Journal of Clinical Anesthesiology: Open Access

Paul et al., JCAO 2019, 3:2

Research Article Open Access

Comparative Evaluation of Efficacy of Nebulised Budesonide with Nebulised Dexamethasone in Reducing Post-operative Sore Throat in Patients undergoing Elective Lumbar Spine Surgery in Prone Position

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Received date: August 22, 2019; **Accepted date**: September 02, 2019; **Published date**: September 10, 2019

Abstract

Aims of the Study: Postoperative Sore Throat (POST), a frequent adverse event after general anesthesia represents a broad spectrum of signs and symptoms. It may vary from laryngitis, pharyngitis, tracheitis, hoarseness, cough, or dysphagia. It may adversely affect the post-operative satisfaction score and activities of the patients after leaving hospital. Aim of this study is to evaluate the effectiveness of inhaled dexamethasone with inhaled budesonide in preventing POST in patients undergoing elective lumbar spine surgeries in prone position.

Patients and Methods: A total of 120 patients of American Society of Anesthesiologists physical status I-II of both sexes, aged 18-65 years were included in this study. Patients were randomly assigned into one of the two groups of 60 patients each: Group B was nebulized with 500 mcg of budesonide while group D was nebulized with 8 mg of dexamethasone before general anesthesia and endotracheal intubation. The intensity of sore throat on arrival to the post-anesthesia care unit was assessed at 5 mins, 30 mins, 1 hour, 2 hours, 24 hours postoperatively.

Results: Incidence and severity of POST were reduced in both the groups. However, patients of Group D demonstrated a statistically significant decline in incidence of sore throat when compared to group B.

Conclusion: Single prophylactic pre-induction nebulization of patients undergoing elective lumbar spine surgery in a prone position with dexamethasone is better than budesonide in preventing POST.

Keywords: Prone; Spine surgery; Sore throat; Nebulization

Introduction

Postoperative Sore Throat (POST), a frequent adverse event after general anesthesia represents a broad spectrum of signs and symptoms. It may vary from laryngitis, pharyngitis, tracheitis, hoarseness, cough, or dysphagia. It may adversely affect the post-operative satisfaction score and activities of the patients after leaving hospital [1]. 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 [1].

Majority of the measures directed at reducing this complication have focused on limiting the physical trauma. Surprisingly few investigations have evaluated the efficacy of Pharmacological interventions. Furthermore, no single drug has achieved widespread acceptance. Perioperative care has witnessed widespread use of corticosteroids for prevention of POST. Corticosteroids have the potential for decreasing the incidence of POST during recovery, and the mechanism has been attributed to ant-inflammatory process. Inhalation mode of drug delivery obviates the systemic side effects of intravenous corticosteroids. Prone position predisposes to change in endotracheal tube cuff pressure and endotracheal tube displacement which can contribute to POST. The primary aim of this study is to evaluate the effectiveness of inhaled dexamethasone with inhaled budesonide in preventing POST in patients undergoing elective lumbar spine surgeries in prone position.

Methods

This prospective, randomized, double-blind comparative study was conducted over a period of 18 months after obtaining approval from hospital ethical committee and patient's written informed consent. One hundred and twenty patients aged 18-65 years, of the American Society of Anesthesiologists (ASA) physical status 1-2 with Mallampatti score of 1-2, undergoing elective lumbar spine surgery in prone position under general anesthesia with endotracheal intubation were included in the study. Patients with anticipated difficult airway, who required more than two attempts at intubation, nasogastric tube insertion, pre-operative sore throat, on analgesics or steroids (systemic or inhaled), history of allergy to the test drug, were excluded from the study. The patients were randomly allotted into two equal groups, labeled B and D, based on computer generated random sequence of numbers. Patients belonging to Group B received 500 mcg budesonide inhalation suspensions, using a nebulizer. In Group D, 8 mg of dexamethasone in 2 ml of normal saline (total volume 4 ml) was used

for nebulization. All patients were nebulized using nebulizer face mask with an oxygen flow of 6 l/min in 20 min. All patients were pre-oxygenated with 100% oxygen for 3 min followed by intravenous administration (i.v) of midazolam (1 mg) and fentanyl (2 mcg/kg). Anesthesia was induced with i.v propofol 2 mg/kg and the lungs were ventilated via facemask with sevoflurane 2% in oxygen. Injection Vecuronium 0.1 mg/kg was administered i.v after induction and three minutes later, the trachea was intubated following a swift and gentle laryngoscopy lasting not more than 15 s.

