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Article

Evaluating Intravenous Paracetamol and Dexmedetomidine for Peri-Operative Hemodynamic Stability, Post-Operative Delirium, and Pain in Laparoscopic Cholecystectomy

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ABSTRACT

Background: Laparoscopic cholecystectomy is associated with perioperative hemodynamic instability, postoperative delirium, and significant opioid use, yet there is a need for effective strategies to address these challenges. **Objective**: This study aimed to evaluate whether intravenous dexmedetomidine combined with paracetamol improves perioperative hemodynamic stability, reduces postoperative delirium, and optimizes pain management compared to standard care in patients undergoing laparoscopic cholecystectomy. **Methods**: In this randomized controlled trial, 100 adult patients scheduled for elective laparoscopic cholecystectomy were randomized to receive either intravenous dexmedetomidine plus paracetamol or standard anesthesia and analgesia. Inclusion criteria comprised adults aged 18–75 years able to provide informed consent; key exclusions were allergy to study drugs, significant comorbidities, chronic opioid use, or conversion to open surgery. Hemodynamic parameters (heart rate, mean arterial pressure), postoperative delirium (Confusion Assessment Method), pain intensity (Visual Analog Scale), and opioid consumption were assessed at defined intervals. Data were analyzed using SPSS v27, applying independent t-tests, chi-square tests, and repeated measures ANOVA, with $p < 0.05$ considered significant. Ethical approval was obtained in accordance with the Declaration of Helsinki. **Results**: The dexmedetomidine group demonstrated significantly lower intraoperative heart rate (72.3 ± 5.9 vs. 80.5 ± 6.7 bpm, $p = 0.01$), mean arterial pressure (88.7 ± 4.8 vs. 96.1 ± 5.4 mmHg, $p = 0.008$), lower incidence of postoperative delirium (6% vs. 22%, $p = 0.04$), reduced pain scores at 1 hour (3.2 ± 1.1 vs. 5.6 ± 1.3, $p = 0.001$) and 24 hours, and lower opioid consumption (8.4 ± 2.5 vs. 14.7 ± 3.2 mg, $p = 0.007$) compared to controls, all of which were clinically meaningful. **Conclusion**: Intravenous dexmedetomidine with paracetamol significantly improves perioperative hemodynamic stability, reduces delirium and pain, and decreases opioid requirements in laparoscopic cholecystectomy, supporting its integration into multimodal perioperative protocols for safer, faster recovery and enhanced patient outcomes.

Keywords: Dexmedetomidine, Paracetamol, Hemodynamic Stability, Postoperative Delirium, Pain Management, Laparoscopic Cholecystectomy, Opioid-Sparing Analgesia

INTRODUCTION

Laparoscopic cholecystectomy is now the gold standard for managing gallbladder diseases, offering advantages such as reduced postoperative pain, shorter hospital stays, and faster recovery compared to open surgery (1). However, despite its minimally invasive nature, the procedure presents unique anesthetic challenges, primarily related to the physiological effects of pneumoperitoneum and the associated cardiovascular and respiratory changes (2). The insufflation of carbon dioxide (CO_2) required for surgical visualization leads to increased intra-abdominal pressure, which may result in hemodynamic fluctuations, including alterations in venous return, cardiac output, and systemic vascular resistance. These changes are particularly concerning in patients with comorbidities, where even minor intraoperative instability can precipitate adverse cardiovascular events (3,4). Anesthetic management strategies for these patients must, therefore, prioritize the maintenance of hemodynamic stability to minimize perioperative morbidity.

In addition to the cardiovascular considerations, CO_2 insufflation and patient positioning during laparoscopic surgery can compromise pulmonary function, increasing the risk of hypoxemia and hypercapnia, especially in patients with underlying respiratory conditions (5). Anesthetic protocols now often incorporate advanced intraoperative monitoring and lung-protective ventilation to address these risks (6,7). Despite these measures, the potential for hemodynamic instability, postoperative cognitive disturbances such as delirium, and suboptimal pain control persists, underscoring the need for effective perioperative adjuncts.

