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Original Research

Propofol versus Sevoflurane for Postoperative Pain following Open Cholecystectomy: A Randomised Controlled Trial

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ABSTRACT:

Postoperative pain (POP) remains a common challenge following open cholecystectomy (OC). In Libya, survey data report that more than 50% of patients experience significant pain within 24 hours, highlighting a critical need for improved analgesic strategies. As a key factor hindering recovery, effective pain management is essential. This randomized controlled trial evaluated whether propofol-based total intravenous anaesthesia (TIVA) reduces early POP compared to standard inhalational techniques in this population. A prospective, double-blind, randomised controlled trial enrolled 80 patients undergoing OC. POP intensity was quantified

by applying the numerical rating scale (NRS) at 2-, 6-, 12-, and 24-hour intervals following surgery. Statistical analyses were conducted with SPSS version 26. Between-group comparisons using independent t-tests and one-way ANOVA indicated that participants receiving propofol-based TIVA exhibited significantly reduced pain scores at 2, 6, and 12 hours postoperatively relative to the sevoflurane-based inhalational anaesthesia (IA) group ($p < 0.05$). However, no statistically significant intergroup difference was observed at the 24-hour assessment ($p > 0.05$). This pattern suggests that the analgesic advantage of propofol TIVA is predominantly evident during the immediate postoperative period. At 24 hours postoperatively, propofol TIVA did not confer superior analgesic efficacy compared with sevoflurane IA in patients undergoing OC. Consequently, these results do not endorse propofol TIVA as the preferred anaesthetic strategy for attenuating POP in this surgical context.

KEYWORDS: Propofol, Sevoflurane, Open Cholecystectomy, Postoperative Pain, Libya.

INTRODUCTION

Postoperative pain (POP) presents a substantial challenge in the recovery from surgical interventions such as open cholecystectomy (OC), with implications for both clinical management and patient well-being (Cole, 2019; Kumar & Reddy, 2021). Optimizing postoperative analgesia is therefore integral to promoting rapid recovery, reducing complications, and enhancing overall surgical outcomes (Mándi, Keleti, & Juhász, 2021). In the context of OC, pain is not only a predominant postoperative complaint but also a significant contributor to delayed convalescence and diminished patient satisfaction (Kumar & Reddy, 2021; Makhlouf, Algabaily, Hawil, & Albkouri, 2025). Additionally, interindividual variability in pain perception, shaped by physiological, psychological, and sociocultural factors, further complicates uniform management approaches (Gim, Lee, Lee, & Woo, 2024).

Inadequately controlled pain may exert long-term effects on healthcare engagement, eroding patient confidence and increasing apprehension toward future medical procedures (Mayer, Torma, Byock, & Norris, 2001; Twycross, 2002).

Enhanced perioperative analgesia could mitigate the reliance on interventions such as propofol-based TIVA and improve patients' overall procedural experience (Cole, 2019; Wong, Chan, Irwin, & Cheung, 2020). Regional data from Libya highlight a considerable burden of POP, with over one-third of surgical patients reporting discomfort and more than 50% experiencing significant pain within 24 hours after surgery (Makhlouf et al., 2025). These figures align with international reports indicating that nearly half of surgical patients endure moderate to severe pain in the first postoperative day (Vijayan, 2011), with OC particularly associated with high early POP prevalence globally (Cole, 2019; Sommer et al., 2008).

The intensity of POP is influenced by a constellation of factors, including demographic characteristics, ASA status, anaesthetic duration and technique, analgesia protocols, pre-existing pain conditions, and

postoperative complications (Yang et al., 2019). Adverse effects such as nausea, vomiting, and sedation can compound discomfort and hinder recovery (Gan, 2017). Consequently, early risk stratification and tailored pain management are vital to facilitating mobilization and preventing adverse sequelae (Ndebea et al., 2020; Schug & Bruce, 2017; Sobol-Kwapinska, Bąbel, Plotek, & Stelcer, 2016).

Two principal anaesthetic techniques are employed during open surgery: propofol-based TIVA and sevoflurane-based IA (Jones & Harris, 2021; Lin et al., 2015). Some evidence suggests that propofol TIVA may confer analgesic advantages over IA, including reduced postoperative opioid consumption (Cheng, Yeh, & Flood, 2008; Ji, Wang, Zhang, Liu, & Peng, 2018).

