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Randomized Controlled Trial Comparing the Effects of Intravenous Dexamethasone and Dexmedetomidine on Post-Operative Sore Throat in Laparoscopic Cholecystectomy

Mohammad Fariduddin Malik[1], Manish Kumar[2]

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Abstract

Introduction Post-operative sore throat (POST) is a common complication after endotracheal intubation, influenced by various factors. Dexamethasone, an anti-inflammatory, and dexmedetomidine, an alpha-2 adrenergic agonist, have both been studied for POST prevention. This trial compared their efficacy in patients undergoing laparoscopic cholecystectomy.

Materials and Methods In this two-year, double-blind, randomized trial, 60 adults undergoing elective laparoscopic cholecystectomy were divided into two groups: Group 1 received dexamethasone (0.2 mg/kg, max 8 mg), and Group 2 received dexmedetomidine (1 µg/kg). POST incidence and severity were assessed, with statistical significance set at $p<0.05$.

Results No significant differences were found in age, gender, or BMI between the groups. Group 2 showed lower heart rates and MAP post-intubation. POST incidence was 33.33% in Group 1 and 46.66% in Group 2 ($p=0.354$), with comparable POST severity and complications.

Conclusion: The incidence and severity of post-operative sore throat and hoarseness were similar while using dexamethasone and dexmedetomidine in patients undergoing elective laparoscopic cholecystectomy under general anaesthesia.

Keyword: Dexamethasone and Dexmedetomidine, Cholecystectomy, Anti-inflammatory.

Author's Affiliation: [1,2] Resident Department of Anaesthesiology and Critical Care, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh 202001, Uttar Pradesh, India.

Corresponding author: Mohammad Fariduddin Malik, Resident Department of Anaesthesiology and Critical Care, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh 202001, Uttar Pradesh, India.

E-mail: faridmalik1387@gmail.com

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INTRODUCTION

Post-operative sore throat (POST) is a prevalent and often distressing complication following endotracheal intubation, experienced by patients undergoing various surgical procedures. Its incidence ranges widely from 14.4% to 90%, influenced by factors such as the size and type of the endotracheal tube, cuff pressure, the duration of intubation, use of suctioning, and patient positioning during surgery.[1-3] These factors contribute to mucosal injury, leading to epithelial loss, glottic hematoma, edema, submucosal tears, and contact ulcer granulomas primarily affecting the vocal cords and epiglottis.

In laparoscopic cholecystectomy, a widely performed minimally invasive procedure, general anesthesia and endotracheal intubation are common, making POST a significant concern for patient recovery and comfort. The procedure requires precision and attention to factors that may increase the risk of POST, adding complexity to the postoperative care required for such patients.

Various pharmacological interventions have been explored to mitigate POST and hoarseness in patients, including lidocaine, ketamine, magnesium sulfate, benzydamine hydrochloride, gabapentin, and corticosteroids like hydrocortisone and dexamethasone. Among these, dexamethasone and dexmedetomidine stand out due to their unique properties.[4,5]

Dexamethasone is a corticosteroid with potent anti-inflammatory effects, reducing edema and suppressing inflammatory mediators around the tracheal mucosa. Its systemic action provides comprehensive relief from POST by addressing underlying inflammation. Pre-operative administration of dexamethasone has been shown to significantly reduce the incidence and severity of POST and hoarseness.[6-10]

Dexmedetomidine, an alpha-2 adrenergic agonist, also offers significant benefits for POST by reducing the stress response and inflammation caused by intubation. Its sedative and analgesic effects, without respiratory depression, make it a unique agent for POST management, potentially reducing opioid use while providing anti-inflammatory benefits.[11-15]

Although both drugs have been individually studied for their efficacy in POST prevention, direct comparisons between dexmedetomidine and dexamethasone are limited, especially in laparoscopic cholecystectomy patients. This randomized controlled trial aimed to fill this gap by evaluating and comparing the effectiveness of intravenous dexamethasone and dexmedetomidine in reducing POST. The primary outcome focused on the incidence of POST, while secondary outcomes include severity, duration, incidence of hoarseness, and potential complications.

