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Original Article

Anaesthesia Section

Gabapentin versus Clonidine Premedication for Haemodynamic Stability and Postoperative Analgesia in Laparoscopic Cholecystectomy: A Randomised Double-blind Control Study

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ABSTRACT

Introduction: Laparoscopic cholecystectomy is associated with haemodynamic stress responses and significant postoperative pain due to CO_2 insufflation and peritoneal irritation. Effective premedication can improve intraoperative stability and postoperative recovery. Gabapentin, a calcium channel modulator and clonidine, an alpha-2 adrenergic agonist, have shown efficacy in addressing these challenges.

Aim: To evaluate and compare gabapentin and clonidine as premedication for improving haemodynamic stability and reducing postoperative analgesic requirements in laparoscopic cholecystectomy.

Materials and Methods: A prospective, randomised, double-blind control study was conducted at Shri Guru Ram Rai Institute of Medical and Health Sciences, Dehradun, Uttarakhand, India on 150 American Society of Anaesthesiologists (ASA) Grade I/II patients undergoing elective laparoscopic cholecystectomy. Patients were divided into three groups: Group I (gabapentin 600 mg), Group II (clonidine 300 µg) and Group III (placebo). Haemodynamic parameters, Visual Analog Scale (VAS) scores and rescue analgesic requirements were recorded. Data were analysed using Statistical Package for Social Sciences (SPSS) version 21.0.

Results: Gabapentin significantly reduced postoperative VAS scores (e.g., at 4 hours: gabapentin 2.9±0.9, clonidine 3.7±1.2, placebo 4.8±1.3; p-value <0.001) and delayed rescue analgesia (gabapentin: 5.2±1.1 hours vs. clonidine: 4.1±0.9 hours and placebo: 3.7±0.8 hours). Clonidine provided superior intraoperative haemodynamic stability (e.g., Heart Rate (HR) at 15 minutes: gabapentin 100.28±9.11 bpm, clonidine 93.90±14.78 bpm, placebo 99.86±9.12 bpm; p-value=0.008). Both drugs demonstrated minimal and comparable adverse effects.

Conclusion: Gabapentin and clonidine are effective premedications for laparoscopic cholecystectomy. Gabapentin is superior for postoperative pain control, while clonidine ensures better intraoperative haemodynamic stability. Both agents are safe and improve perioperative outcomes.

Keywords: Endotracheal intubation, Pain, Sedation, Visual analog scale

INTRODUCTION

Laparoscopic cholecystectomy is a minimally invasive procedure widely used for treating gallbladder diseases, including cholelithiasis and acute or chronic cholecystitis. Although this approach offers significant advantages over open surgery, such as shorter recovery times and reduced postoperative complications, it is associated with distinct challenges, including significant postoperative pain and haemodynamic stress responses caused by CO_2 insufflation and pneumoperitoneum [1,2]. These effects often result in tachycardia, hypertension and increased systemic vascular resistance, which can complicate intraoperative management and prolong recovery [3]. Postoperative pain after laparoscopic cholecystectomy has a complex aetiology, including peritoneal irritation caused by CO_2, surgical site trauma and phrenic nerve stimulation. Despite advancements in pain management strategies, 70% of patients undergoing laparoscopic cholecystectomy report moderate to severe pain in the immediate postoperative period [4,5]. Ineffective management of perioperative pain and haemodynamic stress can increase morbidity, delay recovery and negatively impact quality of life [6].

Various pharmacological interventions have been explored to mitigate these challenges, including Non Steroidal Anti-Inflammatory Drugs (NSAIDs), opioids and anticonvulsants. Among these, gabapentin, a Gamma-aminobutyric Acid (GABA) analogue and clonidine, an alpha-2 adrenergic agonist, have gained attention due to their analgesic, anxiolytic and antihyperalgesic properties [7,8]. Gabapentin modulates calcium channels, reducing neurotransmitter release and attenuating the pressor response to intubation and pneumoperitoneum [9]. Clonidine, by acting on central alpha-2 receptors, provides haemodynamic stability and enhances analgesia through central sympatholytic mechanisms [10]. Preemptive analgesia, which involves administering analgesics before the surgical stimulus has been recognised as an effective approach in minimising postoperative pain. Gabapentin and clonidine, when administered preemptively, have demonstrated promising results in improving perioperative outcomes in various surgical procedures [11,12].