Additional benefits of propofol include lower rates of nausea and vomiting postoperatively, quicker emergence from anaesthesia, and enhanced psychomotor recovery (Absalom & Struys, 2019; Wong et al., 2020).

Nevertheless, the comparative analgesic efficacy of these techniques remains debated. While several studies report lower pain scores with propofol TIVA (Ji et al., 2018; Richebé & Brulotte, 2019; Wong, Choi, Lee, Irwin, & Cheung, 2018), others have found no significant difference relative to IA (Cole, 2019; Peng et al., 2016).

A recent systematic review noted a modest, though statistically significant, reduction in pain within 24 hours of surgery with propofol TIVA, an effect attenuated after adjusting for heterogeneity across studies (Qiu, Choi, Wong, Irwin, & Cheung, 2016).

Most existing evidence originates from high-income settings, with limited data from developing regions where differences in perioperative care, resource availability, and patient profiles may influence outcomes (Wong, Leung, & Cheung, 2019). To date, no study has examined the impact of propofol TIVA versus sevoflurane IA on postoperative pain following OC in Libya, underscoring a gap in context-specific evidence.

MATERIALS AND METHODS

Study Design and Settings

We conducted a prospective, randomized, double-blind controlled trial to compare postoperative pain outcomes following open cholecystectomy under two anaesthetic maintenance techniques: propofol-based total intravenous anaesthesia versus sevoflurane-based inhalational anaesthesia.

The study was carried out from January through June 2025 at Al Wadha Hospital in Dernah and Shahat Hospital, both located in Eastern Libya. Ethical approval was granted by the College of Medical Technology, Dernah (CMTD 01-025), and institutional permissions were secured prior to recruitment. The trial followed the CONSORT guidelines and adhered to the ethical principles outlined in the Declaration of Helsinki.

Participants

Eligibility criteria included adult patients aged 18 years or older who were scheduled for elective open cholecystectomy and classified as American Society of Anaesthesiologists (ASA) physical status I or II. All participants provided informed consent, either written or verbal, before enrolment.

Pain Assessment Tool

Postoperative pain intensity was assessed using an Arabic version of the Numerical Rating Scale (NRS). The scale was linguistically validated through a standardized back-translation process (Brislin, 1986). The NRS is a validated, reliable instrument for quantifying acute pain across different age groups and genders (Karcioglu, Topacoglu, Dikme, & Dikme, 2018; Williamson & Hoggart, 2005).

Pain was evaluated at 2, 6, 12, and 24 hours after surgery using the following severity categories: 0 (no pain), 1–3 (mild), 4–7 (moderate), and 8–10 (severe) (Breivik et al., 2008; Gerbershagen, Rothaug, Kalkman, & Meissner, 2011). Participants also rated the perceived usefulness of preoperative pain-related information on a 0–10 NRS. A trained research assistant collected all pain scores, documented analgesic use during the first 24 hours, and administered a brief demographic form requiring approximately five minutes to complete.

Anaesthetic Protocol

Intravenous access was established using an 18-gauge cannula, and all patients underwent continuous perioperative monitoring. Upon arrival in the operating theatre, baseline vital signs—including arterial oxygen saturation (SaO_2)—were recorded. Premedication consisted of intravenous atropine (0.5 mg/kg) and midazolam (0.03 mg/kg) administered 10 minutes before induction. Anaesthesia was induced with fentanyl (1.5 µg/kg), propofol (1.5 mg/kg), and rocuronium (0.5 mg/kg). Endotracheal intubation was performed within 90 seconds, followed by placement of an orogastric tube for gastric decompression.

Maintenance

TIVA group: Anaesthesia was maintained with a continuous propofol infusion (6 mg/kg/h, equivalent to 100 µg/kg/min) delivered with a 50% oxygen and 50% nitrous oxide mixture. IA group: Anaesthesia was maintained using 1.2% sevoflurane under the same gas mixture. Aesthetic concentrations were titrated to maintain hemodynamic parameters within ±15% of baseline values (propofol range: 50–150 µg/kg/min; sevoflurane range: 0.6–1.5%). To reduce postoperative opioid requirements, all incision sites were infiltrated with 0.25% bupivacaine (Sarac et al., 1996).

