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Prophylactic Effectiveness of Budesonide Inhalation in Reducing Postoperative Throat Complaints

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Abstract

Objective: To evaluate the efficacy of budesonide suspension inhalation in reducing the incidence and severity of postoperative sore throat (POST) and hoarseness induced by tracheal intubation.

Methods: 120 patients scheduled for thyroid surgery with general anaesthesia were randomized into 3 groups. Group A received 200 mcg budesonide inhalation suspension (BIS) 10 min prior to the tracheal intubation and received the same treatment 6 h and 24 h after extubation. Group B received 200 mcg BIS 6 h and 24 h after extubation. Control group received the same scheduled treatment as Group A, but the BIS was replaced with 2 ml normal saline. The patients were evaluated for POST and hoarseness 1, 24 and 48h after extubation and the status of laryngopharynx was examined and recorded as well.

Results: The incidences of post-operation complaints in three groups were 72.5%, 82.5% and 87.55% for POST, and 37.3%, 52.5% and 75% for hoarseness, respectively. There was no statistically significant difference in the incidence of POST between three groups. However, hoarseness occurred significantly less frequently in Group A in comparison to Group B and control group ($P<0.05$). One hour post extubation, Group A exhibited significantly less severe POST and hoarseness compared to the other two groups ($P<0.05$), which disappeared 24 h later. One hour after extubation both VAS scores of POST and hoarseness were significantly lower in Group A than those in the other two groups ($P<0.05$). The mucositis scores of laryngopharynx at 1,24 and 48 h post extubation were significantly lower in Group A compared to the other two groups ($P<0.05$).

Conclusions: The prophylactic use of inhaled budesonide suspension significantly decreases the incidence and severity of sore throat and hoarseness after tracheal intubation.

Keywords: Tracheal intubation; Complaints; Sore throat; Budesonide inhalation

Introduction

Postoperative sore throat (POST) and hoarseness are common complaints from patients receiving tracheal intubation. Although not major complications and usually self-limiting, they affect the satisfaction of patients to a significant extent. Steroids, known for its anti-inflammatory function, are widely used in clinic. The inhaled corticosteroids (ICSs), in particular, are widely used for patients at risk of airway diseases since it can be directly delivered to the airways without introducing a systemic exposure. Previous studies have shown that ICSs is capable of decreasing the incidence and severity of POST, cough, and hoarseness caused by tracheal intubation [1,2].

Therefore, inhaling budesonide suspension might be used as an analgesic to reduce POST following general anesthesia. The present study investigated the effectiveness of budesonide inhalation suspension (BIS) in reducing the incidence and severity of POST and hoarseness, and compared the effectiveness of BIS inhalation between the time of pre- and post-intubation as well.

Methods

A total of 120 patients aging from 18 to 60 years old were enrolled into this study from August to December 2010. These patients were scheduled for electric thyroid surgery under general anesthesia with endotracheal tube intubation. The physical status of all patients was graded as I-II according to the guideline of the American Society of Anesthesiologists (ASA). This study was approved by the hospital Institutional Ethics Committee and the informed consent was obtained from all patients.

Pre-anaesthetic evaluation was performed in all patients and those met one of the following criteria were excluded from the study: (i) a history of recent respiratory tract infection or sore throat; (ii) preoperative use of analgesics such as non-steroidal anti-inflammatory drugs or opioids or steroids; (iii) the status of glottic exposure graded as III or IV according to Cormack-Lehane scoring system; (iv) more than one attempts for tracheal intubation required; (v) with a nasogastric tube; (vi) the duration of tracheal intubation less than 30 mins or longer than120 mins.

Patients were randomized into 3 groups and treated as follows:

• Group A: patients received budesonide suspension for inhalation 200 mcg (Pulmicort Respules®, donated by AstraZeneca LP) via oxygen-driven atomizing inhalation 10 min prior to the tracheal intubation, and 6 h and 24 h after extubation.

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• Group B: patients received BIS 200 mcg 6h and 24 h after extubation.

• Control group: patients received 2 ml normal saline 10 min prior to intubation, and 6 h and 24 h after extubation.

