assessed at approximately 24 and 48 hours after surgery by ward nurses who were blinded to group allocation. The analgesic regimen was standardized for all patients, and intravenous analgesics were administered when the VAS score was ≥4.

Surgeon difficulty score was assessed using a 5-point Likert scale (1 = very easy, 5 = very difficult), reflecting the overall technical difficulty of the procedure, including depth perception, tissue dissection, hand–eye coordination, and anatomical identification during surgery. Image quality score was evaluated using a 5-point Likert scale (1 = very poor, 5 = excellent), based on clarity, depth perception, and visualization of anatomical structures. Both scores were evaluated immediately after completion of the procedure by the operating surgeon. Procedures were performed by eight experienced surgeons familiar with both 2D and 3D laparoscopic systems to ensure procedural consistency and reduce operator-related bias.

Postoperative complications included bile duct injury, postoperative bleeding, wound infection, conversion to open surgery, and readmission.

Statistical analysis

Data analysis was conducted using IBM SPSS Statistics 26. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Data normality was assessed using the Shapiro–Wilk test prior to statistical analysis. Continuous variables were compared using the independent t-test, and categorical variables were compared using the chi-square test or Fisher's exact test as appropriate. A $p < 0.05$ was considered statistically significant.

Results

Between October 2025 and February 2026, a total of 70 patients undergoing elective laparoscopic cholecystectomy were enrolled in this randomized controlled trial at Mahasarakham Hospital. All eligible patients were randomized equally into the two-dimensional laparoscopic cholecystectomy (2D LC) group or the three-dimensional laparoscopic cholecystectomy (3D LC) group, with 35 patients in each group. All randomized patients completed the study and were included in the final analysis.

Patient characteristics

The baseline clinical characteristics of the patients were comparable between the two groups. Females constituted the majority of patients in the 2D LC group, whereas the distribution of males and females was more balanced in the 3D LC group. Age distribution was approximately normal based on the Shapiro–Wilk test; therefore, age was presented as mean ± standard deviation. The mean age of patients was 50.69 ± 13.49 years in the 2D LC group and 48.14 ± 13.72 years in the 3D LC group. The age range was 25–83 years in the 2D group and 22–79 years in the 3D group.

Overall, the baseline demographic characteristics were similar between the two groups. A summary of the demographic data is presented in Table 1.

Table 1 Baseline demographic characteristics of patients

Characteristics	2D LC (n=35) n (%)	3D LC (n=35) n (%)	p-values
Male	11 (31.4)	18 (51.4)	
Female	24 (68.6)	17 (48.6)	0.145
Age (years) mean ± SD	50.69 ± 13.49	48.14 ± 13.72	0.437
Age range	25–83	22–79	
BMI (kg/m²) mean ± SD	22.77 ± 3.06	22.78 ± 3.78	0.99

Operative outcomes

Operative outcomes between the two groups are summarized in Table 2. The mean operative time was 43.94 ± 5.43 minutes in the 2D LC group and 41.83 ± 8.00 minutes in the 3D LC group (p = 0.201). The mean estimated intraoperative blood loss was 11.03 ± 5.57 mL in the 2D group and 9.69 ± 4.48 mL in the 3D group (p = 0.270). The mean surgeon difficulty score was 3.03 ± 0.86 in the 2D group and 2.77 ± 0.69 in the 3D group (p = 0.171), suggesting slightly easier operative conditions with the three-dimensional laparoscopic system.

The image quality score was significantly higher in the 3D LC group compared with the 2D LC group (p = 0.008), as evaluated by the operating surgeon, indicating superior visualization with the three-dimensional system.

