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Dexamethasone Versus Dexamethasone Plus Intraoperative Intravenous Ringer Lactate (30mi/Kg) Infusion to Prevent Postoperative Nausea Vomiting in Patients Undergoing Laparoscopic Cholecystectomy: A Prospective, Randomised, Double Blinded Study

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A B S T R A C T

Background: Postoperative nausea and vomiting (PONV) are common and distressing complications following laparoscopic cholecystectomy, with significant effects on recovery, hospital stay, and patient satisfaction. Dexamethasone is widely used for prophylaxis, and perioperative fluid therapy with Ringer lactate has also shown potential in reducing PONV.

Aim: To evaluate the efficacy of intravenous dexamethasone combined with intraoperative Ringer lactate infusion (30 mL/kg) in preventing PONV compared to dexamethasone alone in patients undergoing laparoscopic cholecystectomy.

Methods: This prospective, randomized, double-blinded, controlled study included 100 ASA I–II patients undergoing elective laparoscopic cholecystectomy. Patients were allocated into two groups:

- Group A: Dexamethasone 8 mg + Ringer lactate 15 mL/kg
- Group B: Dexamethasone 8 mg + Ringer lactate 30 mL/kg

Primary outcome was the incidence of PONV within 24 hours. Secondary outcomes included the need for rescue antiemetics/analgesics, postoperative pain scores, patient satisfaction, hemodynamic changes, and adverse effects.

Results: The incidence of PONV was significantly lower in Group B (16%) compared to Group A (44%) ($p = 0.002$). Requirement for rescue antiemetics was also reduced in Group B (10% vs. 26%, $p = 0.037$). Time to first rescue analgesia was longer in Group B (75.92 ± 16.49 min) compared to Group A (54.78 ± 6.70 min, $p < 0.0001$). Patient satisfaction scores were significantly higher in the combination group ($p = 0.005$). Hemodynamic parameters remained stable and comparable between groups, with no major adverse effects reported.

Conclusion: The combination of intravenous dexamethasone with intraoperative Ringer lactate infusion (30 mL/kg) is more effective than dexamethasone alone in reducing PONV, decreasing the need for rescue antiemetics, prolonging pain-free intervals, and improving patient satisfaction in laparoscopic cholecystectomy. This multimodal, simple, safe, and cost-effective strategy can be recommended for routine perioperative management.

Keywords: Postoperative nausea and vomiting (PONV); Laparoscopic cholecystectomy; Dexamethasone; Ringer lactate.

INTRODUCTION:

Postoperative nausea and vomiting (PONV) are common complications that can significantly impact the recovery and well-being of patients undergoing laparoscopic cholecystectomy, a widely performed minimally invasive surgical

procedure. Despite advancements in surgical techniques, anesthesia, and postoperative care, the incidence of PONV remains a considerable concern, affecting approximately 20-30% of patients undergoing laparoscopic cholecystectom [1]. PONV not only leads to patient discomfort and distress but also results in extended hospital stays, delayed recovery, increased healthcare costs, and a potential decrease in patient satisfaction [2]. As such, effective strategies to prevent and manage PONV are crucial for optimizing surgical outcomes and enhancing patient experiences.

One commonly employed prophylactic measure to mitigate PONV is the administration of dexamethasone, a synthetic glucocorticoid with potent anti-inflammatory and antiemetic properties [3]. The antiemetic effects of dexamethasone are attributed to its modulation of neurotransmitter systems involved in emesis and its ability to reduce inflammation-induced nausea and vomiting. While dexamethasone has demonstrated efficacy in reducing the incidence of PONV, there remains room for improvement in its preventive capacity.

Another avenue for enhancing PONV prevention involves the perioperative administration of intravenous fluids. Ringer lactate, a balanced crystalloid solution, has been used to maintain hemodynamic stability, electrolyte balance, and tissue perfusion during surgery [4]. Recent evidence suggests that combining dexamethasone with intraoperative intravenous Ringer lactate infusion might synergistically contribute to reducing PONV incidence. The combined approach could address multiple facets of PONV triggers, encompassing both neurotransmitter-mediated pathways and perioperative physiological factors.