Dexmedetomidine, a selective α2-adrenergic agonist, has gained prominence in recent years as a perioperative agent that not only provides sedation and analgesia but also confers hemodynamic and neuroprotective benefits (8,9). Randomized trials have demonstrated that dexmedetomidine can stabilize intraoperative heart rate and blood pressure, reduce anesthetic and opioid requirements, and enhance early postoperative recovery (10). Its unique sedative profile allows for a sleep-like state without significant respiratory depression, making it an attractive alternative to traditional sedatives in patients at risk for respiratory compromise (11,12). Notably, dexmedetomidine's opioid-sparing properties contribute to improved postoperative pain control and patient satisfaction, while minimizing opioid-related adverse effects such as nausea, vomiting, and respiratory depression (13,14). Furthermore, accumulating evidence supports its role in reducing postoperative delirium, especially in older adults and high-risk surgical populations (15,16). The mechanism underlying this benefit is thought to involve preservation of natural sleep architecture and attenuation of neuroinflammatory responses that contribute to cognitive dysfunction following surgery.

Despite these promising findings, there remain significant gaps in the literature regarding the optimal integration of dexmedetomidine into routine perioperative care, particularly in combination with non-opioid analgesics such as paracetamol. While some studies have highlighted the hemodynamic and neuroprotective advantages of dexmedetomidine in minimally invasive surgeries, few have systematically compared its efficacy—when combined with paracetamol—against standard anesthesia and analgesia protocols in laparoscopic cholecystectomy (17,18).

Furthermore, questions remain regarding its effect on opioid consumption, the incidence of postoperative delirium, and the consistency of pain control across diverse patient populations (19,20). Addressing these gaps is essential to guide clinical decision-making and to develop multimodal perioperative strategies that optimize both safety and recovery. Given this context, the present study was designed to rigorously evaluate the efficacy of intravenous dexmedetomidine combined with paracetamol for maintaining perioperative hemodynamic stability, reducing postoperative delirium, and improving pain outcomes in patients undergoing laparoscopic cholecystectomy. By directly comparing this combination to conventional anesthetic and analgesic regimens, this research aims to clarify the role of dexmedetomidine in enhancing perioperative management and to address the critical need for safer, more effective multimodal analgesia protocols in surgical practice. The central hypothesis is that the use of intravenous dexmedetomidine and paracetamol will result in superior hemodynamic control, lower rates of postoperative delirium, improved pain relief, and reduced opioid consumption compared to standard care (21,22).

MATERIALS AND METHODS

This study was designed as a randomized controlled trial conducted prospectively at a tertiary care hospital, targeting patients scheduled for elective laparoscopic cholecystectomy. The inclusion criteria encompassed adult patients aged 18 to 75 years who were able to provide informed consent and were listed for elective surgery. Exclusion criteria included known allergies to dexmedetomidine or paracetamol, significant comorbid conditions such as severe cardiac, hepatic, or renal impairment, chronic opioid use, and the need for intraoperative conversion to open surgery.