Low-pressure, high-volume cuffed, wire-reinforced endotracheal tube was used in all the patients. In males, 8 mm and in females, 7 mm internal diameter tubes were employed. All intubations were performed by a conventionally trained and experienced anesthesiologist and confirmed with auscultation and end-tidal capnography. Endotracheal tube cuffs were filled with the minimal volume of air required to prevent an audible leak. Intraoperatively, the cuff pressure was checked immediately after intubation and thereafter, half-hourly using cuff inflator/pressure gauge PORTEX™ (Smiths Medical) cuff pressure monitor, and was maintained at 10-20 cm of H_2O. Patient's position was changed from supine to prone for surgery, and patient's head was positioned on the sponge face pillow without head rotation. After position change from supine to prone, we re-adjusted the cuff pressure between 10 and 20 cm H_2O. Anesthesia was maintained using oxygen in air (1:2) with 2.0%-2.5% end-tidal sevoflurane and intermittent positive pressure ventilation maintaining end-tidal carbon dioxide levels at 30-35 mm Hg. Intravenous Vecuronium 1 mg was repeated at half an hour interval to provide muscle relaxation. Paracetamol 1 gm i.v was administered half an hour after induction. At the end of the surgery, IV ondansetron 4 mg was given intravenously, and the residual muscle paralysis was reversed with IV neostigmine 0.05-0.07 mg/kg and glycopyrrolate 10 mcg/kg.

Extubation was performed following gentle oro-pharyngeal suctioning using a soft suction catheter under vision. Post-operatively, all patients received paracetamol 1 g, 8 hourly, and tramadol 100 mg on-demand intravenously.

POST, cough, and hoarseness of voice were assessed at 5 mins, 30 mins, 1 hour, 2 hours and 24 hours based on the scales described in Table 1.

Sore Throat	
0	No sore throat at any time since the operation
1	Minimal sore throat-patient answers in affirmative when asked about the sore throat
2	Moderate sore throat-patient complained of sore throat on his/her own
3	Severe sore throat-patient is in obvious distress
Cough	
0	No cough at any time since the operation
1	Minimal cough or scratchy throat
2	Moderate cough
3	Severe cough
Hoarseness	
0	No evidence of hoarseness at any time since the operation
1	Minimal change in quality of speech. Patient answers in affirmative only when enquired about (minimal hoarseness)
2	A moderate change in quality of speech of which the patient complains about his/her own (moderate hoarseness)
3	Gross change in the quality of voice perceived by an observer (severe hoarseness)

Table 1: Scale for assessment of post-operative sore throat, hoarseness of voice and cough.

Statistics

To achieve a power of 90% (with 2-sided type I error rate of 5% and applying Pearson χ^2 test) to detect 25% reduction in incidence of POST in intervention dexamethasone (factor 1) or budesonide (factor 2) from reported incidence of 56% of POST, the estimated sample size was 60 in each group (Chart 1).

Postoperative hoarseness usually settles by the third post-operative day, the duration of which is decided by the age of and duration of intubation. The cause of prolonged hoarseness is usually arytenoid cartilage dislocation.

S No.	Group	Description	No. of patients	Percentage
1	Group B	Preoperative Budesonide Nebulization	60	50.0
2	Group D	Preoperative Dexamethasone Nebulization	60	50.0
		Total	120	100.0

Chart 1: Group b and Group d (n=60).

Pearson's Chi-square test or Fisher's exact test was used to compare the categorical variables such as gender, ASA status, Mallampatti score, incidence and severity of POST, hoarseness of voice and cough. Independent sample t-test was used to compare the continuous variables such as age, weight.