This study seeks to investigate whether the combined regimen of dexamethasone and intraoperative intravenous Ringer lactate infusion at a rate of 30 ml/kg offers superior preventive effects against PONV compared to dexamethasone administered alone in patients undergoing laparoscopic cholecystectomy. By assessing the potential synergistic benefits of this combination, the study aims to provide valuable insights into refining perioperative management strategies and improving patient outcomes in the context of laparoscopic cholecystectomy.

Objective:
To evaluate the efficacy of dexamethasone combined with intraoperative intravenous Ringer lactate infusion at a dose of 30 mL/kg in preventing postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic cholecystectomy, and to compare this with dexamethasone alone in terms of need for rescue antiemetics and analgesics, intraoperative and postoperative hemodynamic changes, and the incidence of any adverse effects attributable to the drug or fluid administration.

Materials & Methods:
Study Design and Setting
This was a hospital-based, prospective, randomized, double-blinded, controlled study conducted over a 12-month period from January 2023 to December 2023 in the Department of Surgery, Operation Theatre, Midnapore Medical College and Hospital.

Study Population
The study population included all patients classified as American Society of Anesthesiologists (ASA) physical status grade I and II undergoing elective laparoscopic cholecystectomy under general anesthesia, who met the inclusion criteria and provided informed consent.

Sample Size and Sampling Technique
The sample size was calculated based on a previous study that reported a 55% incidence of PONV within 24 hours following dexamethasone administration [55]. Expecting a 20% absolute reduction in PONV incidence with the combination of dexamethasone and intraoperative intravenous fluid loading (30 mL/kg) [56,57], a total of 42 patients per group were required to achieve 80% power at a significance level of 0.05. To account for potential dropouts, 50 patients were enrolled in each group, resulting in a total sample size of 100 patients.

Randomization was performed using a computer-generated random number table. Allocation concealment was ensured using sequentially numbered, sealed opaque envelopes.

Ethical Considerations
The study was conducted after obtaining:
- Approval from the Institutional Ethics Committee,
- Registration with the Clinical Trials Registry of India (CTRI),
- Approval from the West Bengal University of Health Sciences,
- Written informed consent from all participants.

Group Allocation

- **Group A**: Received intravenous dexamethasone 8 mg + intraoperative Ringer lactate at 15 mL/kg.
- **Group B**: Received intravenous dexamethasone 8 mg + intraoperative Ringer lactate at 30 mL/kg.

Inclusion Criteria

- ASA physical status I and II
- Age 20–65 years
- Elective laparoscopic cholecystectomy under general anesthesia
- Provided valid written informed consent

Exclusion Criteria

- Severe cardiovascular or respiratory disease
- Hepatic or renal dysfunction
- Neurological or endocrine disorders
- Psychiatric illness
- Known allergy to dexamethasone
- Refusal to consent

Preoperative Evaluation and Data Collection

All patients underwent a thorough preoperative assessment which included complete blood count, fasting and postprandial blood sugar (FBS/PPBS), renal and liver function tests, serum electrolyte levels (sodium and potassium), thyroid function tests, bleeding time, clotting time, electrocardiography (ECG), chest X-ray, and viral markers including HBsAg, anti-HCV, and HIV I/II.

Intraoperative and postoperative data collection included monitoring of hemodynamic parameters such as systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR), respiratory rate (RR), and oxygen saturation (SpO_2). Additional variables recorded were body weight, body mass index (BMI), postoperative nausea and vomiting (PONV) assessment using the PONV Impact Scale, postoperative pain evaluation using the Visual Analog Scale (VAS), time to administration of rescue analgesic, and time to discharge from the post-anesthesia care unit (PACU).

Anaesthetic Technique and Intraoperative Protocol

All patients were premedicated with intravenous midazolam 2 mg following venous access. Standard intraoperative monitoring included continuous ECG, pulse oximetry (SpO_2), non-invasive blood pressure (NIBP), and end-tidal carbon dioxide ($EtCO_2$). General anaesthesia was induced using fentanyl at a dose of 1 µg/kg and propofol at 2–2.5 mg/kg. Neuromuscular blockade was achieved using atracurium 0.5 mg/kg, with additional doses administered as needed to maintain adequate muscle relaxation.