This study aimed to compare the efficacy of oral gabapentin and clonidine as premedications in laparoscopic cholecystectomy for attenuating haemodynamic stress responses and reducing postoperative analgesic requirements compared to a placebo group. Through this comparative analysis, the present study aimed to identify an optimal pharmacological strategy to enhance patient outcomes and minimise perioperative complications [13]. Although similar studies exist in the literature, many have limitations such as smaller sample sizes or randomisation involving a placebo group [14,15]. The present study sought to minimise confounding bias by utilising a larger sample size and selecting optimal drug doses, thereby enhancing the reliability and validity of its findings.

MATERIALS AND METHODS

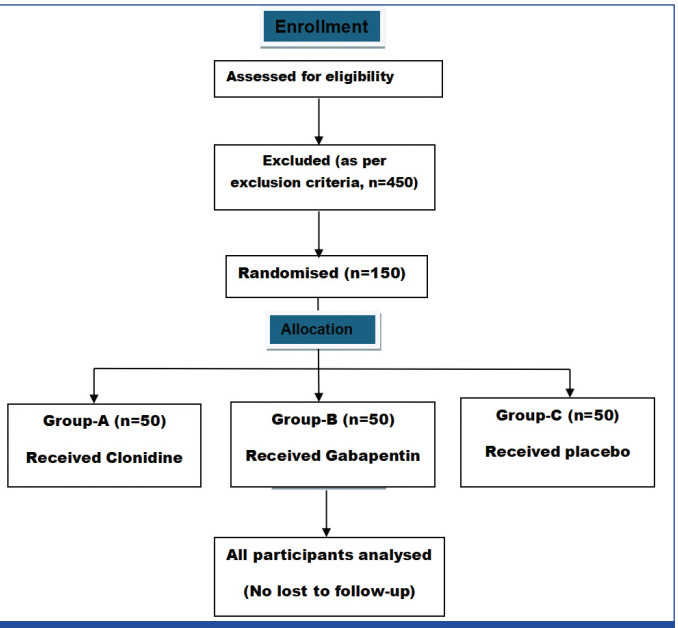
This was a prospective, randomised, double-blind control study conducted in the Department of Anaesthesiology at Shri Guru Ram

Rai Institute of Medical and Health Sciences, Dehradun, a tertiary care centre in North India, from January 2023 to June 2024. After obtaining ethical approval from the Institutional Ethics Committee (IEC) (SGRR/IEC/45/23). This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and informed consent was obtained from all participants.

Inclusion criteria: Patients aged 20 to 60 years, ASA Grade I and II, scheduled for elective laparoscopic cholecystectomy were included in the study.

Exclusion criteria: ASA Grade III and IV patients, patients with known hypersensitivity to the study drugs, history of coronary artery disease, diabetes, epilepsy, or hypertension, conversion to open cholecystectomy during surgery, refusal to participate were excluded from the study.

A total of 150 patients undergoing elective laparoscopic cholecystectomy under general anaesthesia were enrolled in the study [Table/Fig-1].



[Table/Fig-1]: Consort flowchart for randomisation.

Sample size calculation: The sample size was calculated using G-Power software, assuming 80% power and a 5% level of significance using the Cochran formula, as follows:

$$n=(Z^2 a \times P \times (1-P))/d^2$$

Where,

Z is the level of significance at 5% i.e., 95% confidence interval=1.96

P=Proportion of Laparoscopic cholecystectomy is assumed at 6.2%=0.062 based on prevalence of gall bladder disease from reference study [16].

d=Desired error of margin=4%=0.04

Hence, 140 patients were needed for the study. This number was increased to 150 (50 per group) to account for a predicted dropout from treatment. The recruited subjects were randomly divided into three groups of 50 each using a closed-envelope technique.

Study Procedure

Patients were randomised into three groups using a computer-generated random sequence, with allocation concealment maintained via sealed opaque envelopes, ensuring blinding for both participants and investigators. A parallel-group, double-blind, Randomised Controlled Trial (RCT) design was followed. Patients were assigned in a 1:1:1 ratio using block randomisation to ensure equal distribution across groups. The allocation sequence was generated by an independent researcher and kept confidential until intervention assignment. Both patients and outcome assessors remained blinded to group allocation throughout the study to minimise bias.

1. **Group I (Gabapentin):** Received oral gabapentin 600 mg one hour before surgery [17];
2. **Group II (Clonidine):** Received oral clonidine 300 µg one hour before surgery. [14];
3. **Group III (Placebo):** Received a matching placebo tablet one hour before surgery.

