

# Effect of intracuff dexamethasone on incidence and severity of post operative sore -Prospective randomized study

Sunil Rajan, Naina Narayani, Jerry Paul, Lakshmi Kumar

Department of Anaesthesiology, Amrita Institute of Medical Sciences, Amrita Vishwa Vidyapeetham, Kochi, India

## Abstract

**Background and Aims:** Postoperative sore throat (POST) continues to be a common concern following endotracheal intubation. Objectives of the present study were to compare the effects of intracuff dexamethasone on the incidence and severity of POST, postoperative hoarseness of voice (POHV) and cough (POC).

**Material and Methods:** This prospective, randomized, double blinded study was conducted in 60 patients undergoing short laparoscopic surgery lasting <2 h. Patients were randomly allocated into Group A and B. After intubation, endotracheal tube (ETT) cuffs were filled with saline in group A and with 0.1 mg/kg dexamethasone in group B. All patients received general anesthesia as per a standardized protocol. Incidence and severity of POST, POC, and POHV were assessed.

**Results:** As compared to group A, the number of patients who had sore throat was significantly low in group B at 2, 6, 12, and 24 h ( $P < 0.001$ ). Though more number of patients in group A had postop cough at all time points and postop hoarseness of voice at 2, 6, and 12 h, the difference was statistically significant only at 2 h and 6 h for both. Severity as well as the incidence of POST, POC, and POHV showed a downward trend in both groups with time. In group B, no patient had POST after 12 h, POC after 6 h, and none complained of POHV in the postoperative period.

**Conclusion:** Intracuff dexamethasone 0.1 mg/kg significantly reduces incidence and severity of POST, POC, and POHV which occur following general anesthesia with endotracheal intubation in patients undergoing short pelvic laparoscopic procedures lasting <2 h.

**Keywords:** Cough, dexamethasone, hoarseness, postoperative, sore throat

## Background

Ever since the adoption of endotracheal intubation into anesthesia practice, concerns regarding postoperative sore throat (POST) began, which continues till date. Although it is a self-limiting condition, it may delay discharge after day care surgeries. The incidence of POST can be as high as 45.4% following intubation and the common predictors are airway management, female sex, younger patients, gynecological surgeries, and succinylcholine.<sup>[1]</sup>

Many modalities of intervention have been tried to prevent its development, but not all yielded promising results. Of late, studies have shown that use of intracuff dexamethasone can be an effective method in reducing postoperative pharyngo-laryngeal complications.<sup>[2-4]</sup> The primary objective of the present study was to compare the effect of intracuff dexamethasone on the incidence and severity of POST. The secondary objectives included comparison of the effect on postoperative hoarseness of voice (POHV) and cough (POC).

Address for correspondence: Dr. Sunil Rajan,  
Department of Anaesthesiology, Amrita Institute of Medical Sciences,  
Kochi, Kerala, India.  
E-mail: sunilrajan@aims.amrita.edu

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## Material and Methods

This prospective, randomized, double blinded study was conducted after obtaining hospital ethical committee clearance and patients' consent. The study was registered in Clinical Trial Registry of India (CTRI/2019/01/016992). Sixty patients aged 18 years to 60 years with American Society of Anesthesiologists (ASA) Physical status 1-2 undergoing short laparoscopic surgery lasting less than 2 h like diagnostic pelvic laparoscopy and laparoscopic sterilization were included in the study. While those who required nasogastric tube insertion, three or more attempts at laryngoscopy or bougie for intubation were excluded from the study. Those who sustained trauma while intubation or nasogastric tube insertion as evidenced by blood on cuff after extubation or blood stained secretions while suctioning before extubation, MP score of 3,4, those with preoperative sore throat (edema/inflammation noticed during laryngoscopy) or already on analgesics or steroids (systemic or inhaled) and hoarseness of voice or respiratory infection were also excluded.

Patients were randomly allocated into Group A and B with 30 patients in each group who received intracuff saline and 0.1 mg/kg of dexamethasone, respectively. Randomization was done using computer generated random sequence of numbers and allocation concealment was ensured using sequentially numbered opaque-sealed envelopes.

