e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2025; 17(8); 1808-1812

Original Research Article

A Prospective, Randomise Double Blind Study Between Preoperative Nebulised Budesonide and Nebulised Dexamethasone in Reducing Post Operative Sore Throat in Patients Undergoing Laparoscopic Cholecystectomy Under General Anesthesia

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Received: 01-06-2025 / Revised: 16-07-2025 / Accepted: 26-08-2025

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Conflict of interest: Nil

Abstract

Introduction: Postoperative sore throat (POST) is a common complication following general anesthesia, particularly after endotracheal intubation during laparoscopic cholecystectomy. Preoperative nebulisation with corticosteroids may reduce its incidence and severity.

Aims: To compare the efficacy of preoperative nebulised budesonide and nebulised dexamethasone in preventing POST in patients undergoing laparoscopic cholecystectomy under general anesthesia.

Materials and Methods: This hospital-based, prospective, double-blind, randomized controlled study was conducted on patients undergoing laparoscopic cholecystectomy under general anesthesia at Deben Mahata Government Medical College Purulia over 12 months (September 2021–August 2022). Eligible patients meeting the inclusion criteria were randomly assigned to receive either nebulised budesonide (Group B, n=55) or dexamethasone (Group D, n=55) preoperatively. The sample size of 110 accounted for a projected 25% reduction in postoperative sore throat (POST) incidence from a previously reported 56%, with 80% power, 95% confidence, and 10% anticipated dropout. The primary outcome was the incidence and severity of POST, with perioperative monitoring of hemodynamic parameters.

Results: In our study of 110 participants, equally divided into Group-B and Group-D, there were no statistically significant differences between the groups in terms of age, sex, ASA grade, or Mallampati score. Age distribution showed most participants in the 31–40 years range, with 50.9% in Group-D and 30.9% in Group-B ($p = 0.054$). Females comprised 50.9% of Group-B and 41.8% of Group-D, while males were 49.1% and 58.2%, respectively ($p = 0.339$). ASA grade distribution was comparable, with Grade 1 ASA in 52.7% of Group-B and 54.5% of Group-D, and Grade 2 ASA in 47.3% and 45.5%, respectively ($p = 0.8483$). Mallampati scores were similar across groups, with MPS I in 45.45% of Group-B and 41.82% of Group-D, and MPS II in 54.54% and 58.18%, respectively ($p = 0.1470$)

Conclusion: Preoperative nebulisation with either budesonide or dexamethasone effectively reduces the incidence and severity of postoperative sore throat in patients undergoing laparoscopic cholecystectomy under general anesthesia, with both drugs demonstrating comparable efficacy and safety.

Keywords: Postoperative Sore Throat, Budesonide, Dexamethasone, Nebulisation, Laparoscopic Cholecystectomy, General Anaesthesia.

Introduction

Airway management refers to the practice of establishing and securing a patent airway and is the cornerstone of general anaesthesia. Tracheal intubation is the gold standard of airway management. Tracheal intubation is usually facilitated by direct laryngoscopy [1]. Postoperative Sore Throat (POST), represents a broad spectrum of signs and symptoms like laryngitis, pharyngitis, tracheitis, hoarseness, cough or dysphagia and may adversely affect the postoperative satisfaction score and activities of patients after discharge from hospital. Understandably, the incidence of POST is highest in patients with endotracheal intubation, however, POST has also found to be associated

with the use of laryngeal mask airway and bag and mask ventilation [2].

Not only prolonged intubation, but even uneventful intubation for routine surgical procedures can also cause pathological changes that may provide an organic basis for patient's post-operative throat symptoms. Pathological changes secondary to intubation consists of epithelial loss, Glottic hematoma, Glottic edema, Submucosal tears, chronic ulcer Granuloma [3, 4].

Majority of the non-pharmacological interventions are directed at reducing the complications have focused on limiting the physical trauma, use of smaller endotracheal tube to reduce contact area with mucosa [5,6], cuff filled with saline or xylocaine to prevent cuff expansion during anaesthesia [7,8], lignocaine coated ET tube has been tried[9].Pharmacological interventions include trials of various drugs of which steroids, ketamine [10] magnesium sulphate have been found to be effective.