Table 2 Operative outcomes

Operative outcomes	2D LC (n=35)	3D LC (n=35)	p-values
Operative time (min)	43.94 ± 5.43	41.83 ± 8.00	0.201
Blood loss (mL)	11.03 ± 5.57	9.69 ± 4.48	0.270
Surgeon difficulty score	3.03 ± 0.86	2.77 ± 0.69	0.171
Image quality score	4.09 ± 0.37	4.37 ± 0.49	0.008

Postoperative outcomes

Postoperative outcomes, including postoperative pain scores and length of hospital stay, are summarized in Table 3. Patients in the 3D LC group reported significantly lower pain scores compared with those in the 2D LC group. The mean pain score on postoperative day 1 was 4.00 ± 0.80 in the 2D group and 3.57 ± 0.65 in the 3D group (p = 0.017). Similarly, the mean pain score on postoperative day 2 was 1.80 ± 0.63 in the 2D group and 1.40 ± 0.50 in the 3D group (p = 0.005).

Table 3 Postoperative outcomes

Pain scores	2D LC (n=35)	3D LC (n=35)	p-values
Pain score POD1 (VAS)	4.00 ± 0.80	3.57 ± 0.65	0.017
Pain score POD2 (VAS)	1.80 ± 0.63	1.40 ± 0.50	0.005
Average VAS score	2.90 ± 0.72	2.49 ± 0.58	0.011
Length of hospital stay (days)	2.03 ± 0.17	2.00 ± 0.00	0.324

Postoperative complications

No major postoperative complications, including bile duct injury, postoperative bleeding, wound infection, or conversion to open surgery, were observed in either group.

Discussion

The present randomized controlled trial demonstrated that three-dimensional laparoscopic cholecystectomy provides improved visualization and significantly lower postoperative pain scores compared with conventional two-dimensional laparoscopy, while operative time, intraoperative blood loss, and surgeon difficulty scores were comparable between the two techniques. Previous randomized-controlled trials have reported similar findings. Koppatz et al. demonstrated that 3D laparoscopy improved surgical performance during laparoscopic cholecystectomy, although the reduction in operative time was modest [11]. Schwab et al. also reported improved visualization during dissection of Calot's triangle with 3D imaging but no significant difference in operative duration [12].

Recent systematic reviews and meta-analyses have further suggested that 3D imaging enhances depth perception and surgical precision while maintaining comparable operative outcomes and complication rates [8,9,13]. The results of the present study are consistent with these findings, demonstrating improved visualization and lower postoperative pain scores with the 3D system without increasing operative risk. Improved visualization may facilitate safer dissection of anatomical structures within Calot's triangle and may reduce unnecessary tissue manipulation during surgery.

Although patients and postoperative assessors were blinded to group allocation, complete blinding may not have been fully achievable because postoperative incision characteristics could potentially suggest the operative modality. Although postoperative pain scores were statistically lower in the 3D group, the absolute differences in VAS scores were relatively small and may not represent substantial clinical significance.

Importantly, no major complications or 30-day readmissions were observed in either group. The inclusion of both in-hospital and 30-day follow-up strengthens the validity of the safety outcomes and reduces the likelihood of underreporting delayed complications. These findings support the safety profile of both 2D and 3D laparoscopic systems when performed by experienced surgeons.

Limitations

The present study did not include a formal cost-effectiveness analysis between the 3D and 2D laparoscopic systems. Further studies evaluating the economic impact of 3D laparoscopy are warranted. Rescue analgesic consumption was not evaluated in the present study.

Conclusion

In conclusion, three-dimensional laparoscopic cholecystectomy may provide improved visualization and slightly lower postoperative pain scores compared with conventional two-dimensional laparoscopic cholecystectomy, while operative time and intraoperative blood loss remained comparable between the two techniques. Although no major complications were observed in either group, the present study was not powered to compare complication rates. These findings suggest that three-dimensional laparoscopic cholecystectomy may represent a useful alternative to conventional two-dimensional laparoscopic cholecystectomy in elective LC procedures. However, the clinical significance of the observed differences remains uncertain, and further multicenter studies with larger sample sizes are required to confirm these findings.

Conflict of Interest

The author(s) declare that there are no conflicts of interest.

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