



STUDY ON EFFECT OF NEBULISED BUDESONIDE ON POST-OPERATIVE SORE THROAT, HOARSENESS OF VOICE AND COUGH.

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ABSTRACT

Background: Post-operative sore throat (POST) is often an inevitable consequence of tracheal intubation associated with cough and hoarseness. Effect of nebulised budesonide was studied on the incidence and severity of POST. **Methods:** In this prospective randomised study, 60 patients undergoing laparoscopic surgeries lasting <2 h were randomly allotted into two equal groups. Group A received 500 µg budesonide nebulisation, 15 min before intubation. No such intervention was performed in Group B. The primary outcome was the incidence and severity of POST. Secondary outcomes included the incidence of post-operative hoarseness and cough. Pearson's Chi-square test, Fisher's exact test and Independent sample t-test were used as applicable. **Results:** Compared to Group B, significantly fewer patients had POST in Group A at 2, 6, 12 and 24 h ($P < 0.001$) along with post-operative hoarseness of voice and cough. **Conclusion:** Nebulized budesonide is effective in significantly reducing the incidence and severity of POST.

KEYWORDS : Budesonide, Cough, Hoarseness, Intubation, Nebulized

INTRODUCTION:

Post-operative sore throat (POST) with hoarseness of voice and cough is often associated with endotracheal intubation with incidence of 21-78.1%. (1) To relieve POST steroids, ketamine, lidocaine and magnesium sulphate, administered topically or systematically have been studied. (2) Present study was conducted to find effectiveness of nebulised budesonide, on the incidence and severity of POST and associated cough and hoarseness in surgical patients following endotracheal intubation

METHODS:

Prospective, randomised, double blinded study was conducted after hospital ethical committee approval and patients' written, informed consent.

60 patients aged 18–60 years, of the American Society of Anaesthesiologists (ASA) physical status 1–2 with Mallampatti score of 1–2, undergoing elective laparoscopic surgeries lasting <2 h under general anaesthesia were included.

The patients were randomly allotted into two equal groups, labelled A and B, based on computer-generated random sequence of numbers. Patients with anticipated difficult airway, history of allergy to the test drug, who required more than one intubation attempt, with pre-operative sore throat or already on analgesics or steroids (systemic or inhaled) were excluded.

Patients belonging to Group A received 500 µg budesonide nebulisation, 15 min before intubation. In Group B, no such intervention was performed.

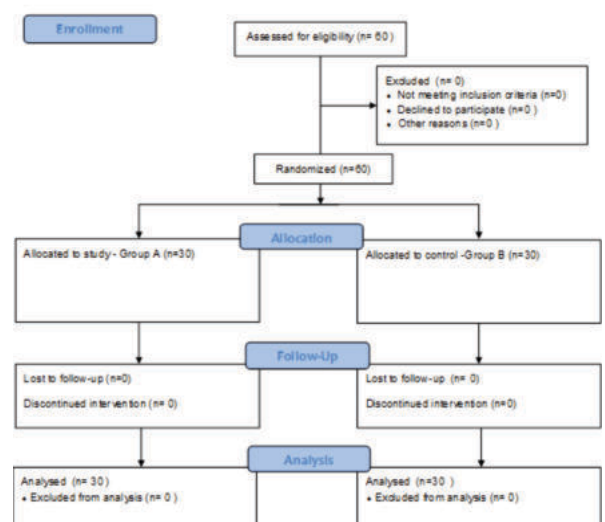
All patients were anaesthetised using standardised protocol. Pre-oxygenation- 100% oxygen for 3 min, premedication and sedation intravenous (IV) glycopyrrolate 0.2 mg, midazolam 1 mg and fentanyl 2 µg/kg. Induction-IV propofol 2 mg/kg then mask ventilated with isoflurane 1% in oxygen. Relaxant- IV Atracurium 0.5 mg/kg. 3 min later, intubated with laryngoscopy lasting not more than 15 s with a low-pressure, high-volume cuffed polyvinyl chloride endotracheal tube (males, 8 mm and in females, 7 mm internal diameter) by the same anaesthesiologist and confirmed with auscultation and end-tidal capnography (ETCO₂ maintained between 30 to 35 cm of H₂O). Endotracheal tube cuffs were filled with air cuff pressure was checked immediately and thereafter, half-hourly using PORTEX™ (Smiths Medical) cuff pressure monitor, and was maintained at 20–22 cm of H₂O.