Preoperative preparation: All patients underwent a thorough preanaesthetic evaluation, including a detailed history, physical examination and investigations such as complete blood count, renal function tests, Electrocardiogram (ECG) and chest X-ray. Premedication with oral alprazolam 0.25 mg and pantoprazole 40 mg was administered the night before surgery. Patients were instructed to remain Nil Per Oral (NPO) for eight hours for solids and two hours for clear liquids prior to surgery.

Intraoperative management: Upon arrival in the operating room, standard ASA monitoring was established, including:

- Electrocardiogram (ECG).
- Non Invasive Blood Pressure (NIBP).
- Pulse oximetry (SpO_2).

Patients were premedicated with intravenous ondansetron (0.08 mg/kg) and fentanyl (1.5 µg/kg). General anaesthesia was induced with propofol (2 mg/kg) and vecuronium (0.1 mg/kg) to facilitate endotracheal intubation. Anaesthesia was maintained with isoflurane (0.5-1%) and intermittent doses of vecuronium. Mechanical ventilation was adjusted to maintain normocarbia ($EtCO_2$: 36-44 mmHg).

Pneumoperitoneum was established with CO_2, maintaining intra-abdominal pressure at 12 mmHg. Haemodynamic parameters, including Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Mean Arterial Pressure (MAP), were recorded at baseline, preinduction, one minute postintubation, five minutes postintubation and at 1, 5, 15 and 30 minutes after pneumoperitoneum, as well as at the end of the surgery.

Postoperative monitoring: Postoperative pain was assessed using the VAS, which ranges from 0 to 10 and rescue analgesia (intravenous tramadol 50 mg) was administered if VAS scores exceeded four. The time to the first rescue analgesic was recorded. Adverse effects, such as nausea, vomiting and sedation, were noted.

Outcome Measures

Primary outcomes:

- Intraoperative haemodynamic stability (HR, SBP, DBP, MAP).
- Postoperative pain scores (Visual Analog Scale [VAS]).
- Time to first rescue analgesic.

Secondary outcomes:

- Incidence of adverse effects, including sedation, nausea and vomiting.

STATISTICAL ANALYSIS

Data were analysed using SPSS version 21.0. Continuous variables were expressed as mean±Standard Deviation (SD) and were compared using the Kruskal-Wallis test for intergroup analysis and the Friedman test for intragroup analysis. Categorical variables were analysed using the Chi-square test. A p-value <0.05 was considered statistically significant.

RESULTS

The demographic characteristics, including age, gender distribution, weight, ASA grade and duration of surgery, were comparable across all three groups (Gabapentin, Clonidine and Placebo). No statistically significant differences were observed among the groups (p-value >0.05) [Table/Fig-2].

Parameter	Gabapentin (Group I)	Clonidine (Group II)	Placebo (Group III)	p-value
Age (years)	36.48±10.12	38.08±9.80	35.82±10.17	0.514
Gender (Male/Female)	20/30	18/32	21/29	0.822
Weight (kg)	64.90±8.15	66.08±9.07	65.36±8.64	0.789
ASA grade (I/II)	32/18	30/20	26/24	0.463
Duration of surgery (mins)	55.90±11.85	52.70±13.33	54.60±11.81	0.430

[Table/Fig-2]: Demographic data.
No significant differences were observed (p-value >0.05)

Baseline HR was comparable across the groups (p-value=0.306). Significant differences were observed at 15 minutes postpneumoperitoneum, where the HR in the Gabapentin group (100.28±9.11 bpm) and the Placebo group (99.86±9.12 bpm) were higher than in the Clonidine group (93.90±14.78 bpm, p-value=0.008). At the end of surgery, the HR was significantly higher in the Gabapentin (99.82±7.85 bpm) and Placebo groups (101.32±8.38 bpm) compared to the Clonidine group (93.58±14.22 bpm, p-value=0.001) [Table/Fig-3].

No significant differences in SBP were noted at baseline and preinduction among the groups (p-value >0.05). Postintubation, SBP remained more stable in the Clonidine group compared to the Gabapentin and Placebo groups [Table/Fig-3]. Similar trends were observed for DBP and MAP, with Clonidine maintaining more stable haemodynamic parameters compared to Gabapentin and Placebo [Table/Fig-3].

Postoperative pain, assessed using the VAS, was significantly lower in the Gabapentin group compared to the Clonidine and Placebo groups at all recorded intervals (p-value <0.001) [Table/Fig-4]. The time to first rescue analgesic was longest in the Gabapentin group (5.2±1.1 hours) compared to the Clonidine group (4.1±0.9 hours) and the Placebo group (3.7±0.8 hours) (p-value <0.001).