Systemic corticosteroids administered before elective extubation in the critical care setting mitigate inflammatory laryngeal edema due to an endotracheal tube and prevent postextubation airway events.

Dexamethasone is a potent corticosteroid with anti-inflammatory, analgesic, anti-emetic actions with minimal side effects after a single dose administration and is shown to be an effective treatment for moderate to severe pharyngitis. Dexamethasone (in intravenous and aerosolised form) have been individually studied for their potency in attenuating post-operative sore throat in patients undergoing surgery under general anaesthesia.

Budesonide, known to decrease the airway hyper responsiveness, number of inflammatory cells and mediators present in the airways of patients with asthma, was the first formulation designed for drug delivery by means of nebulization in infants and children under 8 years of age with persistent asthma . In the form of preoperative nebulisation as well as by preoperatively by metered dose inhalation. Budesonide has been shown to be effective in reducing POST. Carboperitoneum created at 10-15 mm of Hg for laparoscopic cholecystectomy distends the peritoneal cavity and increases the intra-abdominal pressure. The pressure is transmitted to the thoracic cage thereby raising the endotracheal tube (ETT) cuff pressure and use of nitrous oxide accentuates it [19]. Administration of budesonide significantly reduced the incidence of postoperative cough, hoarseness of voice and POST among subjects undergoing laparoscopic cholecystectomy.

Only literature available on comparison between aerosolised steroid dexamethasone and budesonide in mitigating incidence of postoperative sore throat was in spine surgeries under general anaesthesia in prone position [2], while no study till date reported comparison of nebulised dexamethasone and budesonide in prevention of POST in patients undergoing laparoscopic cholecystectomy.

It was hypothesized that both dexamethasone and budesonide in form of inhalation would be effective in reducing POST in patients undergoing laparoscopic cholecystectomy. Thus, the present randomised control trial was carried out with the primary objective of comparing the efficacy of these two steroids in nebulized form in reducing the incidence and severity of POST, while perioperative hemodynamic and glycemic alteration comparison between the groups being the secondary objectives.

The primary objective of the study was to compare the efficacy of nebulised dexamethasone versus nebulised budesonide in reducing the incidence and severity of postoperative sore throat (POST), including sore throat, cough, and hoarseness. The secondary objectives included comparing perioperative hemodynamic parameters between the two groups and evaluating intra-group and inter-group glycemic changes from the pre-nebulisation period to the postoperative period.

Materials and Methods

Study Design: Hospital based, prospective, double blinded, randomized control study on a cohort of patients undergoing Laparoscopic cholecystectomy under general anaesthesia.

Study Settings and Timeline: The surgery was carried out in Surgery operation theatre complex, PACU, ward of Deben Mahata Government Medical College Purulia for a period of approximately 12 months.

Study Area: Comparison of Nebulised Budesonide and Dexamethasone in reduction of POST in patients undergoing laparoscopic cholecystectomy under general anaesthesia.

Study Period: 12 months from September 2021 to August 2022.

Study Population: All eligible patients who underwent laparoscopic cholecystectomy under general anaesthesia fulfilling the inclusion criteria**.**

Sample Size: 110.

Sample Design: Patients were allocated randomly into two groups after obtaining institutional ethical committee approval and informed consent from patient, after being fully explained about the study procedure. In Group B nebulisation was done with 0.5 mg Budesonide and in Group D nebulisation

was done with 8 mg Dexamethasone in normal saline for 15 minutes in the pre-operative period.

Inclusion Criteria

- Age group between 18-60 years of either sex
- ASA grade 1 or 2.
- Mallampati score of 1-2.
- BMI <30 kg/m²

Exclusion Criteria

- Patients with anticipated difficult airway.
- Patients requiring more than two attempts at intubation or nasogastric tube insertion.
- Patients with pre-operative sore throat or already on steroids (systemic or inhaled).