The intragroup comparison was performed using Wilcoxon Signed Rank Test. Statistical analyses were performed using SPSS Version 20.0 for Windows (IBM Corporation ARMONK, NY, USA).

Results

S No.	Variable	Group B (n=60)		Group D (n=60)		Total (N=120)	
		No.	%	No.	%	No.	%
1	Age Group						
	Upto 25	3	5	5	8.3	8	6.7
	26-35	8	13.3	17	28.3	25	20.8
	36-45	16	26.7	7	11.7	23	19.2
	46-55	26	43.3	24	40	50	41.7
	56-65	7	11.7	7	11.7	14	11.7
		χ″=7.342 (δφ=4); π=0.119					
	Min-Max (Median)	23-60 (48.0)		19-64 (47.0)		19-64 (47.5)	
	Mean ± SD	45.02 ± 9.90		42.32 ± 12.14		43.67 ± 11.11	
2	Gender						
	Female	28	46.7	18	30	46	38.3
	Male	32	53.3	51	70	74	61.7
		χ″=3.525(δφ=1); π=0.060					

Chart 2: Group comparison of demographic variables.

S No.	Variable	Group B (n=60)		Group D (n=60)		Total (N=120)	
		No.	%	No.	%	No.	%
1	Diagnosis						
	PIVD	44	73.3	32	53.3	76	63.3
	Subluxation	7	11.7	10	16.7	17	14.2
	PIVD +Subluxation	2	3.3	3	5.0	5	4.2
	Others	7	11.7	15	25.0	22	18.3
		χ^2=5.533 (df=3); p=0.136					
2	Procedure						
	Excision	0	0.0	2	3.3	2	1.7
	Laminar fusion	0	0.0	2	3.3	2	1.7
	Laminectomy	53	88.3	42	70.0	95	79.2
	Spinal fusion	7	11.7	14	23.3	21	17.5
		χ^2=7.607 (df=3); p=0.055					

Chart 3: Group comparison of diagnosis and type of lumbar spine surgery.

Patients of both the groups were matched for demographic variables, for diagnosis and surgical procedure (Charts 2 and 3).

Pre-operative assessment of patients including airway assessment of both the groups were comparable. Duration of surgery and number of attempts in securing the airway of patients of both the groups was also found to be comparable (Chart 4).

Duration of surgery ranged between 120 minutes to 210 minutes. The median duration of surgery was 160 minutes.

The difference in the mean duration of surgery among patients of Group B (159.75 ± 18.47 minutes) and Group D (164.67 ± 26.00 minutes) was not found to be statistically significant [2].

Group	No. of patients	Min.	Max.	Median	Mean	SD
Group B	60	130	200	160	159.75	18.47
Group D	60	120	210	155	164.67	26.00
Total	120	120	210	160	162.21	22.59

Chart 4: Group comparison of duration of surgery.

Incidence of sore throat was higher in Group B as compared to Group D at all the periods of follow up i.e. 5 min (100.0% vs. 93.3%), 30 min (95.0% vs. 85.0%), 1 hr (95.0% vs. 61.7%), 6 hr (91.7% vs. 10.0%) and at 24 hr (38.7% vs. 5.0%).

Differences in the incidence of sore throat of above two groups were statistically significant at all the periods of follow up except at 30 min (p=0.068) (Chart 5).

Follow up Period	Total (N=120)	Group B (n=60)		Group D (n=60)		Significance of difference	
		No.	%	No.	%	χ^2	p
5 min	116	60	100.0	56	93.3	4.138	0.042
30 min	108	57	95.0	51	85.0	3.333	0.068
1 hr	94	57	95.0	37	61.7	19.640	<0.001
6 hr	61	55	91.7	6	10.0	80.056	<0.001
24 hr	26	23	38.7	3	5.0	19.640	<0.001

Chart 5: Group comparison of the incidence of Post-Operative Sore Throat (POST).