All patients received general anesthesia as per a standardized protocol. They were preoxygenated with 100% oxygen for 3 min followed by intravenous glycopyrrolate 0.2 mg, midazolam 1 mg, and fentanyl 2 µg/kg. Patients were induced with propofol 1.5 to 2.5 mg/kg and were mask ventilated with isoflurane 1% in oxygen. Vecuronium 0.1 mg/kg IV was administered after induction, and 3 min later, the patients were intubated following a gentle and quick laryngoscopy lasting not more than 15 s with a low-pressure, high-volume cuffed poly vinyl chloride endotracheal tube (ETT). In male and female patients, 8 mm and 7 mm internal diameter tubes were used, respectively. All intubations were performed by the same anesthesiologist and were confirmed with bilateral air entry on auscultation and appearance of regular end tidal capnographic waveform. ETT cuffs were filled with minimal volume of test solution required to prevent a leak audible to ear. In group B, the calculated dose of dexamethasone was initially injected to ETT cuff followed by required volume of saline.

Anesthesia was maintained using oxygen in air (1:2) with 1–1.2% isoflurane (end tidal, 0.7 to 1 MAC) and intermittent positive pressure ventilation maintaining endtidal carbon dioxide levels at 30–35 mm Hg. Vecuronium 0.05 mg/kg was repeated

at 30-min interval to provide muscle relaxation. Paracetamol 1 gm was intravenously administered half an hour after induction. Rise in heart rate and/or mean arterial pressure more than 20% from the baseline value was initially treated with increasing the inspired concentration of isoflurane to 1.5–2% transiently. If not responding, fentanyl was repeated at 0.5 µg/kg as boluses.

At the end of surgery, ondansetron 0.1 mg/kg was given intravenously and the residual muscle paralysis was reversed with neostigmine 0.05 to 0.07 mg/kg and glycopyrrolate 10 µg/kg IV. Extubation was performed following gentle oro-pharyngeal suctioning. Postoperatively all patients received paracetamol 1 gm at 8-h interval and tramadol 1.5 mg/kg on demand intravenously. If this failed to control surgical site pain, intravenous fentanyl 0.5 µg/kg incremental boluses were given. Total perioperative opioid consumption and duration of intubation were also documented.

POST, POHV, and POC were assessed at 2, 6, 12, and 24 h based on the scales described in Table 1,<sup>[5]</sup> by a nursing staff in the postoperative care unit who was unaware of the intervention performed intraoperatively. The patients were also blinded to the type of solution used to fill the cuff. Those with grade III sore throat were managed with dispersible Aspirin 75 mg gargle, which was repeated as many times as needed till there was relief from the symptoms.

As there was no similar study published in the past with the dose of the test drug we intended to use, we conducted a pilot study with 20 patients in two groups with one group receiving intracuff dexamethasone and the other saline. Incidence of POST at 2 h was found to be 10% in dexamethasone group as compared to 55% in saline group. Based on this result with 99% power and 20% error, sample size was calculated as 26 per group using the formula  $n = (Z^{\alpha/2} + Z^{\beta})^2 \times [P_1(1 - P_1) + P_2(1 - P_2)] \div (P_1 - P_2)^2$ . However, we recruited a total of 60 patients in our study.

Pearson's Chi-square test or Fisher's exact test was used to compare categorical variables such as distribution of gender, Mallampatti score and ASA physical status, number of attempts at intubation as well as incidence, and severity of POST, POHV, and POC. Independent sample *t*-test was used to compare continuous variables such as age, weight, intraoperative opioid consumption, and duration of intubation among the groups. Statistical analyses were performed using SPSS Version 20.0 for Windows (IBM Corporation ARMONK, NY, USA).

## Results

Both groups were comparable with respect to mean age

and weight, distribution of sex, ASA physical status, and Mallampatti score. Both group A and B had comparable intraoperative fentanyl consumption. However, the duration of intubation was significantly longer in Group B ( $114.4 \pm 3.04$  vs.  $105.03 \pm 10.85$  min,  $P = <0.001$ , [Table 2]).