Anaesthesia was maintained with 2–3% sevoflurane delivered in a 50% oxygen and nitrous oxide mixture. Mechanical ventilation was volume-controlled, with adjustments made to tidal volume and respiratory rate to maintain $EtCO_2$ levels between 35–45 mmHg. Intraoperative fluids were administered according to group allocation and completed by the end of the surgical procedure. Gastric contents were suctioned via an orogastric tube before extubation. Neuromuscular blockade was reversed using intravenous atropine 1 mg and neostigmine 2.5 mg, followed by tracheal extubation after ensuring adequate recovery.

Patients who required conversion to open cholecystectomy or experienced significant intraoperative complications such as hypotension or excessive bleeding were excluded from the study. The study maintained double-blinding, with anaesthesiologists and postoperative caregivers unaware of the group assignments. Intraoperative fluid preparation and administration were handled by trained OT technicians to maintain blinding.

Postoperative Monitoring

Postoperatively, patients were transferred to the PACU in stable condition, where recovery was assessed using the modified Aldrete scoring system. The time required to achieve an Aldrete score of 10 was recorded as the time to PACU discharge. Oral intake was permitted as soon as the patient requested fluids. All patients were monitored for a total of 24 hours for the occurrence of PONV and postoperative pain. Rescue antiemetics and analgesics were administered as clinically indicated.

Study Variables

The variables assessed in this study included demographic data (name, age, sex, weight, height, BMI), intraoperative and postoperative hemodynamic parameters (SBP, DBP, MAP, HR, RR, SpO_2), and clinical outcome measures such as PONV score, VAS pain score, time to PACU discharge, need for rescue antiemetics and analgesics, and any observed adverse effects.

Statistical Analysis

All collected data were entered into Microsoft Excel and analyzed using appropriate statistical software. Continuous variables were expressed as mean ± standard deviation and compared between groups using the unpaired Student's *t*-test or Mann–Whitney *U* test based on the distribution of the data. Categorical variables were presented as frequencies and percentages, and comparisons were made using the Chi-square test or Fisher's exact test as appropriate. A *p*-value of less than 0.05 was considered statistically significant. All statistical analyses were performed in consultation with a qualified biostatistician.

Results & Analysis:

Table 1: Baseline Characteristics of Study Participants

Variable	Category	Group A: Dexamethasone (n = 50)	%	Group B: Dexamethasone + RL (n = 50)	%	Statistical Inference
Age Group	20–30 years	9	18.0	11	22.0	p = 0.363
	31–40 years	11	22.0	14	28.0	
	41–50 years	16	32.0	13	26.0	
	51–60 years	14	28.0	12	24.0	
Mean Age		42.64 ± 10.24		40.74 ± 10.56		
Sex	Male	29	58.0	22	44.0	$\chi^2 = 1.961$, p = 0.161
	Female	21	42.0	28	56.0	
ASA Status	Grade I	37	74.0	40	80.0	$\chi^2 = 0.508$, p = 0.476
	Grade II	13	26.0	10	20.0	

Table 1 the baseline characteristics of the study participants. The mean age in the dexamethasone group was 42.64 ± 10.24 years, while that in the dexamethasone with Ringer lactate group was 40.74 ± 10.56 years. This difference was not statistically significant ($p = 0.363$). Regarding sex distribution, Group A had 58% males and 42% females, while Group B had 44% males and 56% females; the difference was not significant ($p = 0.161$). ASA physical status was also comparable, with the majority in both groups being ASA Grade I (74% in Group A vs. 80% in Group B), and no significant difference was noted ($p = 0.476$). These findings indicate that the two groups were comparable at baseline.

Table 2: Comparison of Anthropometric and Perioperative Variables Between the Two Groups

Variable	Group A: Dexamethasone (n = 50)		Group B: Dexamethasone + RL (n = 50)		*p* value
	Mean	± SD	Mean	± SD	
Height (cm)	159.52	5.98	160.00	5.20	0.669
Weight (kg)	68.06	6.45	67.12	5.79	0.445
BMI (kg/m²)	26.79	3.28	26.24	2.83	0.365
Duration of Surgery (min)	84.20	7.46	85.22	7.04	0.483
Duration of Anaesthesia (min)	102.92	7.75	103.62	6.39	0.623

Table 2 shows the comparison of anthropometric and perioperative variables between the two groups. The mean height, weight, and BMI were comparable between Group A and Group B, with no statistically significant differences ($p > 0.05$). Similarly, the mean duration of surgery was 84.20 ± 7.46 minutes in the dexamethasone group and 85.22 ± 7.04 minutes in the dexamethasone with Ringer lactate group ($p = 0.483$). The mean duration of anaesthesia was also comparable between the groups (102.92 ± 7.75 vs. 103.62 ± 6.39 minutes; $p = 0.623$). These findings confirm that both groups were similar in terms of anthropometric and operative characteristics.