Incidence of hoarseness was higher in Group B as compared to Group D at all the periods of follow up i.e. 5 min (95.0% vs. 93.3%), 30 min (95.0% vs. 88.3%), 1 hr (95.0% vs. 55.0%), 6 hr (79.3% vs. 13.3%) and at 24 hr (46.7% vs. 0.0%).

Differences in incidence of hoarseness of above two groups were not found to be statistically significant at initial follow up to 30 minutes of surgery (5 min and 30 min) (Chart 6).

Follow up Period	Total (N=120)	Group B (n=60)		Group D (n=60)		Significance of difference	
		No.	%	No.	%	χ^2	p
5 min	113	57	95.0	56	93.3	0.152	0.697
30 min	110	57	95.0	53	88.3	1.745	0.186
1 hr	90	57	95.0	33	55.0	25.600	<0.001
6 hr	55	47	79.3	8	13.3	51.055	<0.001
24 hr	28	28	46.7	0	0.0	36.522	<0.001

Chart 6: Group comparison of the incidence of post-operative hoarseness.

Incidence of cough was higher in Group B as compared to Group D at all the periods of follow up i.e. 5 min (50.0% vs. 6.7%), 30 min (23.3% vs. 0.0%), 1 hr (10.0% vs. 0.0%), 6 hr (30.0% vs. 8.3%) and at 24 h (5.0% vs. 0.0%). Differences in the incidence of cough among patients of above two groups were found to be statistically significant at all the follow-up periods except at 24 hr (Chart 7).

Follow up Period	Total (N=120)	Group B (n=60)		Group D (n=60)		Significance of difference	
		No.	%	No.	%	χ^2	p
5 min	34	30	50.0	4	6.7	27.743	<0.001
30 min	14	14	23.3	0	0.0	15.849	<0.001
1 hr	6	6	10.0	0	0.0	6.316	0.012
6 hr	31	26	43.3	5	8.3	19.181	0.003
24 hr	3	3	5.0	0	0.0	3.077	0.079

Chart 7: Group comparison of the incidence of post-operative cough. The severity of POST, hoarseness, and cough reduced with time in each group but the decline was more pronounced in Group D (Figure 1).

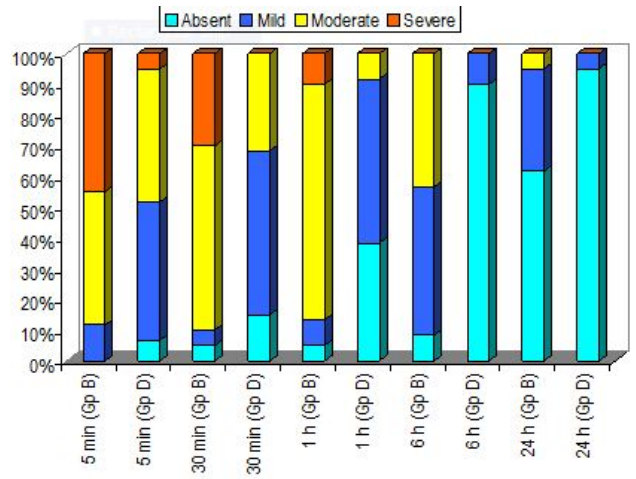

Figure 1: Progressive reduction in the severity of POST. Group D showed greater reduction in incidence of POST at all time intervals ($p<0.001$).

Discussion

Incidence of POST is reported to range from 14.4% to 50.0% [3,4]. Aseptic inflammatory process seems to be a common endpoint leading to POST and factors like age, sex, the size and cuff pressure of the endotracheal tube, the duration for which the tube is in place, number of suctioning attempts, the time and manipulations needed to insert the tube, gynecologic surgery, and the use of succinylcholine seem to lead to it [5,6].

Postoperative hoarseness usually settles by the third post-operative day, the duration of which is decided by the age of and duration of intubation. The cause of prolonged hoarseness is usually arytenoid cartilage dislocation [7,8]

The change in cuff pressure and tube displacement in prone position can affect the incidence of POST, hoarseness, and cough [5,6,9] Incidence and severity of POST in prone position is expected to be high as it requires the use of comparatively thicker wire reinforced tracheal tube (larger outer diameter) requiring use of a rigid stylet and an obvious position change that occurs twice in the perioperative period .