While comparing the presence or absence of postop sore throat, hoarseness of voice, and cough among the groups, it was found that compared to group A, the number of patients who had sore throat was significantly low in group B at 2, 6, 12, and 24 h ( $P < 0.001$ ). Although more patients in group A had postop cough at all time points and postop hoarseness of voice at 2, 6, and 12 h, the difference was statistically significant only at 2 h and 6 h for both [Table 3]. Severity as well as the incidence of POST showed a downward trend in both groups with time [Figure 1]. Similar trend was seen with hoarseness of voice and cough as well [Figures 2 and 3].

## Discussion

In the present study, it was observed that incidence and severity of POST, POHV, and POC were significantly lower when ETT cuffs were filled with dexamethasone. In this group, no patient had POST after 12 h, POC after 6 h, and none complained of POHV.

Endotracheal intubation imparts safety by protecting the airway, but with a higher risk of postoperative sore throat. The proposed mechanisms include an aseptic inflammatory process caused by irritation of the pharyngeal mucosa during laryngoscopy, and continued irritation of tracheal mucosa due to the presence of ETT cuff. Another major contributing factor is trauma that might occur during laryngoscopy and intubation.<sup>[6-8]</sup> Various drugs and routes of administration have been tried to prevent and treat POST.

Steroids continue to play a major role in preventing and managing these post-extubation respiratory complications. Betamethasone gel,<sup>[9]</sup> budesonide inhalation,<sup>[10]</sup> intravenous dexamethasone,<sup>[11]</sup> and hydrocortisone<sup>[12]</sup> have proven their efficacy in this regard. A meta-analysis of seven RCTs have shown that intravenous dexamethasone reduces the risk and severity of POST, the effective dosage being over 0.1 mg/kg.<sup>[13]</sup> The potential mechanism of intracuff dexamethasone is presumably based on its anti-inflammatory activity, which includes inhibition of leukocyte migration, maintenance of cell membrane integrity, attenuation of lysosome release, and reduction of fibroblast proliferation.<sup>[6]</sup>

Anesthetic gases and lipophilic drugs diffuse through ETT cuff by permeation. It is a three-step process: adsorption onto

**Table 1: Assessment of severity of postoperative sore throat, cough, and hoarseness of voice**

Postoperative sore throat	
Severity	Grade
No sore throat at any time since the operation	0
Minimal-Patient answered in the affirmative when asked about sore throat	1
Moderate-Patient complained of sore throat on his/her own	2
Severe-Patient is in obvious distress	3
Postoperative cough	
No cough at any time since the operation	0
Minimal	1
Moderate	2
Severe	3
Postoperative hoarseness of voice	
No complaint of hoarseness at any time since the operation	0
Minimal-Minimal change in quality of speech. Patient answers in the affirmative only when enquired about	1
Moderate-Moderate change in quality of speech of which the patient complains on his/her own	2
Severe-Gross change in the quality of voice perceived by the observer	3

**Table 2: Comparison of demographics, ASA physical status, Mallampatti score, intraoperative fentanyl consumption, and duration of intubation**

Continuous variables	Group A Mean $\pm$ SD	Group B Mean $\pm$ SD	P
Age in years	44.3 $\pm$ 16.1	49.8 $\pm$ 16.7	0.193
Weight in kg	61.6 $\pm$ 10.8	67.9 $\pm$ 10.4	0.055
Height in cm	159.5 $\pm$ 8.4	162.7 $\pm$ 8.5	0.145
Fentanyl consumption in $\mu$ g	139.8 $\pm$ 43.7	135.0 $\pm$ 45.9	0.678
Duration of intubation in min	105.03 $\pm$ 10.85	114.4 $\pm$ 3.04	<0.001*
Categorical variables	n	n	
Gender			
Male	10 (33.3)	12 (40.0)	0.592
Female	20 (66.7)	18 (60)	
Mallampatti score			
1	22 (73.3)	16 (53.3)	0.180
2	8 (26.7)	14 (46.7)	
ASA physical status			
I	14 (46.7)	12 (40.0)	0.602
II	16 (53.3)	18 (60.0)	

SD=Standard deviation, ASA=American Society of Anesthesiologists

the polymer, diffusion across the bulk of the polymer, and desorption on to the tracheal mucosa. Only minute amount of drug diffuses across the cuff and exert anti-inflammatory action on the mucosa.<sup>[14]</sup> Although perioperative single-dose dexamethasone was not found to be associated with the increased risk of infection or delayed wound healing, it results in slight hyperglycemia on the first postoperative day.<sup>[15]</sup> When it is used inside the ETT cuff, the chance of developing even this side effect becomes minimal.