MATERIALS AND METHODS

The study was conducted over a period of two years, from 2022 to 2024. It was designed as a prospective, randomized, double-blind trial, with a total of 60 adult participants undergoing laparoscopic cholecystectomy. The study took place in the Department of Anaesthesiology at Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Aligarh. Ethical approval was obtained from the institution's ethical committee (Ref No/IECJNMC/789, dated 21/10/2023), and the study was registered with the Indian Clinical Trials Registry (CTRI/2024/03/064770).

The study population included patients aged 25-55 years, with a weight range of 30-80 kg, classified as ASA grade 1 and 2, who were scheduled for elective laparoscopic cholecystectomy. Patients were excluded if they had a history of steroid use, surgery lasting more than an hour, smoking, diabetes mellitus, pregnancy, recent respiratory tract infections, NSAID use within 24 hours of surgery, or significant comorbidities like cardiac, hepatic, or major renal diseases.

Patients were randomized into two groups using computer-generated codes. Group 1 received dexamethasone at a dose of 0.2 mg/kg (maximum 8 mg) in 10 ml volume over 10 minutes, while Group 2 received dexmedetomidine at 1 µg/kg in 10 ml volume over 10 minutes. All patients were premedicated with midazolam (0.03 mg/kg) and fentanyl (2 µg/kg). Induction was achieved using propofol (2 mg/kg), and muscle relaxation was facilitated with vecuronium (0.08 mg/kg). Orotracheal intubation was performed with cuffed endotracheal tubes (sizes 6.5-8.0 mm based on gender), and cuff pressure was maintained at 20 cm HO.

Laryngoscopy and intubation times were recorded in seconds, measured from device insertion to confirmation by capnography. The incidence of post-operative sore throat (POST) and hoarseness was assessed, with POST graded on a 4-point scale (0-3), and hoarseness on a separate

4-point scale.[16,17] Complications such as blood staining, dental injury, and lip injury were also documented.

Statistical analysis was performed using SPSS software (ver. 25.0). Categorical data were presented as numbers and percentages, while quantitative data were expressed as means ± SD. Normality of the data was assessed using the Shapiro-Wilk test, and depending on the distribution, either a t-test or non-parametric tests were applied for quantitative variables. Qualitative variables were analyzed using the Chi-square test or Fisher's exact test when necessary. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The age distribution in the study population revealed that within the 25-35 years age group, Group 1 had 12 patients (40%) while Group 2 had 6 patients (20%). In the 36-45 years category, Group 1 had 14 patients (46.66%) compared to 19 patients (63.34%) in Group 2. For the 46-55 years age group, Group 1 had 4 patients (13.34%) and Group 2 had 5 patients (16.66%) with a p-value of 0.082, indicating no statistically significant difference between the groups. The mean age was 37.53 ± 6.56 years for Group 1 and 40.03 ± 5.14 years for Group 2, also showing no significant difference with a p-value of 0.082.

In terms of gender distribution, Group 1 included 9 males (30%) and 21 females (70%), while Group 2 had 10 males (33.33%) and 20 females (66.67%), resulting in a p-value of 0.801, suggesting no significant gender difference. Regarding Body Mass Index (BMI), 21 participants (70%) in Group 1 had a normal BMI of 18.5-24.9 kg/m², while 9 (30%) were classified as overweight. In Group 2, 23 participants (76.64%) had a normal BMI and 7 (23.33%) were overweight, with a p-value of 0.851 indicating no significant difference. The mean BMI was similar between the groups, with Group 1 at 23.59 ± 2.23 kg/m² and Group 2 at 23.48 ± 1.99 kg/m² (p=0.851).