Anaesthesia was maintained using oxygen in air (1:2) with 1% isoflurane and intermittent positive pressure ventilation, IV Atracurium 5mg was repeated every 30 minutes. Adequate analgesia and anaesthesia depth maintained.

At the end of the surgery, IV ondansetron 4 mg given and paralysis was reversed with IV neostigmine 0.05–0.07 mg/kg and glycopyrrolate 10 µg/kg. Extubated after gentle suctioning. Post-operatively, non opioid analgesics were used. opioid consumption documented.

POST (0-absent, 1-complains when asked, 2-complains himself, 3-in distress), cough (0-no, 1-minimal, 2-moderate, 3-severe) and hoarseness (0-absent, 1-complains when asked, 2-complains himself, 3-grossly change) graded at 2, 6, 12 and 24 h. Grade 3 sore throat were given dispersible Aspirin 75 mg gargle till relief. Based on study Chen *et al.* (3) considering the incidence of POST who received budesonide nebulization as compared to control group (72.5% vs. 87.5%), with 95% confidence interval and 80% power, minimum sample size to obtain statistically significant result was 30. Statistical analyses done using SPSS 20.0

CONSORT Diagram



RESULTS:

Both groups were comparable (Table-1) in mean age, weight, distribution of sex, ASA physical status, Mallampatti score,

duration of intubation as well as intra-operative fentanyl consumption.

Table-1 Comparison of variables			
Parameter	Group A	Group B	P-Value
Continuous Variables (mean±SD)			
Age (Years)	48.4±12.2	44.2±10.2	0.125
Weight (Kg)	70.2±10.4	69.2±6.02	0.142
Fentanyl (mcg)	150±34.23	148.54±30.23	0.121
Surgical time(min)	98.45±15.45	95.65±12.21	0.245
Categorical Variables, n (%)			
Gender			
Male	18(60)	16(53)	0.554
Female	12(40)	14(47)	
ASA physical status			
I	21(70)	24(80)	0.514
II	9(30)	6(20)	
Mallampatti Score			
1	18(60)	16(53)	0.524
2	12(40)	14(47)	
Rescue therapy needed			
Yes	3(10)	18(60)	<0.001
No	27(90)	12(40)	

Compared to Group B, POST, hoarseness, cough were significantly lower in Group A at 2, 6, 12 and 24 h ($P < 0.001$).

Table 2- Comparison of incidence of POST, Hoarseness of voice and cough

Time (hr)	Occurrence	Group A n (%)	Group B n (%)	P
POST				
2	NO	12(40)	6(20)	<0.001
	YES	18(60)	24(80)	
6	NO	15(50)	12(40)	<0.001
	YES	15(50)	18(60)	
12	NO	26(87)	14(46)	<0.001
	YES	4(13)	16(54)	
24	NO	30(100)	26(87)	<0.001
	YES	0	4(13)	
Hoarseness of voice				
2	NO	14(47)	4(13)	<0.001
	YES	16(53)	26(87)	
6	NO	18(60)	10(33)	<0.001
	YES	12(40)	20(67)	
12	NO	24(80)	19(63)	<0.001
	YES	6(20)	11(37)	
24	NO	30(100)	24(80)	<0.001
	YES	0	6(20)	
Cough				
2	NO	15(50)	3(10)	<0.001
	YES	15(50)	27(90)	
6	NO	24(80)	18(60)	<0.001
	YES	6(20)	12(40)	
12	NO	28(93)	24(80)	<0.001
	YES	2(7)	6(20)	
24	NO	30(100)	28(93)	<0.001
	YES	0	2(7)	

Symptoms resolved with time and by 24 h no patient in Group A and 13 % Group B had POST. Significantly more number of patients in Group B required rescue therapy for POST (60% vs. 10%, $P = < 0.001$).