The incidence of adverse effects, such as sedation, nausea and vomiting, was minimal and comparable among the three groups (p-value=0.524 for nausea/vomiting and p-value=0.678 for sedation) [Table/Fig-5].

Time	Parameter	Group I	Group II	Group III	p-value
Baseline	HR (bpm)	80.8±13.29	78.62±12.2	77.02±11.37	0.306
	SBP (mmHg)	110.77±7.21	111.60±6.26	112.22±6.83	0.569
	DBP (mmHg)	85.14±4.21	84.37±4.80	85.06±4.51	0.682
	MAP (mmHg)	93.68±3.60	93.44±3.99	94.11±3.72	0.67
Preinduction	HR (bpm)	81.8±13.2	79.6±12.2	78.02±11.37	0.308
	SBP (mmHg)	111.7±7.21	112.6±6.26	113.2±6.83	0.569
	DBP (mmHg)	86.14±4.21	85.37±4.80	86.06±4.51	0.644
	MAP (mmHg)	94.68±3.60	94.44±3.99	95.11±3.72	0.66
Postinduction (1 minute)	HR (bpm)	91.1±11.31	84.18±12.87	86.42±10.58	0.011
	SBP (mmHg)	108.83±6.11	107.86±4.60	109.20±5.59	0.447
	DBP (mmHg)	89.65±4.55	88.94±5.29	89.80±5.03	0.651
	MAP (mmHg)	96.04±3.99	95.24±4.04	96.26±4.14	0.416
Postinduction (5 minutes)	HR (bpm)	93.6±10.76	88.58±11.61	89.68±9.74	0.051
	SBP (mmHg)	111.89±7.37	111.39±5.88	112.54±6.71	0.688
	DBP (mmHg)	87.91±4.54	87.52±5.45	88.10±5.12	0.846
	MAP (mmHg)	95.91±4.16	95.48±4.34	96.24±4.19	0.66
Postpneumoperitoneum (1 minute)	HR (bpm)	97.4±10.89	92.2±12.61	95.28±10.14	0.071
	SBP (mmHg)	110.32±7.21	109.47±5.8	110.76±6.72	0.608
	DBP (mmHg)	86.91±4.47	86.31±5.19	86.50±4.72	0.814
	MAP (mmHg)	94.71±4.17	94.02±4.35	94.58±4.18	0.69
Postpneumoperitoneum (5 minutes)	HR (bpm)	100.36±10.2	93.6±13.9	97.76±10.1	0.014
	SBP (mmHg)	108.63±6.75	107.725±5.78	109.18±6.20	0.499
	DBP (mmHg)	87.85±4.22	87.03±4.77	87.80±4.54	0.599
	MAP (mmHg)	94.78±3.89	93.93±4.08	94.92±3.86	0.40
Postpneumoperitoneum (15 minutes)	HR (bpm)	100.28±9.1	93.90±14.7	99.86±9.12	0.008
	SBP (mmHg)	109.61±6.79	108.80±5.86	110.14±6.22	0.563
	DBP (mmHg)	90.98±5.95	90.51±6.16	91.06±6.19	0.887
	MAP (mmHg)	85.61±10.39	81.0±8.06	84.16±10.93	0.06
Postpneumoperitoneum (30 minutes)	HR (bpm)	96.50±8.6	92.39±12.5	96.54±9.96	0.081
	SBP (mmHg)	111.77±7.21	112.608±6.27	113.22±6.83	0.608
	DBP (mmHg)	86.14±4.21	85.37±4.80	86.06±4.51	0.644
	MAP (mmHg)	94.68±3.60	94.44±3.99	95.11±3.73	0.67
End of surgery	HR (bpm)	99.82±7.8	93.58±14.2	101.32±8.38	0.001
	SBP (mmHg)	108.83±6.11	107.863±4.60	109.20±5.59	0.688
	DBP (mmHg)	89.65±4.55	88.94±5.29	89.80±5.03	0.651
	MAP (mmHg)	96.04±3.99	95.24±4.05	96.26±4.14	0.416

[Table/Fig-3]: Intergroup comparison of mean Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Mean Arterial Pressure (MAP) at different time intervals.

VAS score	Gabapentin	Clonidine	Placebo	p-value
2 hours	2.6±0.8	3.4±1.0	4.2±1.2	<0.001
4 hours	2.9±0.9	3.7±1.2	4.8±1.3	<0.001
6 hours	3.1±1.0	3.9±1.3	5.1±1.4	<0.001

[Table/Fig-4]: Postoperative VAS scores.
This table displays VAS scores at 2, 4 and 6 hours, postoperatively. Gabapentin significantly reduced postoperative pain compared to Clonidine and Placebo (p-value <0.001)

Adverse effects	Gabapentin	Clonidine	Placebo	p-value
Nausea and vomiting	4 (8%)	5 (10%)	6 (12%)	0.524
Sedation	3 (6%)	4 (8%)	2 (4%)	0.678

[Table/Fig-5]: Adverse effects.