Regarding ASA grade distribution, Group 1 had 21 participants (70%) classified as ASA Grade 1 and 9 (30%) as ASA Grade 2, whereas Group 2 had 26 (86.66%) in Grade 1 and 4 (13.34%) in Grade 2. The p-value of 0.057 indicated no significant difference, although Group 2 had a slightly higher proportion of healthier individuals. Heart rate measurements showed that Group 1 had a mean pre-intubation heart rate of 83.80 ± 7.09 bpm, while Group 2 had a higher rate of 93.23 ± 6.97 bpm (p=0.000). Post-intubation, Group 1's heart rate increased slightly to 85.53 ± 8.86 bpm, whereas Group 2's decreased to 78.93 ± 6.31 bpm (p=0.003). Significant differences persisted across all time points except at 24 hours post-intubation, where the heart rates were 84.73 ± 7.22 bpm for Group 1 and 89.23 ± 17.84 bpm for Group 2 (p=0.195).

Mean Arterial Pressure (MAP) results demonstrated that Group 1 had a pre-intubation MAP of 85.23 ± 3.30 mmHg compared to 87.96 ± 5.66 mmHg for Group 2 (p=0.016). Post-intubation, Group 1's MAP was 84.63 ± 5.02 mmHg, while Group 2's MAP was 81.03 ± 6.16 mmHg (p=0.008). However, no significant differences were observed at later time points. Oxygen saturation (SpO2) levels remained similar across groups at all intervals measured, with no significant differences found. The incidence of postoperative sore throat was reported by 10 participants (33.33%) in Group 1 and 14 (46.66%) in Group 2, leading to a p-value of 0.354, indicating no significant difference. In terms of severity, 66.66% of patients in Group 1 had no sore throat (Grade 0), compared to 53.33% in Group 2. Mild sore throat (Grade 1) was observed in 26.66% of patients in Group 1 and 36.66% in Group 2, while moderate sore throat (Grade 2) occurred in 6.66% of Group 1 and 10% of Group 2. The p-value of 0.326 for the severity comparison also suggests no significant difference between the groups. (table 1)

Table 1: Severity of post-operative sore throat in the Study Population

Severity	Group 1 N (%)	Group 2 N (%)	p-Value
Grade-0	20 (66.66%)	16 (53.33%)	
Grade-1	08 (26.66%)	11 (36.66%)	0.326
Grade-2	02 (06.66%)	03 (10%)	

The incidence and severity of hoarseness post-operatively shows no statistically significant difference between the two groups. In terms of incidence, 26.66% of participants in Group 1 experienced hoarseness, compared to 40% in Group 2. When analyzing the severity, Group 1 had a

higher proportion of participants (73.33%) with no hoarseness (Grade 0) compared to 60% in Group 2. Mild hoarseness (Grade 1) was reported by 26.66% of Group 1 participants and 40% in Group 2 which was not statistically significant. (Table 2)

Table 2: Severity of Hoarseness in the Study Population

Severity	Group 1 No (%)	Group 2 No (%)	p-Value
Grade-0	22 (73.33%)	18 (60%)	0.326
Grade-1	08 (26.66%)	12 (40%)	

Lastly, in terms of complications, blood staining occurred in 6.66% of Group 1 and 10% of Group 2 participants, while dental injuries were noted in 3.33% of Group 1 and 6.66% of Group 2. Lip injuries were reported in 10% of Group 1 and 6.66% of Group 2. Overall, the data suggested no significant differences in complication rates between the two groups, indicating comparable outcomes across the study population. (Fig. 1)