Approximately 15 minutes before the end of surgery, each patient received 8 mg of intravenous dexamethasone as prophylaxis against postoperative nausea and vomiting. Residual neuromuscular blockade was reversed using neostigmine (2.5 mg) and atropine (0.5 mg). Anaesthesia was discontinued upon the return of spontaneous respiration. Following oropharyngeal suctioning, extubation was performed once the patients demonstrated adequate responsiveness and sustained spontaneous breathing.

Recovery Assessment

Extubating time was defined as the interval from cessation of anaesthetic administration to endotracheal tube removal (Erk et al., 2005). Eye-opening time in response to verbal command was recorded as an indicator of early recovery. Ventilation was supported using a reservoir bag set to approximately six times the patient's tidal volume (500–600 mL), accommodating both spontaneous and controlled breathing (Habrat, 2025).

Oxygen saturation (SpO_2) was categorized as <90%, 90–94%, or >95%. Consciousness was

evaluated based on responsiveness and the ability to follow simple commands. Recovery was assessed every 10 minutes during the first 30 minutes post-anaesthesia by a blinded anaesthesia resident unaware of group assignment. Full recovery was confirmed by the patient's ability to correctly state personal identification details (name, date of birth, and address).

Statistical Analysis

The primary hypothesis that propofol TIVA would provide superior postoperative analgesia compared to sevoflurane IA was tested using inferential statistics. The null hypothesis (H_0) posited no difference in pain reduction between groups, while the alternative hypothesis (H_1) specified better pain control with TIVA. The significance threshold was set at $\alpha = 0.05$ (two-tailed).

A p-value below 0.05 was considered statistically significant, warranting rejection of H_0. A consulting statistician reviewed the analysis plan before study initiation.

Descriptive statistics summarized demographic and clinical variables, including age, sex, marital status, ASA classification, education level, anaesthetic group, chronic pain history, and analgesic use. Categorical data are presented as frequencies and percentages; continuous variables as means ± standard deviation and ranges.

Between-group differences in pain scores were analysed using independent t-tests and one-way analysis of variance (ANOVA). Changes in pain scores over time were evaluated using a one-way repeated-measures ANOVA. Normality of distribution was assessed with the Kolmogorov–Smirnov test. All analyses were conducted using SPSS version 26.

RESULTS AND DISCUSSION

Participant Characteristics

Figure 1 illustrates the CONSORT flow of participants through the trial. Of 100 patients assessed for eligibility, 90 met the inclusion criteria and were randomized to TIVA (n=45) or IA (n=45). Following exclusions, 80 participants (40 per group) completed the study protocol and were included in the final analysis. Demographic and clinical characteristics are detailed in Table 1. The overall mean age was 31.0 years (SD=1.0, range 18–68), with 58.7% female participants. ASA physical status distribution was 57.5% Grade I and 37.5% Grade II. Groups were well-balanced across demographic variables.

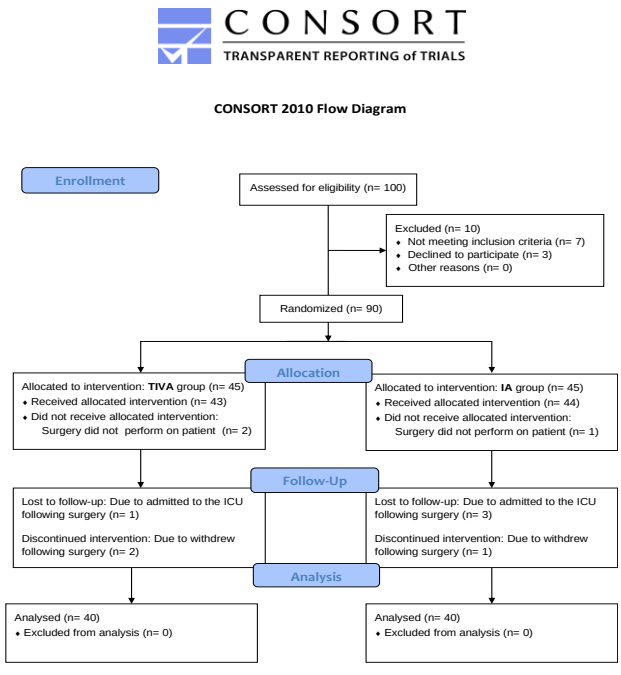

Figure: (1) CONSORT flow diagram for the study.