Most of the studies which investigated the efficacy of various drugs on the incidence of POST have administered the drugs either intravenously, topically as intracuff medication, nebulization or gargle. Topical benzydamine hydrochloride [10] intracuff and topical Lidocaine, [11] Magnesium sulfate gargle [12] nebulizations of ketamine and magnesium sulfate [13], Strepsils® [14] are few examples.

Topical and systemic steroids have been demonstrated to reduce the incidence of POST presumably because of their systemic anti-inflammatory effects. The prophylactic use of steroids reduced the incidence of sore throat and hoarseness during recovery, probably by modifying the inflammatory process caused by tissue injury. This anti-inflammatory process includes inhibition of leukocyte migration to the site of inflammation and inhibition of release of cytokines probably by maintaining cellular integrity. Fibroblast proliferation may also be inhibited [15,16].

A meta-analysis published in 2014 that included seven randomized controlled trials suggested that an intravenous dose of dexamethasone greater than 0.1 mg/kg reduced the incidence and severity of postoperative sore throat at 24 hours (RR 0.68 and standardized mean difference-1.15) [17]. The smallest tracheal tube used in these studies was 7.0 mm ID, one study used only double-lumen tubes and tracheal cuff pressures were controlled in only one study.

The application of triamcinolone paste (0.1%) to the tracheal tube and cuff was associated with a reduction in the incidence and severity of POST at 24 hours compared with Chlorhexidine gel [18]. Similarly, betamethasone gel (0.05%) reduced the incidence compared with 2% lidocaine gel [19]. Preoperative inhaled fluticasone have also been shown to reduce the incidence and severity of POST [20].

Chen et al concluded that the use of one time prophylactic inhaled budesonide suspension significantly decreases the incidence and severity of sore throat and hoarseness after tracheal intubation in patients scheduled for thyroid surgery with general anesthesia. These results showed a higher incidence of sore throat in the control group compared with the current study. It may be due to the type of surgery in which there are manipulation and hyperextension of the neck [20]. Rajan et al observed in patients undergoing laparoscopic procedures of short duration pre-induction budesonide inhalation which was repeated 6 hours post-extubation resulted in fewer patients having POST at 2, 6, 12 and 24 h ($p<0.001$). Although more patients in control group had post-operative hoarseness of voice and cough at all-time points, the difference was statistically significant only at 12 h and 24 h for post-operative hoarseness and at 2 hr and 12 hr for post-operative cough. These findings are well in concurrence with the findings of our study [21]. Abbasi S et al. [22] in their study on critically ill patients observed that the pre-extubation nebulization with budesonide resulted in reduced incidence of respiratory distress. Findings of our study are in contradiction of study by Atef et al using pre-induction dexamethasone nebulization where they observed that at 24 hours, incidence of POST, that is zero was similar to the control group which was nebulized with normal saline [23].

Our study compared single prophylactic pre-induction nebulization with budesonide or dexamethasone in patients undergoing lumbar spine surgery in the prone position and observed the dexamethasone was better than budesonide at all time intervals understudy in preventing post-operative sore throat, hoarseness of voice and cough. Findings partially could be attributed to half-lives of dexamethasone (t1/2-36 hours) and budesonide (t1/2-3 hours). Findings of our study suggest that nebulized dexamethasone achieve the same effect on incidence of POST as intravenous dexamethasone at 24 hours post-extubation thereby obviating potential systemic side effects [17]. This study is unique as it compares two commonly utilized steroids in patient group undergoing surgery in a position which predisposes to increased incidence of POST. Post extubation use of fiberoptic bronchoscopy to assess upper airway could have lent some objectivity and correlation to an otherwise subjective assessment score.

Conclusion

POST is not the most important adverse event to avoid, nevertheless, it is an adverse event that could easily be significantly decreased or even potentially eliminated. Single prophylactic pre induction nebulization of patients undergoing elective lumbar spine surgery in prone position with dexamethasone is better than budesonide in preventing POST.

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