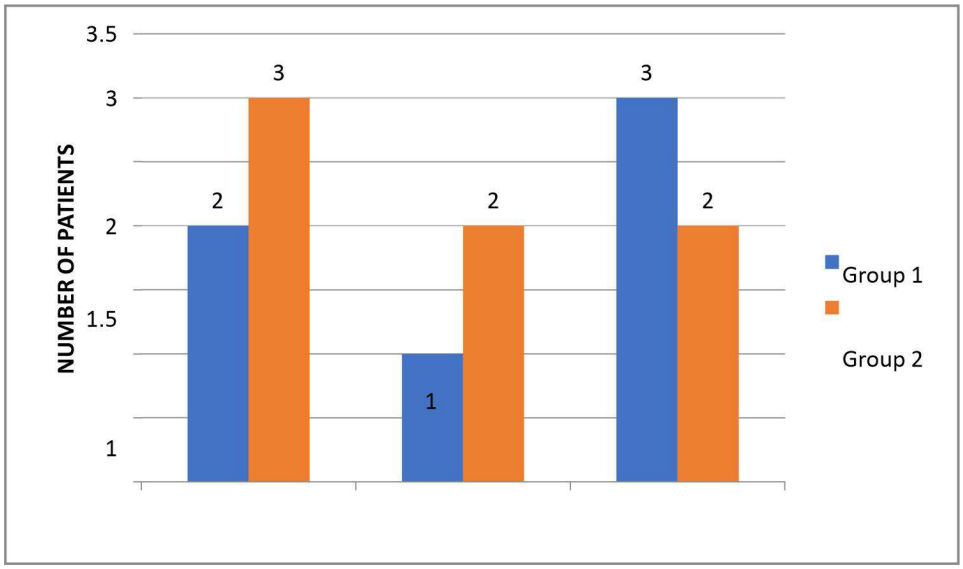

Fig. 1: Complications in the two groups

DISCUSSION

The study evaluated several parameters, including age, gender, BMI, ASA grade, heart rate, mean arterial pressure (MAP), oxygen saturation, and the incidence, severity, and duration of post-operative sore throat and hoarseness.

Dexamethasone, a potent corticosteroid, effectively reduces inflammation and edema, making it suitable for treating post-intubation sore throat and airway swelling. It inhibits phospholipase-A2 and cyclo-oxygenase, lowering inflammatory mediators. While intravenous use can lead to side effects like adrenal suppression and glucose intolerance, a single dose usually avoids major adverse effects. In contrast, dexmedetomidine, an α2 receptor agonist, reduces sympathetic activity and catecholamine release, alleviating perioperative stress and inflammation. By inhibiting neurotransmitter release at α2A receptors, it provides sedation and analgesia while modulating pain through α2B receptors, contributing to its effectiveness in reducing post-operative sore throat.

The study found no significant differences in age or gender distribution between the two groups, indicating these factors did not influence outcomes related to post-operative sore throat or hoarseness. Both groups also had similar BMI distributions and ASA grades, with no statistically significant effect on the incidence or severity of

post-operative sore throat. The heart rate and MAP were significantly different between the groups, with dexmedetomidine causing a notable decrease in heart rate and MAP due to its bradycardic and hypotensive effects. Oxygen saturation levels remained consistent between the groups at all time points, reflecting effective oxygenation management.