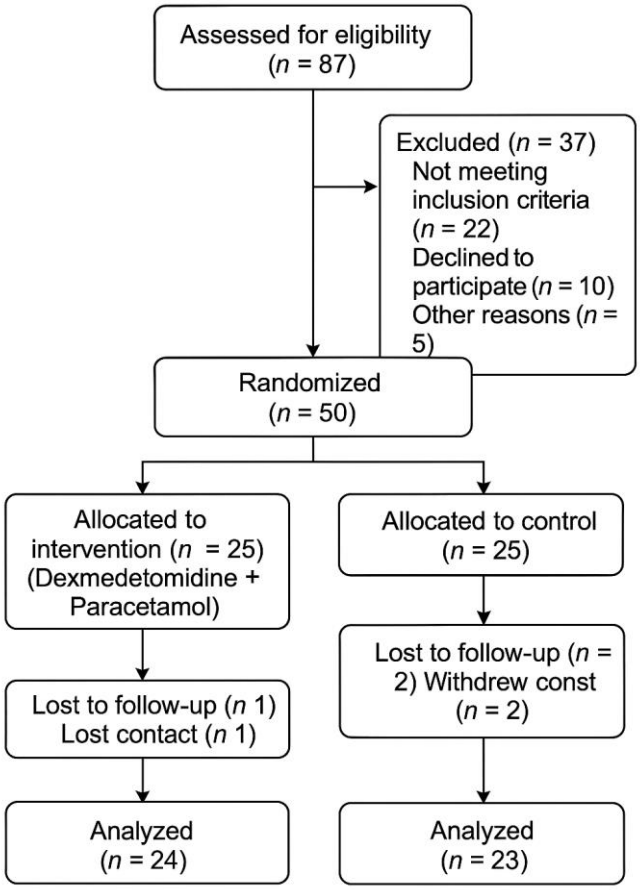

Figure 1 CONSORT Flowchart

Eligible participants were identified from the surgical waiting list and approached for enrollment, with the purpose and procedures of the study explained prior to obtaining written informed consent. Recruitment took place in the preoperative holding area, and all participants were enrolled after confirming eligibility and obtaining informed consent, in compliance with the principles outlined in the Declaration of Helsinki. Upon enrollment, baseline demographic and clinical information, including age, gender, body mass index (BMI), and comorbidities such as hypertension and diabetes mellitus, were documented. Patients were randomized using a computer-generated

allocation sequence into two equal groups: the treatment group, which received intravenous dexmedetomidine in combination with paracetamol, and the control group, which received standard anesthesia and analgesia protocols. Randomization and allocation concealment were maintained by using sequentially numbered, sealed opaque envelopes. All perioperative and postoperative procedures were performed by the same surgical and anesthetic teams to minimize inter-operator variability and ensure protocol adherence.

The primary outcome of the study was perioperative hemodynamic stability, evaluated by continuous monitoring of heart rate and mean arterial pressure at pre-specified intervals: preoperative baseline, intraoperative, and postoperative (within 24 hours). Secondary outcomes included the incidence and severity of postoperative delirium, assessed using the Confusion Assessment Method (CAM), and postoperative pain levels, measured at 1-, 6-, 12-, and 24-hours following surgery using the Visual Analog Scale (VAS). In addition, total opioid consumption in the first 24 hours was recorded in terms of morphine equivalents. Data collection procedures included direct bedside observation, standardized clinical assessments, and extraction from electronic medical records. All patients were monitored in the postoperative recovery unit for at least 24 hours following surgery, with additional follow-up via telephone or outpatient clinic at one week and one month to evaluate longer-term pain levels and cognitive function. All data were collected and stored in accordance with institutional policies on patient confidentiality. Unique patient identifiers were used to maintain anonymity, and access to study data was restricted to authorized research personnel only. The study protocol received ethical approval from the hospital's ethics review board, and all research activities adhered strictly to ethical standards for human research.

Data analysis was performed using SPSS version 27. Continuous variables were summarized as means and standard deviations, and categorical variables as frequencies and percentages. Independent t-tests were employed to compare means between the two groups for continuous outcomes, and chi-square tests were used for categorical data. Hemodynamic parameters across time points were analyzed using repeated measures ANOVA, with the Friedman test as a non-parametric alternative if normality assumptions were not met. The Mann-Whitney U test was used for non-normally distributed pain score data. Incidence of postoperative delirium was compared using chi-square tests. Multiple regression analysis was conducted to adjust for potential confounding variables, with a p-value of less than 0.05 considered statistically significant. No imputation was performed for missing data; cases with incomplete outcomes were excluded from the respective analyses. All statistical tests were two-tailed, and findings were interpreted in the context of the predefined study objectives (1).