Table:(1) Participant demographic and clinical characteristics (n=80)

Characteristic	TIVA group (n = 40)	IA group (n = 40)	Total (n = 80)
Gender; n (%):			
Male	14 (35)	19 (47.5)	33 (41.3)
Female	26 (65)	21 (52.5)	47 (58.7)
Age (years); n (%)			
18–28	7 (17.5)	9 (22.5)	16 (20)
29–39	8 (20)	12 (30)	20 (25)
40–50	12 (30)	10 (25)	22 (27.5)
51–61	8 (20)	5 (12.5)	13 (16.3)
≥ 68	5 (12.5)	4 (10)	9 (11.3)
Marital status; n (%):			
Single	9 (22.5)	6 (13.3)	15 (18.8)
Married	21 (52.5)	19 (47.5)	40 (50)
Divorced	4 (10)	7 (17.5)	11 (13.8)
Widowed	6 (15)	8 (20)	14 (17.5)
Education; n (%):			
Elementary	7 (17.5)	6 (13.3)	13 (16.3)
Intermediate	20 (50)	21 (52.5)	41 (51.3)
Undergraduate degree	9 (22.5)	8 (20)	17 (21.3)
Postgraduate degree	4 (10)	5 (12.5)	9 (11.3)
Annually Salary; n (%):			
Monthly salary (LYD)	23 (57.5)	27 (67.5)	50 (62.5)
No income	17 (42.5)	13 (32.5)	30 (37.5)
ASA score; n (%):			
1	22 (55)	24 (60)	46 (57.5)
2	18 (45)	16 (40)	34 (42.5)
Type of Anaesthesia; n (%):			
Inhalational anaesthesia:			
Sevoflurane	0 (0.0)	40 (100)	40 (50)
Intravenous anaesthesia:			
Propofol	40 (100)	0 (0.0)	40 (50)
History of chronic pain; n (%):			
Yes	25 (62.5)	22 (55)	47 (58.8)
No	15 (37.5)	18 (45)	33 (41.2)
Medication for pain; n (%):			
Non-opioids only	18 (45)	21 (52.5)	39 (48.8)
Weak opioids only	8 (20)	6 (16.7)	14 (17.5)
Non-opioids and Weak opioids	9 (22.5)	8 (20)	17 (21.3)
Non-opioids and Strong opioids	2 (5.0)	3 (7.5)	5 (6.3)
Multimodal therapy	3 (7.5)	2 (27)	5 (6.3)

SD = Standard Deviation; n = number; % = percentage; < = less than; > = greater than; ASA = American Society of Anaesthesiologists; LYD = Libyan Dinar; TIVA = Total Intra-Venous Anaesthesia; IA = Inhalational Anaesthesia

Postoperative Pain Scores

Table 2 presents mean pain scores across assessment timepoints. Patients receiving propofol TIVA reported significantly lower pain at 2 hours (4.3 ± 0.8 vs 4.8 ± 0.8, $p < 0.05$), 6 hours (3.2 ± 0.6 vs 3.4 ± 0.7, $p < 0.05$), and 12 hours (2.4 ± 0.5 vs 2.7 ± 0.6, $p < 0.05$) postoperatively compared to the IA group. However, no significant between-group difference emerged at 24 hours (1.5 ± 0.3 vs 1.7 ± 0.4, $p > 0.05$).

Table:(2). Postoperative pain scores across assessment timepoints

Outcome Measure	TIVA (Mean ± SD)	IA (Mean ± SD)	Test Statistic	p-value	Partial η²
Overall Mean Pain (24 h)	5.2 ± 1.5	5.5 ± 0.96	$F(1,57) = 2.21$	> 0.05	0.037
Pain Reduction Over Time	—	—	$F(2.92,166.63) = 32.52$	< 0.001	0.363
Interaction Effect (Time × Group)	—	—	F = (reported value)	< 0.001	0.170

Statistical Effects

Repeated-measures ANOVA revealed a significant main effect of time ($F[2.92,166.63] = 32.52$, $p < 0.001$, partial $\eta^2 = 0.363$), reflecting the expected decline in pain intensity during the first postoperative day. The interaction between time and anaesthetic group was statistically significant ($F[2.92,166.63] = 11.668$, $p < 0.001$, partial $\eta^2 = 0.170$), indicating different pain reduction trajectories between TIVA and IA groups (Figure 2).