DISCUSSION

The present study aimed to evaluate and compare the efficacy of gabapentin and clonidine as premedication for managing haemodynamic stress responses and postoperative analgesia in laparoscopic cholecystectomy. The findings suggest that both gabapentin and clonidine are effective, with distinct advantages in different perioperative aspects. Gabapentin excelled in postoperative pain management, while clonidine provided better intraoperative haemodynamic stability.

Gabapentin acts by binding to the α2δ subunit of voltage-gated calcium channels, inhibiting the release of excitatory neurotransmitters such as glutamate and substance P. This mechanism reduces nociceptive transmission, explaining the significant reduction in postoperative pain scores and the delayed need for rescue analgesics observed in the present study [18]. Clonidine, on the other hand, acts as a selective partial agonist of alpha-2 adrenergic receptors, reducing sympathetic outflow from the central nervous system. This central sympatholytic effect stabilises HR and blood pressure, which was evident in present study results, where clonidine maintained superior intraoperative haemodynamic stability compared to gabapentin and placebo [8].

The results of the present study are consistent with those of Das P et al., and Sahu KC, who found that both drugs effectively reduced perioperative pain and maintained haemodynamic stability, with gabapentin showing greater analgesic benefits [2]. Similarly, Prakash R et al., reported that both gabapentin and clonidine attenuated the stress response to pneumoperitoneum, findings mirrored in the present study [1]. However, the data from this study further emphasise the differential roles of these agents, with gabapentin being more beneficial for postoperative recovery and clonidine for intraoperative management.

The findings of Gayathri L et al., support the conclusions of this study that gabapentin provides better postoperative pain control and reduces analgesic consumption, whereas clonidine ensures better intraoperative haemodynamic stability. However, their study observed that clonidine leads to a higher incidence of dry mouth, which was not a significant issue in the present study [19]. Additionally, the results of the present study were similar to those of Tyagi M et al., who also noted greater attenuation of intraoperative haemodynamic stress response with clonidine (300 mcg) and superior postoperative analgesia with gabapentin (600 mg). However, their study was limited due to a lack of a placebo group for comparison [15].

Unlike earlier studies by Mohammadi SS and Seyedi M, Bayoumi HM et al., which reported higher rates of sedation with gabapentin, the present study found minimal and comparable sedation across all groups. This difference might be attributed to the careful dose selection in present study protocol [4,12]. Additionally, while Majumdar S et al., emphasised clonidine's role in reducing postoperative analgesic requirements, present study findings suggest that gabapentin outperforms clonidine in this regard [5].

In summary, the findings of the present study highlight the complementary roles of gabapentin and clonidine in perioperative management. Gabapentin, through its antinociceptive effects, effectively reduces postoperative pain and analgesic requirements, while clonidine provides superior intraoperative haemodynamic stability through its central sympatholytic action. These insights may guide the tailored use of these agents to optimise patient outcomes in laparoscopic cholecystectomy. Future studies with larger, multicentre populations and long-term follow-up are recommended to further validate these findings.

The strengths of the present study include its robust design as a prospective, randomised, double-blind trial, which minimises bias and ensures the reliability of the results. The use of standardised anaesthetic protocols and comprehensive monitoring of haemodynamic parameters adds to the credibility of present study findings. Furthermore, the comparative evaluation of two widely studied premedicants against a placebo allows for a holistic understanding of their roles in perioperative management.

Limitation(s)

The sample size, although statistically adequate, may limit the generalisability of the findings to larger populations or diverse surgical settings. The study was conducted at a single centre, which may introduce institutional biases. Additionally, long-term outcomes, such as the incidence of chronic pain or prolonged recovery, were not assessed, which could provide further insights into the benefits of gabapentin and clonidine.

CONCLUSION(S)

Gabapentin and clonidine are effective premedications for laparoscopic cholecystectomy, with gabapentin excelling in postoperative pain management and clonidine providing superior intraoperative haemodynamic stability. Both drugs were well-tolerated with minimal side-effects. Tailored use based on patient needs can optimise perioperative outcomes.

Further large-scale studies are warranted to explore optimal dosing strategies, long-term effects and comparative efficacy with other premedication options.

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