All anaesthetic procedures were performed by the same experienced anesthesiologist who was blinded to the group allocation. Induction was accomplished with fentanyl 100μg kg^{-1} and propofol 2mg kg^{-1}, followed by rocuronium 0.6 mg kg-1. Before intubation, ventilation was controlled with 100% oxygen via a mask. Tracheal intubation under the direct laryngoscopy was performed 2 mins after the rocuronium injection. The trachea was intubated with a low volume pressure cuff tracheal tube (Safety-Flex®, donated by Mallinckrodt Medical, Ireland) with an inner diameter of 7.5 mm for male or 7.0 mm for female patients. Immediately after intubation, the tracheal tube cuff was inflated with room air until no air leakage could be heard at a peak airway pressure of 20cm H_2O. No humidifier or heat/moisture exchangers were used in any group. Anesthesia was maintained with 2% isoflurane, rocuronium and 100% oxygen, with positive pressure ventilation in a circle system. The end-tidal CO_2 was maintained at 35-40 mmHg.

At the end of the surgery, the patients were given prostigmin 2 mg kg^{-1} and atrophin 0.2 mg kg^{-1} intravenously. The lungs were ventilated with 100% O_2 until the patient was fully awake and had recovered from the muscle relaxant. The trachea was extubated after deflating the cuff when the TOF Ratio was at least 70% and the patient was fully awake. All patients received oxygen by a mask after operation.

The investigators who interviewed the patients and collected the data did not perform any of the procedures, and they were also blinded to the group allocation. The incidences of POST, cough, and hoarseness were measured 1, 24 and 48 hours after the operation. The scores of the complaints were self-evaluated by patients using a visual analog scale (VAS; where 0=no pain and 100=worst pain imaginable). At the same time, an ENT doctor was in charge of examining the throat of all the patients after surgery. Severity of mucositis of the laryngopharynx was assessed based on the scoring system in Table 1.

Statistical analyses were performed using SPSS (ver. 17.0, SPSS Inc., Chicago, IL, USA). One-Way ANOVA was used for comparison among groups in age, height, weight, body mass index (BMI), duration of tracheal intubation and the VAS scores of POST and hoarseness. Between-group differences in the incidence of POST and hoarseness after operation were analyzed using chi-square test. A Kruskal-Wallis test was applied to compare the differences in the severity of mucositis of the laryngopharynx among groups. A P-value<0.05 was considered significant.

Results

Characteristics of the enrolled patients are shown in Table 2. As shown, there was no significant difference in sex, age, height, weight, BMI or duration of intubation among three groups, indicative of the comparability of the subjects.

Score	Sign of laryngopharynx
0	no change in the mucosa of the pharynx
1	Localized erythema with no pain
2	Generalized erythema without pain or localized erythema or ulcers with mild pain
3	Multiple ulcers or generalized erythema with moderate pain
4	Generalized erythema or ulcers with moderate to severe pain

Table 1: Scoring system for mucositis in laryngopharynx.

	Group A (n=40)	Group B (n=40)	Control group (n=40)	*P*
Gender (male/female)	3/37	5/35	9/31	0.147
Age (yr)	50.13 ± 8.60	40.65 ± 8.42	46.95 ± 11.32	0.279
Height (cm)	162.10 ± 5.95	163.30 ± 6.28	162.35 ± 7.53	0.694
Weight (kg)	62.85 ± 11.13	65.21 ± 10.14	60.31 ± 10.94	0.129
BMI (kg/m2)	23.86 ± 3.51	24.45 ± 3.52	22.76 ± 2.86	0.072
Duration of tracheal intubation (min)	76.60 ± 18.40	71.50 ± 20.58	75.25 ± 19.18	0.479

BMI: Body Mass Index; Values are presented as Mean ± SD.

Table 2: Characteristics of study population.

	Group A (n=40)	Group B (n=40)	Control group (n=40)	*p*
POST (n)	29(72.5%)	33(82.5%)	35(87.5%)	0.222
Hoarseness (n)	15(37.5%)	21(52.5%)	30(75%)	0.003

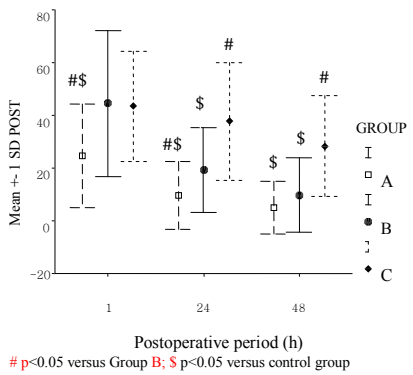
Table 3: The incidence of POST and hoarseness.