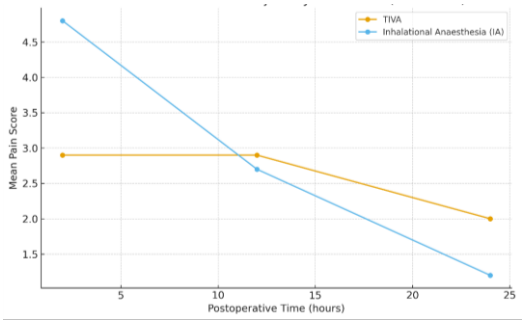

Figure: (2). Interaction Effect: Pain Trajectory Over Time (TIVA VS IA)

Comparative Analysis

When contrasted with data from a comparable Iranian cohort, Libyan patients in our study reported higher mean pain scores at every postoperative assessment point (2, 6, 12, and 24 hours), irrespective of anaesthetic technique employed (Table 3).

Table:(3). Comparative pain scores: Libyan versus Iranian patients

Time (hours)	Group	Libyan Mean ± SD (n=40 for TIVA, n=40 for IA)	Iranian Mean ± SD (n=55 for TIVA, n=67 for IA)
2h	TIVA	3.4 ± 0.8	3.2 ± 1.5
	IA	4.8 ± 0.8	3.3 ± 1.3
6h	TIVA	3.2 ± 0.6	2.4 ± 1.7
	IA	3.5 ± 0.7	2.5 ± 1.8
12h	TIVA	2.2 ± 0.5	2.1 ± 1.2
	IA	2.7 ± 0.6	2.3 ± 1.1
24h	TIVA	1.5 ± 0.3	0.9 ± 1.2
	IA	1.7 ± 0.4	1.1 ± 1.1

This randomized controlled trial represents the first investigation comparing propofol-based TIVA versus sevoflurane-based IA for postoperative pain management in Libyan patients undergoing open cholecystectomy. Our principal finding indicates that while TIVA provides superior analgesia during the initial 12 postoperative hours, this advantage diminishes and becomes non-significant by 24 hours.

The observed early analgesic benefit of propofol TIVA aligns with several previous investigations. Lin et al. (2015) reported that patients anesthetized with propofol experienced less postoperative pain than those receiving isoflurane, while Goswami, Babbar, and Tiwari (2015) documented reduced pain scores and opioid consumption with propofol compared to sevoflurane. The mechanisms underlying this effect may involve propofol's anti-inflammatory properties (Wong et al., 2020) or differential modulation of nociceptive pathways compared to volatile agents (Richebé & Brulotte, 2019).

Conversely, our finding of equivalent pain scores at 24 hours corresponds with other studies reporting no significant long-term differences between anaesthetic techniques. Ortiz et al. (2014) found comparable pain outcomes between propofol and sevoflurane groups following laparoscopic cholecystectomy, while Peng et al. (2016), in a meta-analysis of 24 trials, concluded that any analgesic benefits of propofol were modest and time-limited.

The significant time versus group interaction identified in our analysis suggests distinct pain reduction trajectories between techniques. Patients receiving TIVA experienced more rapid initial pain relief but demonstrated a slower continuing decline, whereas IA patients showed more gradual initial improvement but ultimately achieved comparable or slightly better pain control by 24 hours. This pattern may reflect differences in drug pharmacokinetics, with propofol's shorter context-sensitive half-time potentially contributing to its early advantage (Absalom & Struys, 2019).

Notably, Libyan patients in our cohort reported higher pain scores compared to Iranian patients undergoing similar procedures, regardless of anaesthetic technique. This disparity may reflect cultural variations in pain expression, differences in perioperative analgesic protocols, or healthcare system factors affecting pain management. Previous research has documented considerable cross-cultural variation in pain reporting and management, highlighting the importance of context-specific evidence (Vijayan, 2011).

Several limitations warrant consideration. First, recruitment from Eastern Libyan hospitals may limit generalizability to other regions with potentially differing patient populations or clinical practices. Second, although our sample size was adequate to detect the primary early analgesic effects, it fell below the estimated requirement for identifying more subtle long-term differences. Third, while we controlled for several potential confounders, unmeasured variables such as surgical technique variations or individual pain sensitivity thresholds may have influenced outcomes.