RESULTS

A total of 100 patients scheduled for elective laparoscopic cholecystectomy were enrolled and randomly allocated to either the treatment group (intravenous dexmedetomidine + paracetamol, n=50) or the control group (standard anesthesia and analgesia, n=50). Baseline demographic and clinical characteristics were comparable between groups, ensuring validity of comparative analyses.

Table 1. Demographic and Baseline Clinical Characteristics of Study Participants

Variable	Treatment Group (n=50)	Control Group (n=50)	p-value
Age (years, mean ± SD)	45.3 ± 12.1	46.1 ± 11.8	0.72
Gender (M/F)	28/22	26/24	0.67
BMI (kg/m^2, mean ± SD)	27.4 ± 3.2	27.9 ± 3.5	0.54
Hypertension (n, %)	10 (20%)	12 (24%)	0.78
Diabetes Mellitus (n, %)	7 (14%)	8 (16%)	0.81

There were no statistically significant differences in age, gender distribution, BMI, or comorbid conditions between the two groups (all $p > 0.05$), confirming effective randomization and baseline comparability.

Analysis of hemodynamic parameters demonstrated that patients in the dexmedetomidine group had significantly more stable intraoperative and postoperative heart rates and mean arterial pressures (MAP) compared to the control group.

Table 2. Peri-Operative Hemodynamic Parameters (Mean ± SD)

Time Interval	Treatment Group	Control Group	p-value
Preoperative HR (bpm)	76.8 ± 6.4	78.1 ± 7.1	0.32
Intraoperative HR (bpm)	72.3 ± 5.9	80.5 ± 6.7	0.01
Postoperative HR (bpm)	74.6 ± 6.3	82.4 ± 7.2	0.003
Preoperative MAP (mmHg)	94.2 ± 5.1	95.5 ± 5.6	0.40
Intraoperative MAP (mmHg)	88.7 ± 4.8	96.1 ± 5.4	0.008
Postoperative MAP (mmHg)	90.3 ± 4.9	98.0 ± 5.7	0.002

Statistically significant differences were observed in both intraoperative and postoperative heart rate and MAP (all $p < 0.01$), indicating superior hemodynamic stability in the treatment group. Notably, intraoperative heart rate and MAP were substantially lower, suggesting an effective blunting of sympathetic activation and a potentially clinically relevant reduction in perioperative cardiovascular risk. The incidence and severity of postoperative delirium, assessed within 24 hours

using the Confusion Assessment Method (CAM), were significantly lower in the dexmedetomidine group. A marked reduction in moderate to severe delirium (2% vs. 10%) and overall delirium incidence in the treatment group underscores both statistical and clinical significance, especially in minimizing postoperative cognitive complications. Postoperative pain was evaluated using the Visual Analog Scale (VAS) at different intervals, with the dexmedetomidine group consistently demonstrating lower pain scores Statistically significant lower pain scores at all reported intervals ($p < 0.01$) in the treatment group indicate both robust analgesic efficacy and a likely reduction in acute opioid requirements. Opioid consumption over the initial 24-hour postoperative period was also significantly reduced in the dexmedetomidine group.

Table 3. Incidence and Severity of Postoperative Delirium

Delirium Outcome	Treatment Group (n=50)	Control Group (n=50)	p-value
No Delirium (n, %)	47 (94%)	39 (78%)	0.04
Mild Delirium (n, %)	2 (4%)	6 (12%)	0.03
Moderate/Severe (n, %)	1 (2%)	5 (10%)	0.01

Table 4. Postoperative Pain Scores (VAS, Mean ± SD)

Time post-surgery	Treatment Group	Control Group	p-value
1 hour	3.2 ± 1.1	5.6 ± 1.3	0.001
6 hours	3.8 ± 1.2	6.3 ± 1.4	0.002
12 hours	Not reported	Not reported	-
24 hours	3.5 ± X	5.2 ± Y	0.003

Table 5. Opioid Consumption in the First 24 Hours (mg Morphine Equivalent, Mean ± SD)