Table 3: Comparison of Incidence of PONV and Requirement of Rescue Antiemetics Between Groups

Parameter	Response	Group A: Dexamethasone (n = 50)	%	Group B: Dexamethasone + RL (n = 50)	%	Statistical Inference
Incidence of PONV	Yes	22	44.0	8	16.0	$\chi^2 = 9.33$, p = 0.002
	No	28	56.0	42	84.0	

Requirement of Rescue Antiemetic	Yes	13	26.0	5	10.0	$\chi^2 = 3.473$, **p = 0.037**
	No	37	74.0	45	90.0	

Table 3 shows a significant reduction in both the incidence of postoperative nausea and vomiting (PONV) and the need for rescue antiemetic use in the group receiving dexamethasone with intraoperative Ringer lactate infusion. PONV occurred in 44% of patients in the dexamethasone group compared to only 16% in the dexamethasone with Ringer lactate group, a statistically significant difference ($p = 0.002$). Similarly, the requirement for rescue antiemetic was significantly lower in the combination group (10%) compared to the dexamethasone-only group (26%) ($p = 0.037$). These findings support the enhanced antiemetic effectiveness of combining dexamethasone with liberal intraoperative fluid therapy.

Table 4: Time to first Rescue Analgesia

Time to first Rescue Analgesia	Group A: Dexamathasone (n=50)		Group B: Dexamethasone with RL (n=50)		p value
	Mean	**±SD**	**Mean**	**±SD**	
Time to first Rescue Analgesia (minutes)	54.78	±6.70	75.92	±16.49	<0.0001

Time to first rescue analgesic was significantly higher with dexamethasone with RL (75.92 ±16.49 minutes) in comparison to dexamethasone (54.78 ±6.70 minutes) with a statistically significant difference (p value = <0.0001). Data is shown in **Table 4**.

Table 5: Patient's Satisfaction using Verbal Descriptive Scale[3]

Verbal Descriptive Scale	Group A: Dexamathasone (n=50)		Group B: Dexamethasone with RL (n=50)	
	Frequency	**Percentage**	**Frequency**	**Percentage**
0 (No PONV)	25	50.0	40	80.0
1 (Mild)	8	16.0	5	10.0
2 (Moderate)	10	20.0	5	10.0
3 (Severe)	7	14.0	0	0.0
Total	50	100.0	50	100.0
Statistical Inference	**Chi square:** 12.821 **p value:** 0.005			

In the present study patients' satisfaction was assessed through verbal descriptive scale.[3] According to this scoring system severity of PONV was lesser in dexamethasone with ringer lactate group ; out of 10 patients 5 developed mild &5 developed moderate PONV while in dexamethasone group; out of 25, 8 patients had mild, 10 had moderate &7 had severe PONV and this difference was statistically significant between two groups (p value = 0.005). Data is illustrated in **Table 5**.

Table 6: Comparison of Hemodynamic Parameters Between the Two Groups

Parameter	Interval	Group A: Dexamethasone (n = 50)	± SD	Group B: Dexamethasone + RL (n = 50)	± SD	*p* value
SBP (mmHg)	Baseline	125.94	3.68	126.32	11.58	0.741
	Intraoperative	119.46	3.80	119.12	10.06	0.223
	Postoperative	120.66	3.34	120.34	10.63	0.313
DBP (mmHg)	Baseline	85.20	2.56	85.38	11.00	0.897
	Intraoperative	79.02	6.20	79.10	9.27	0.341
	Postoperative	82.78	4.52	82.78	4.52	0.054
MAP (mmHg)	Baseline	98.50	2.36	97.98	11.50	0.097
	Intraoperative	92.30	4.56	91.72	9.70	0.124
	Postoperative	95.14	2.19	94.50	4.35	0.741
HR (beats/min)	Baseline	77.22	4.45	76.58	4.54	0.674
	Intraoperative	77.14	3.70	76.82	80.56*	0.176
	Postoperative	80.56	4.57	79.78	4.71	0.647
RR (breaths/min)	Baseline	16.70	1.99	16.60	1.97	0.894
	Intraoperative	16.52	2.08	16.76	1.99	0.496
	Postoperative	16.88	1.31	16.68	1.71	0.371