Our findings have practical implications for anaesthesia practice in resource-limited settings. While propofol TIVA may be preferred when early postoperative pain control is paramount, sevoflurane IA represents an equally effective alternative for long-term pain

management. The choice between techniques can therefore incorporate factors beyond analgesic efficacy, including drug availability, cost considerations, and institutional preferences, provided both are implemented within standardized multimodal analgesic protocols.

Future research should address several unanswered questions. Larger, multicentre trials across diverse Libyan regions would enhance generalizability and statistical power. Investigations comparing different propofol infusion regimens or sevoflurane concentrations might identify optimized protocols. Additionally, studies examining the integration of regional anaesthesia techniques or enhanced recovery protocols with different anaesthetic maintenance strategies could further improve postoperative pain management in this population.

CONCLUSION

Propofol-based total intravenous anaesthesia provides superior analgesia during the first 12 hours following open cholecystectomy compared to sevoflurane-based inhalational anaesthesia in Libyan patients. However, this early advantage does not translate into sustained benefits beyond 24 hours postoperatively.

Both anaesthetic techniques demonstrate comparable efficacy for long-term pain management when implemented within comprehensive multimodal analgesic regimens. These findings support clinical decision-making based on factors including resource availability, patient characteristics, and institutional protocols rather than presumed superior analgesic properties of either technique.

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ETHICS

This study received ethical approval from the College of Medical Technology, Derna, Libya (Reference: CMTD 01-025) on January 5, 2025.

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الملخص

لا يزال الألم التالي للجراحة يمثل تحديًا شائعًا بعد استئصال المرارة المفتوح. في ليبيا، تشير بيانات المسح إلى أن أكثر من 50% من المرضى يعانون من ألم شديد خلال 24 ساعة، مما يُبرز الحاجة الماسة إلى استراتيجيات مُحسّنة لتسكين الألم. ونظرًا لأن الألم عامل رئيسي يُعيق التعافي، فإن الإدارة الفعّالة له ضرورية. قيّمت هذه التجربة السريرية العشوائية المضبوطة ما إذا كان التخدير الوريدي الكلي القائم على البروبوفول يُقلل من الألم التالي للجراحة في وقت مبكر مقارنةً بتقنيات التخدير الاستنشاقي القياسية لدى هذه الفئة من المرضى. شملت هذه التجربة السريرية العشوائية المضبوطة، ذات التصميم المستقبلي والمزدوج التعمية، 80 مريضًا خضعوا لاستئصال المرارة المفتوح. تم قياس شدة الألم التالي للجراحة باستخدام مقياس التقييم العددي (NRS) على فترات زمنية قدرها 2 و6 و12 و24 ساعة بعد الجراحة. أُجريت التحليلات الإحصائية باستخدام برنامج SPSS الإصدار 26. وأظهرت المقارنات بين المجموعات، باستخدام اختبارات t المستقلة وتحليل التباين أحادي الاتجاه (ANOVA)، انخفاضًا ملحوظًا في درجات الألم لدى المشاركين الذين تلقوا التخدير الوريدي الكلي (TIVA) القائم على البروبوفول بعد ساعتين وست ساعات واثنتي عشرة ساعة من الجراحة، مقارنةً بمجموعة التخدير الاستنشاقي القائم على السيفوفلوران ($p < 0.05$). مع ذلك، لم يُلاحظ أي فرق ذي دلالة إحصائية بين المجموعات عند التقييم بعد 24 ساعة ($p > 0.05$). يشير هذا النمط إلى أن الميزة المسكنة للتخدير الوريدي الكلي بالبروبوفول تظهر بشكل أساسي خلال الفترة التالية للجراحة مباشرةً. بعد 24 ساعة من الجراحة، لم يُظهر التخدير الوريدي الكلي بالبروبوفول فعالية مسكنة أفضل مقارنةً بالتخدير الاستنشاقي القائم على السيفوفلوران لدى المرضى الذين خضعوا لعملية استئصال المبيض. وبالتالي، لا تدعم هذه النتائج استخدام التخدير الوريدي الكلي بالبروبوفول كاستراتيجية التخدير المُفضلة لتخفيف الألم بعد العملية الجراحية في هذا السياق الجراحي.

الكلمات المفتاحية: بروبوفول سيفوفلوران، استئصال المرارة المفتوح، ألم ما بعد الجراحة، ليبيا.