DISCUSSION:

POST results from an aseptic inflammatory process caused by irritation of the pharyngeal mucosa during laryngoscopy associated trauma and tracheal mucosa due to endotracheal tube cuff. (4) Studies which investigated the efficacy of various drugs on the incidence of POST could result in the development of unwanted side effects. Ketamine gargles(5) can have adverse effects on haemodynamic or on central nervous system.

Gargling may not be acceptable for all patients. As intracuff lidocaine (6) diffuses out, though the chance of POST is reduced, the possibility of hoarseness increases due to nerve paresis. Magnesium sulfate gargles or nebulisations(5), topical benzydamine hydrochloride(7) have also been studied

Steroids when given prophylactically act through their anti-inflammatory action by inhibition of leukocyte migration to the inflammation site and inhibition of release of cytokines by maintaining cellular integrity and by inhibition of fibroblast proliferation. It had been shown that both topical as well as intravenous dexamethasone(4) reduced the incidence of POST. However side effects such as fluid retention, delayed wound healing and glucose intolerance are concerns with the use of intravenous steroids.

The advantage of using the inhaled route is that the total dose administered is minimal, at the same time the maximum concentration of the drug is made available at the site of action, thereby reducing the magnitude of side effects. Budesonide is a corticosteroid with potent glucocorticoid and weak mineralocorticoid activities. As one of the most commonly used inhaled glucocorticoids which decreases airway hyperactivity, used in the management of bronchial asthma. Its usefulness in prevention of POST had been investigated with promising results when administered before induction of anaesthesia through oxygen driven atomising inhalation. (3) The dose of budesonide used in our study was well within the therapeutic limits used in bronchial asthma and used only once so chance of overdosing or development of side effects was minimal.

Hoarseness of voice and cough are symptoms very often associated with POST. Use of larger-sized endotracheal tubes and laryngeal trauma are considered to be the common reasons for post-operative cough. Although hoarseness of voice is common after intubation, prolonged hoarseness is very rare. Usually, it settles by the third post-operative day, the duration of which is decided by the age of patient and duration of intubation. The cause of prolonged hoarseness is usually arytenoid cartilage dislocation. Use of smaller-sized tubes and periodic measurement of cuff pressure greatly reduce mucosal damage and thereby hoarseness.(8)

We have not used metered dose inhaler(MDI) as it requires patient education, hand breath coordination or sometimes an aerosol cloud enhancer spacer with a one-way valve for efficient drug delivery during one time actuation. Also cost of MDI and spacer may not make it feasible for use in multiple patients. We reused nebulisation mask and tubing multiple times after thorough washing and ETO sterilisation making it cost effective.

All the intubations performed by a single anaesthetist which eliminated subjective variations due to differences in experience. We recruited patients who were undergoing short laparoscopic surgeries like sterilisation, diagnostic laparoscopy, laparoscopic appendicectomy or cholecystectomy as post-operative pain following these procedures would be minimal, and hence, incidence and severity of POST would be better appreciated. Compared to open surgeries, patients who undergo laparoscopic surgeries have a high incidence of POST as cuff pressure increases due to pneumoperitoneum.

Limitations of the study were that actual delivery of the drug to the site of action and loss of drug during nebulisation might not have been uniform in all patients. Another limitation was though both groups were comparable in Patient position (Trendelenberg or reverse-Trendelenberg) and degree of table tilt which affects the incidence of POST was not given significant consideration(9).

CONCLUSION:

Nebulised budesonide 500µg dose 15 minutes before induction of anaesthesia, was effective in significantly reducing the incidence and severity of POST, hoarseness of voice and cough seen in patients following endotracheal intubation.

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Conflicts Of Interest: No conflicts of interest

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