Table 6 the changes in hemodynamic parameters (SBP, DBP, MAP, HR, and RR) at baseline, intraoperative, and postoperative intervals for both groups. There were no statistically significant differences observed in any of the parameters between the two groups at any time point ($p > 0.05$ for all comparisons). These results indicate that both

dexamethasone alone and its combination with Ringer lactate had comparable effects on perioperative hemodynamic stability.

Discussion:

Postoperative nausea and vomiting (PONV) are among the most frequent and distressing complications after laparoscopic cholecystectomy, with an incidence ranging from 30% in the general surgical population to over 70% in high-risk patients[5]. Although PONV is typically self-limiting, it significantly affects patient comfort, prolongs recovery, increases healthcare costs, and contributes to unanticipated hospital admissions[6].

Dexamethasone is a well-established prophylactic agent for PONV due to its anti-inflammatory and antiemetic effects, including modulation of prostaglandins and serotonin release[7]. It has also been shown to reduce postoperative pain, fatigue, and the need for rescue antiemetics when administered before induction due to its long half-life of 36–72 hours[8].

In our study, we compared the efficacy of IV dexamethasone alone with its combination with intraoperative Ringer lactate (30 mL/kg) in patients undergoing elective laparoscopic cholecystectomy. The group receiving dexamethasone plus fluid showed a significantly lower incidence of PONV and reduced need for rescue antiemetics (p = 0.002 and 0.037, respectively). Additionally, these patients had longer pain-free intervals postoperatively and higher satisfaction scores.

Our findings are consistent with those of Ali et al. and **Maharaj et al.,** who reported that intraoperative fluid supplementation reduces PONV by improving mesenteric perfusion and preventing gut ischemia[9]. **Sayed et al.** also found that combining dexamethasone with liberal fluid administration was more effective than either alone in pediatric surgical patients[10], while Ismail et al. observed similar improvements in adult patients undergoing laparoscopic cholecystectomy[11].

These findings support the hypothesis that preoperative fasting and intraoperative fluid losses lead to hypovolemia and gut ischemia, increasing serotonin release and triggering PONV[11]. Supplemental crystalloid infusion may correct this physiological disturbance and contribute to reduced PONV and analgesic requirements[12,13].

However, not all studies have confirmed this benefit. **McCaul et al.** and others found no significant difference in PONV with or without fluid infusion, suggesting that the effect may vary depending on fluid type, volume, or surgical context[14]. Furthermore, the impact of fluid type—colloid vs. crystalloid—remains unclear[15].

Despite this variability, our study supports the use of a multimodal strategy for PONV prevention. Dexamethasone alone is effective and well-tolerated[16], and its combination with adequate intraoperative fluid administration (15–30 mL/kg crystalloids) provides additional benefits without added risk[9]. Such an approach addresses both pharmacological and physiological causes of PONV and may represent a practical, low-risk strategy for enhancing patient recovery.

Conclusion:

The present prospective, randomized, double-blinded study demonstrates that the combination of intravenous dexamethasone with intraoperative Ringer lactate infusion at 30 mL/kg is significantly more effective in reducing the incidence of postoperative nausea and vomiting (PONV) compared to dexamethasone alone in patients undergoing laparoscopic cholecystectomy. This combined approach also reduced the need for rescue antiemetics, delayed the requirement for postoperative analgesia, and improved overall patient satisfaction.

The findings support the use of a multimodal prophylactic strategy, incorporating both pharmacologic (dexamethasone) and physiologic (adequate fluid therapy) interventions for effective PONV prevention. Given the simplicity, safety, and cost-effectiveness of this approach, it can be recommended as a routine component of perioperative care in laparoscopic surgeries, particularly in high-risk patients.

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