Study Variables

- Name of patients.
- Age
- Sex
- Weight

Statistically Analysis: Data from the study were analyzed using SPSS software, with continuous variables (e.g., age, liver enzyme levels) expressed as mean ± SD and compared using t-tests or Mann–Whitney U tests. Categorical variables (e.g., gender, CBD stones, and complications) were presented as frequencies and percentages, and compared using Chi-square or Fisher's exact tests. Diagnostic accuracy (sensitivity, specificity, PPV, NPV, and accuracy) was calculated for MRCP-first and EUS-first strategies, using ERCP/intraoperative findings as the reference. Kaplan-Meier analysis may be used for time-to-intervention comparisons. A p-value < 0.05 was considered significant.

Result

Table 1: Association of Study Participants According to Age and Sex in Group-B and Group-D

		Group-B	Group-D	Total	p Value
Age in Group	18-30	15(27.3%)	13(23.6)	28(25.5%)	0.054
	31-40	17(30.9%)	28(50.9)	45(40.9)	
	41-50	16(29.1%)	13(23.6%)	29(26.4%)	
	51-60	7(12.7%)	1(1.8%)	8(7.3%)	
	Total	55(100%)	55(100%)	110(100%)	
Sex	Female	28(50.9%)	23(41.8%)	51(46.4%)	0.339
	Male	27(9.1%)	32(58.2%)	59(53.6%)	
	Total	55(100%)	55(100%)	110(100%)	

Table 2: Association of Study Participants According to ASA Grade and MPS Classification in Group-B and Group-D

		Group-B	Group-D	Total	P Value
ASA Grade	Grade 1	29 (52.7%)	30 (54.5%)	59(53.6%)	0.8483
	Grade 2	26 (47.3%)	25 (45.5%)	51 (46.4%)	
	Total	55(100%)	55(100%)	110 (100%)	
MPS	I	25 (45.45%)	23(41.82%)	48 (43.64%)	0.1478
	II	30 (54.54%)	32 (58.18%)	62 (56.36%)	
	Total	55(100%)	55(100%)	110 (100%)	

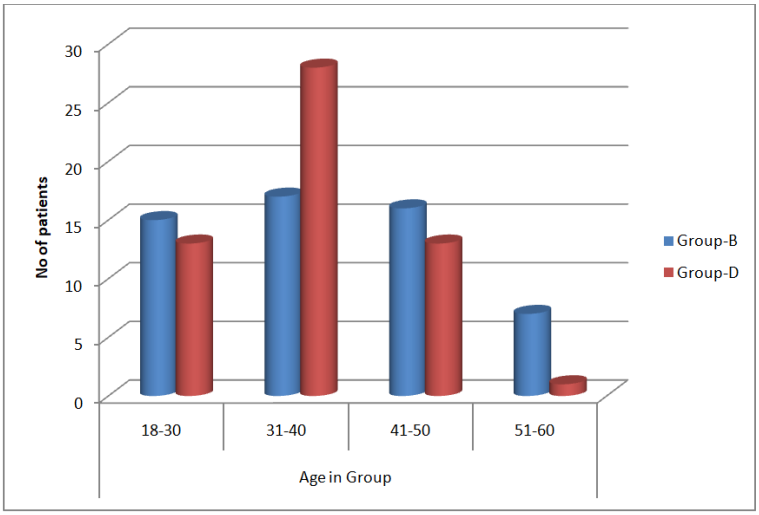

Figure 1: Association of Study Participants According to Age and Sex in Group-B and Group-D

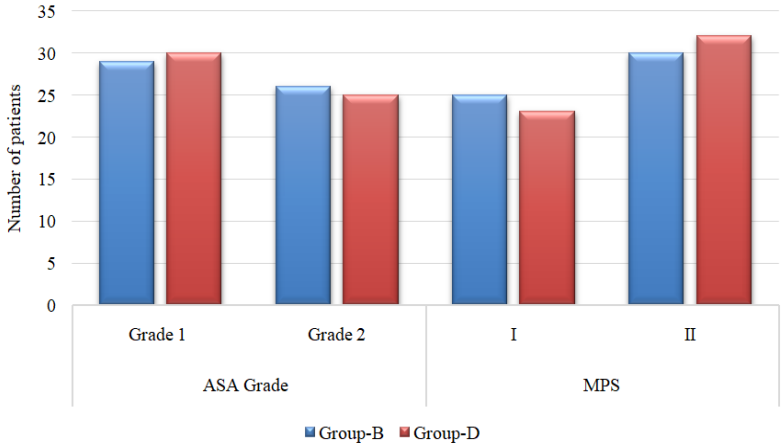

Figure 2: Association of Study Participants According to ASA Grade and MPS Classification in Group-B and Group-D