Use of nitrous oxide during general anesthesia is shown to increase intracuff pressure and results in an increased

**Table 3: Comparison of incidence of postop sore throat, cough, and hoarseness of voice**

Time	Occurrence	Group A n	Group B n	P
Postoperative sore throat				
2 h	No	3 (10.0)	26 (86.7)	<0.001*
	Yes	27 (90.0)	4 (13.3)	
6 h	No	6 (20.0)	29 (96.7)	<0.001*
	Yes	24 (80.0)	1 (3.3)	
12 h	No	17 (56.7)	30 (100.0)	<0.001*
	Yes	13 (43.3)	-	
24 h	No	19 (63.3)	30 (100.0)	<0.001*
	Yes	11 (36.7)	-	
Postoperative cough				
2 h	No	4 (13.3)	28 (93.3)	<0.001*
	Yes	26 (86.7)	2 (6.7)	
6 h	No	16 (53.3)	30 (100.0)	<0.001*
	Yes	14 (46.7)	-	
12 h	No	24 (80.0)	30 (100.0)	<0.024*
	Yes	6 (20.0)	-	
24 h	No	27 (90.0)	30 (100.0)	<0.237
	Yes	3 (10)	-	
Postoperative hoarseness of voice				
2 h	No	5 (16.7)	30 (100)	<0.001*
	Yes	25 (83.3)	-	
6 h	No	17 (56.7)	30 (100)	<0.001*
	Yes	13 (43.3)	-	
12 h	No	24 (80.0)	30 (100)	0.024*
	Yes	6 (20.0)	-	
24 h	No	30 (100)	30 (100)	NA
	Yes	-	-	

\*Statistically significant

incidence of POST when cuff is filled with air.<sup>[16]</sup> This is because nitrous oxide diffuses into air-filled cuff faster than nitrogen can escape from it, leading to increase in volume and, subsequently, pressure inside cuff.<sup>[17]</sup> Filling an ETT cuff with a liquid possibly prevents rise in intracuff pressures intraoperatively.<sup>[18,19]</sup> The reason for the relatively stable cuff pressure with liquid media is liquids do not expand when gases dissolve in them. The mean number of cuff deflations required to maintain baseline intracuff pressure was found to be less when liquid media was used to inflate ETT cuff during general anesthesia.<sup>[20]</sup> This could have also contributed to lesser incidence and severity of the postoperative pharyngolaryngeal complications observed in our study.

Few studies have tested the efficacy of intracuff steroids on attenuating POST. Rafiei *et al.*<sup>[2]</sup> investigated the effect of intracuff dexamethasone and concluded that it was effective in reducing the severity of POC and not effective in reducing the incidence or severity of POST and POHV. Conflicting results were observed by Choubsaz *et al.*<sup>[21]</sup> who found that inflating ETT cuff with dexamethasone 4 mg did not reduce POST. However, in our study, we observed a reduction