In our study, the incidence of post-operative sore throat was 33.33% in the dexamethasone group and 46.66% in the dexmedetomidine group. Although the dexmedetomidine group had a higher incidence, the difference was not statistically significant (p=0.354). This suggests that the use of either dexamethasone or dexmedetomidine in patients undergoing laparoscopic cholecystectomy under general anesthesia results in a similar incidence of post-operative sore throat. There is no existing study comparing these two drugs directly in the literature. However, Choi E et al. (2023)[15] found that dexmedetomidine significantly reduced the incidence and severity of post-operative sore throat compared to remifentanil in spinal surgery patients, highlighting dexmedetomidine's efficacy as a prophylactic agent against post-operative sore throat. Similarly, Munir N et al. (2022)[18] observed a significant reduction in the incidence of sore throat in patients receiving dexamethasone compared to saline before abdominal and gynecological surgeries, emphasizing dexamethasone's protective effect. These findings align with results reported by Thomas S et al. (2020)[19], who found no significant difference in post-operative sore throat incidence between patients receiving nebulized dexmedetomidine and ketamine (14.3% vs. 20.4%, p=0.424). Ghatani R et al. (2020)[20] also observed varying incidences of post-operative sore throat with different agents (ketamine, dexamethasone, and saline), though significant differences were noted only at specific time points, underscoring the importance of evaluating post-operative sore throat at multiple intervals. concise little bit Regarding the severity of post-operative sore throat, 66.66% of participants in the dexamethasone group experienced no sore throat (Grade 0), compared to 53.33% in the dexmedetomidine group, with no statistically significant difference (p=0.326). This contrasts with the findings of Niu J et al. (2022),[21] who demonstrated that a combination of dexmedetomidine and ropivacaine for surface anesthesia before intubation significantly reduced the severity of post-operative sore throat compared to ropivacaine alone. Their study, conducted in spinal surgery patients, highlights the potential benefits of combining agents for reducing sore throat severity. In contrast, studies like those by Kuriyama A et al. (2019)[22] and Jiang Y et al. (2018)[23] indicated that dexamethasone significantly reduced the incidence and severity of post-operative sore throat compared to placebo, possibly due to factors like operator inexperience, elevated cuff pressure, and larger tracheal tubes. While dexamethasone has shown efficacy in reducing post-operative sore throat, the lack of significant findings in our study may be attributable to differences in study protocols, including intervention timing and dosage. The mean duration of post-operative sore throat was similar between the two groups (12.0 ± 3.90 hours in the dexamethasone group vs. 12.14 ± 4.25 hours in the dexmedetomidine group, p=0.578), indicating that both groups had comparable experiences regarding the duration of sore throat. This finding is consistent with studies by Kadar M et al. (2015)[24] and Lee S et al. (2016),[25] which found no significant differences in the duration of post-operative sore throat between patients receiving different treatments, including dexamethasone and lignocaine. Similarly, Song Z et al. (2021)[26] reported that both dexamethasone and dexmedetomidine provided comparable durations of analgesia in peripheral nerve blocks. The incidence of post-operative hoarseness was 30% in the dexamethasone group and 40% in the dexmedetomidine group, with no significant difference between the two groups (p=0.448). Additionally, the severity of hoarseness did not differ significantly, though the dexmedetomidine group had a slightly higher percentage of Grade 1 hoarseness (40%) compared to the dexamethasone group (26.66%). This finding is in line with the study by Kim et al. (2020)[27], which evaluated the impact of dexmedetomidine and remifentanil on post-operative sore throat and found that dexmedetomidine was associated with a lower incidence and severity of both post-operative sore throat and hoarseness in thyroidectomy patients. However, the absence of a significant difference in our study may suggest that other factors, such as individual patient characteristics or surgical techniques, could play a more substantial role in the development of hoarseness. These results align with those of Zhao X et al. (2015)[28], who found that dexamethasone was effective in reducing hoarseness one hour post-extubation, though its effect was not significant at the 24-hour mark. Similarly, Manandhar K et al. (2018)[29] observed that dexamethasone reduced the incidence and severity of hoarseness shortly after surgery. In our study, surgical duration, intubation time, and the number of intubation attempts did not differ significantly

between the groups.[30] Additionally, complication rates, including blood staining, dental injury, and lip injury, were comparable with no significant findings. Overall, the study demonstrated that both dexamethasone and dexmedetomidine were effective in managing post-operative sore throat, with no significant differences in their efficacy, though dexmedetomidine may offer additional benefits in terms of sedation and pain modulation.

CONCLUSION

The incidence and severity of post-operative sore throat and hoarseness were similar while using dexamethasone and dexmedetomidine in patients undergoing elective laparoscopic cholecystectomy under general anaesthesia.

LIMITATION

The study's limitations include a focus on healthy ASA Grade 1 and 2 patients, restricting applicability to ASA Grade 3 and 4 populations. Findings from elective laparoscopic cholecystectomy patients may not extend to emergency procedures. The age range of 25-55 years limits applicability to geriatric and pediatric groups, while the small sample size prevents generalization to the broader population. Conducted at a single center, results may not reflect other settings. The short follow-up period only captured immediate post-operative effects, potentially missing long-term outcomes. Additionally, variability in dosing regimens could influence efficacy comparisons.

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