In our study included a total of 110 participants, equally divided into Group-B and Group-D (55 patients each). The age distribution among the groups was as follows: in the 18–30 years category, 15 patients (27.3%) were in Group-B and 13 patients (23.6%) in Group-D; in the 31–40 years group, 17 patients (30.9%) were in Group-B and 28 patients (50.9%) in Group-D; in the 41–50 years range, 16 patients (29.1%) were in Group-B and 13 patients (23.6%) in Group-D; and in the 51–60 years category, 7 patients (12.7%) were in Group-B and 1 patient (1.8%) in Group-D. The difference in age distribution between the groups was not statistically significant (p = 0.054).Regarding sex distribution, 28 patients (50.9%) in Group-B and 23 patients (41.8%) in Group-D were female, while 27 patients (49.1%) in Group-B and 32 patients (58.2%) in Group-D were male. Next 51 patients (46.4%) were female and 59 patients (53.6%) were male. The difference in sex distribution between the groups was also not statistically significant (p = 0.339).

In our study among the 110 participants, the distribution of ASA grades was comparable between the two groups. In Group-B, 29 patients (52.7%) had Grade 1 ASA and 26 patients (47.3%) had Grade 2 ASA, while in Group-D, 30 patients (54.5%) had Grade 1 and 25 patients (45.5%) had Grade 2. Overall, 59 patients (53.6%) had Grade 1 and 51 patients (46.4%) had Grade 2 ASA. The difference in ASA grade distribution between the groups was not statistically significant (p = 0.8483).

Regarding Mallampatti score (MPS), 25 patients (45.45%) in Group-B and 23 patients (41.82%) in Group-D were classified as MPS I, while 30 patients (54.54%) in Group-B and 32 patients (58.18%) in Group-D were MPS II. Next 48 patients (43.64%) were MPS I and 62 patients (56.36%) were MPS II. The difference between the groups was not statistically significant (p = 0.1478).

Discussion

Postoperative sore throat (POST) is a common complication following general anesthesia with endotracheal intubation, causing significant patient discomfort [11,12]. Various pharmacological interventions have been explored to mitigate this condition, among which corticosteroids, particularly budesonide and dexamethasone, have shown promising results [13,14].

Budesonide, a potent inhaled corticosteroid, has been reported to significantly reduce the incidence and severity of POST, hoarseness, and cough in patients undergoing endotracheal intubation [15,16]. Similarly, dexamethasone has been evaluated for POST prevention, with studies showing its preoperative administration reduces the incidence and severity of POST, and may also decrease postoperative hoarseness [17,18].

Comparative studies have highlighted the relative efficacy of these two agents. Rani Devi et al. found that both budesonide and magnesium sulfate nebulization were effective in reducing POST, with no significant difference between the groups [19]. Kad et al., however, reported that budesonide nebulization resulted in lower grades of POST, hoarseness, and cough compared to dexamethasone, suggesting a potential advantage of budesonide for airway comfort postoperatively [16] .Overall, both preoperative nebulized budesonide and dexamethasone are effective in reducing POST in patients undergoing laparoscopic cholecystectomy under general anesthesia. While both agents are beneficial, budesonide may offer additional advantages in reducing hoarseness and cough. Further head-to-head studies are warranted to establish definitive recommendations for prophylaxis against POST [15,16,19,20].

Conclusion

The present prospective, randomized, double-blind study demonstrated that preoperative nebulisation with budesonide significantly reduced both the incidence and severity of postoperative sore throat in patients undergoing laparoscopic cholecystectomy under general anaesthesia, compared with nebulised dexamethasone. The beneficial effect of budesonide was evident in the early postoperative period and persisted for up to 12 hours without any observed drug-related adverse effects. Given its favourable safety profile, ease of administration, and superior efficacy, preoperative budesonide nebulisation may be considered a simple and effective prophylactic measure for improving postoperative patient comfort in elective laparoscopic surgeries requiring endotracheal intubation.

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