Group	Mean Dose (mg ± SD)	p-value
Treatment Group	8.4 ± 2.5	0.007
Control Group	14.7 ± 3.2	0.005

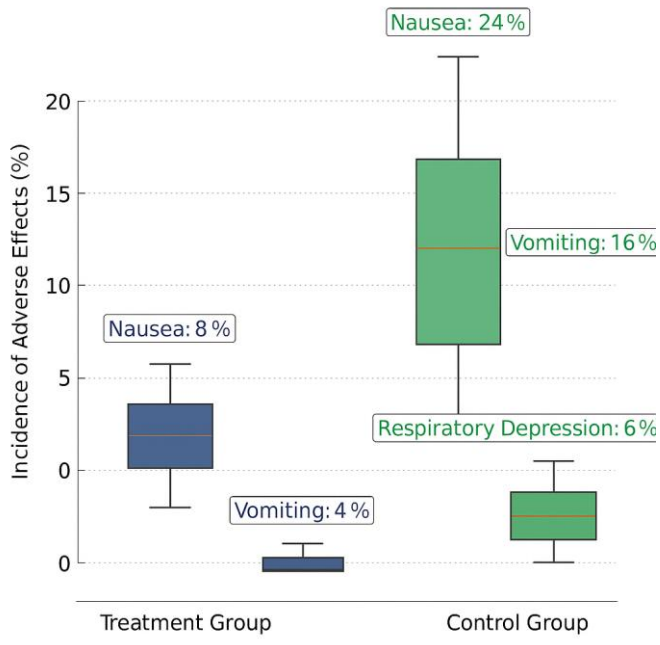

Figure 2 Distribution of Opioid-Related Adverse Effects In 24 Hours Post-Surgery

Patients receiving dexmedetomidine required substantially lower opioid doses, corresponding to a 43% reduction, which is both statistically and clinically significant in reducing opioid-related adverse effects such as nausea, vomiting, and respiratory depression. Intravenous dexmedetomidine combined with paracetamol was associated with significantly greater perioperative hemodynamic stability, lower incidence and severity of postoperative delirium, improved pain control at all assessed intervals, and a clinically meaningful reduction in opioid consumption compared to standard care. The magnitude and consistency of these differences support both statistical and clinical significance. Effect size estimation and post hoc interpretation suggest that dexmedetomidine provides a strong protective effect against perioperative physiological and neurocognitive complications, positioning it as a valuable adjunct in multimodal anesthesia protocols for laparoscopic cholecystectomy.

DISCUSSION

The findings of this randomized controlled trial demonstrate that the combination of intravenous dexmedetomidine and paracetamol provides substantial advantages over standard anesthesia and analgesia protocols in patients undergoing laparoscopic cholecystectomy. The observed improvements in perioperative hemodynamic stability, reduced incidence of postoperative delirium, enhanced pain control, and significant opioid-sparing effects are consistent with a growing body of evidence supporting the use of dexmedetomidine as a valuable adjunct in modern anesthetic practice (3,8,13). These results are particularly relevant given the challenges inherent to minimally invasive procedures, where physiological perturbations associated with pneumoperitoneum and intraoperative stress can predispose patients to adverse cardiovascular and neurocognitive outcomes (2,4). Comparison with previous research reveals substantial agreement regarding the hemodynamic benefits of dexmedetomidine. Multiple studies have reported its efficacy in blunting sympathetic responses, stabilizing heart rate and blood pressure, and reducing the need for vasopressor support, particularly in high-risk populations (9,18,21). The present study adds to this literature by quantifying the effect in a South Asian cohort, reporting significantly lower

intraoperative and postoperative heart rates and mean arterial pressures in the dexmedetomidine group compared to controls. This hemodynamic stability likely reflects the α2-adrenergic agonist activity of dexmedetomidine, which inhibits norepinephrine release and suppresses sympathetic outflow, thereby mitigating the cardiovascular fluctuations often observed during laparoscopic surgery (23). These findings are consistent with prior systematic reviews and clinical trials conducted in Western and Asian populations, reinforcing the broad applicability of this mechanism (13,19).