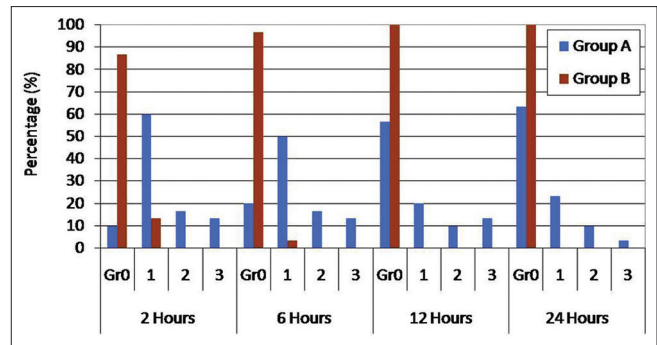


Figure 1: Incidence and severity of postoperative sore throat

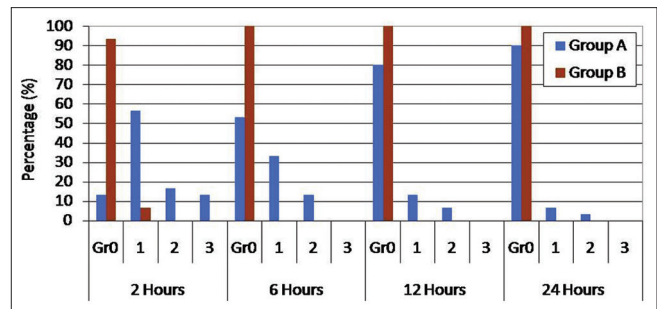


Figure 2: Incidence and severity of postoperative cough

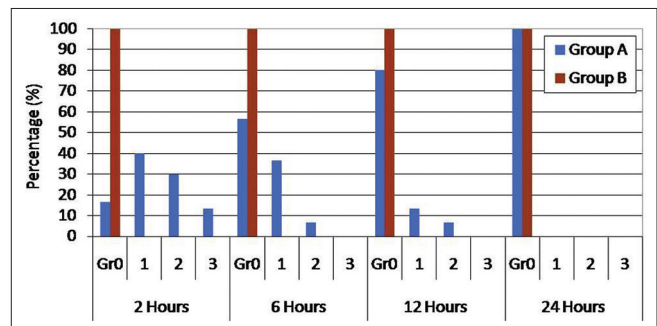


Figure 3: Incidence and severity of postoperative hoarseness of voice

in POST with intracuff dexamethasone. This could be because we used a higher concentration of dexamethasone like 0.1 mg/kg, whereas in the study by Choubsaz *et al.*<sup>[21]</sup> a fixed dose of 4 mg was used to inflate the cuff irrespective of body weight. The study by Desai *et al.*<sup>[3]</sup> had showed that intracuff alkalized lignocaine and dexamethasone were better than saline in preventing POST and POC. In their study, intracuff dexamethasone group had shown to have higher incidence of hoarseness of voice even though they used 8-mg dexamethasone in the cuff. Another study by Sugathan *et al.*<sup>[4]</sup> showed that intracuff dexamethasone 8 mg reduced the incidence of POST and POC as compared to intracuff normal saline but not postoperative hoarseness of voice.

The duration of intubation was significantly longer in Group B ( $114.4 \pm 3.04$  vs.  $105.03 \pm 10.85$  min) in our study. However, postoperative laryngopharyngeal complications

were less in that group. This observation is also in favor of efficacy of intracuff dexamethasone in attenuating POST, POC, and POHV. The mean difference in the duration of intubation, approximately by 10 min, though statistically significant, may not have any clinical relevance.

The strong points of our study were that all the intubations were performed by a single anesthesiologist, which eliminated subjective differences due to experience and skill. We have included only patients undergoing short pelvic laparoscopic surgeries in our study because postoperative pain in these patients would be minimal so that appreciation of POST would not get affected. In our study the same degree of tilt was given for all cases. So ETT migration in both groups would have been uniform thereby eliminating any bias due to different degrees of table tilt. The major drawback of our study was that we were not able to measure the intracuff pressure because fluid would enter the manometer and damage the equipment. We used minimal volume of fluid required to prevent an audible leak to fill the cuff; therefore, the intracuff pressures might not have been uniform in all the cases. The number of times aspirin gargle was used to control POST was not recorded.

## Conclusion

Intracuff dexamethasone 0.1 mg/kg significantly reduces the incidence and severity of postoperative sore throat, hoarseness of voice, and cough which occur following general anesthesia with endotracheal intubation in patients undergoing short pelvic laparoscopic procedures lasting less than 2 h.

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## Conflicts of interest

There are no conflicts of interest.

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