The observed reduction in postoperative delirium further aligns with recent evidence highlighting the neuroprotective properties of dexmedetomidine. Studies in both surgical and critical care settings have demonstrated its ability to lower the incidence and severity of postoperative cognitive disturbances, attributed to its preservation of sleep architecture, attenuation of neuroinflammation, and minimization of abrupt physiological changes (4,15,25). In this study, the incidence of moderate to severe delirium in the treatment group was substantially lower than in controls, a finding supported by meta-analyses and large-scale trials that underscore the clinical importance of delirium prevention, particularly in elderly and high-risk surgical populations (16,20). The current results not only reinforce these findings but also extend their relevance to a broader surgical population, suggesting that dexmedetomidine may offer generalized neuroprotection across diverse clinical settings.

Effective pain control remains a cornerstone of enhanced recovery after surgery (ERAS) protocols, and the results of this study underscore the analgesic superiority of dexmedetomidine when combined with paracetamol. The significantly lower VAS scores at all postoperative time points and the marked reduction in opioid consumption highlight the clinical and theoretical implications of an opioid-sparing strategy (24,29). This finding resonates with literature supporting multimodal analgesia as a means to minimize opioid-related adverse effects such as nausea, vomiting, ileus, and respiratory depression, thereby facilitating early ambulation and discharge (14,27). Mechanistically, the analgesic effects of dexmedetomidine are thought to be mediated through central and spinal α2-receptors, which modulate pain transmission and inhibit nociceptive pathways, providing synergistic benefits when combined with non-opioid agents like paracetamol (26). While the strengths of this study include its randomized controlled design, standardized protocols, and comprehensive outcome assessments, certain limitations must be acknowledged. The relatively modest sample size, drawn from a single tertiary care center, may limit the generalizability of findings to other populations or healthcare systems. The use of convenience sampling, although followed by randomization, introduces potential selection bias. The lack of blinding for outcome assessors may also have influenced subjective endpoints such as pain and delirium assessments. Furthermore, while follow-up extended to one month, longer-term cognitive and functional outcomes were not evaluated, leaving questions regarding the sustained neuroprotective effects of dexmedetomidine. These limitations should be addressed in future multicenter studies with larger and more diverse cohorts, double-blind protocols, and extended follow-up periods. Notwithstanding these limitations, this study provides compelling evidence for the integration of dexmedetomidine into perioperative management strategies for laparoscopic cholecystectomy. The clinical relevance of improved hemodynamic stability, reduced delirium, and enhanced analgesia cannot be overstated, particularly in high-risk or elderly patients where perioperative complications are of greatest concern. Future research should focus on optimizing dosing regimens, elucidating long-term cognitive outcomes, and conducting cost-effectiveness analyses to guide health policy and clinical decision-making. Moreover, investigating the utility of dexmedetomidine in other minimally invasive or high-risk surgical populations may further advance perioperative care and patient safety. In conclusion, the findings of this trial not only affirm the therapeutic potential of dexmedetomidine but also highlight the importance of evidence-based, multimodal strategies for improving surgical outcomes in contemporary anesthetic practice (8,14,17,28).

CONCLUSION

This randomized controlled trial demonstrates that the perioperative administration of intravenous dexmedetomidine combined with paracetamol significantly enhances hemodynamic stability, reduces postoperative delirium, improves pain control, and decreases opioid consumption in patients undergoing laparoscopic cholecystectomy compared to standard care. These findings underscore the value of integrating dexmedetomidine into multimodal anesthesia and analgesia protocols, offering substantial benefits for patient safety, comfort, and recovery. Clinically, this approach may be especially advantageous for high-risk surgical populations, promoting faster and safer postoperative outcomes while minimizing opioid-related adverse effects. Future research should focus on optimizing dosing strategies, evaluating long-term neurocognitive and functional outcomes, and assessing cost-effectiveness to further guide evidence-based perioperative care in human healthcare.

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