Score	Group A (n=40)	Group B (n=40)	Control group (n=40)	*P*
1 h				<0.01
0	13	5	2	
1	21	11	14	
2	6	12	21	
3	0	11	3	
4	0	1	0	
24 h				<0.01
0	31	21	11	
1	9	18	25	
2	0	0	4	
3	0	0	0	
4	0	0	0	
48 h				0.04
0	38	36	28	
1	2	4	12	
2	0	0	0	
3	0	0	0	
4	0	0	0	

Table 4: The mucositis score of laryngopharynx.

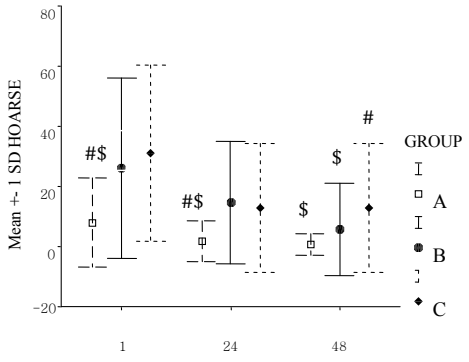
Our study observed that most POST occurred one hour after extubation and its overall incidence in Group A, B and control group was 72.5%, 82.5% and 87.55%, respectively (Table 3), of which no significant difference was detected. In contrast, the incidence of hoarseness was 37.3%, 52.5% and 75% in Group A, B and control group, respectively (Table 3). The incidence of hoarseness in Group A was significantly lower than the other groups (P<0.05), supporting the effectiveness of budesonide inhalation in reducing post-operative hoarseness. In addition, the relatively lower incidence of hoarseness in Group A compared to Group B suggests that prophylactic administration of budesonide prior to intubation can further prevent the occurrence of subsequent uncomfortness.

The severity of POST and hoarseness graded by VAS scoring system 1, 24 and 48 hours after extubation was listed in Figure 1 and 2, respectively. As shown, one hour and 24 hours after extubation both VAS scores of POST and hoarseness were significantly lower in group A than in the other two groups (P<0.05). But there was no difference of POST and hoarseness between Group B and control group one hour after extubation and there was no statistical difference of hoarseness between the same two groups 24 hours after extubation. 48 hours after



# p<0.05 versus Group B; $ p<0.05 versus control group

Figure 1: The VAS score of POST.



# p<0.05 versus Group B; $ p<0.05 versus control group

Figure 2: The VAS score of hoarseness.

extubation, both VAS scores of POST and hoarseness in Group A and B were significantly lower than that in the control group (P<0.05), although no difference was detected between the two treatments.

The scores of laryngopharynx mucositis 1, 24 and 48 hours after extubation are shown in There was statistically significant difference among these three groups (P<0.01). The severity of the mucositis in laryngopharynx was more prominent in Group A than in the other two groups.

Discussion

POST and hoarseness are the most common complaints after surgery. The incidence of POST ranges from 21% to 84% in accordance with different surgical [3-6] and anesthetic manipulations [7,8]. In the present study, the incidence of POST was 87.55% in control group, higher than expected. Several previous studies have reported that females tend to have a higher incidence of POST than males [9,10]. There were more female patients than male patients in our study, which may explain the increased incidence of POST. In addition, all patients in our present study received thyroid surgery, which may also contribute to the elevation in POST incidence, since several studies indicate that there is a greater incidence of POST after thyroid surgery [5,11]. The correlation between thyroid surgery and increased POST incidence might be attributed to several factors such as the pressure and movement of tube cuff in the trachea, or the supine position of patients with their heads hyper-extended during operation that facilitates the movement of tube tips [11].

It is believed that the postoperative symptoms are the results of mucosal injury-induced inflammation. Under normal circumstances, the inflammation of mucosa (mucositis) is considered an immune response to airway instrumentation (i.e., laryngoscopy and suctioning) or irritating foreign objects (i.e., endotracheal tube, LMA [12-14], or oral airway). After the potential role of inflammation in the postoperative sequelae of airways had been recognized, the use of inhaled and topical corticosteroids was described [15,16]. It is well known that inhaled corticosteroids (ICSs) inhalation is a direct method of treating airway diseases (i.e., asthma, chronic obstructive pulmonary disease (COPD) [17-19] and acute pharyngitis [20]) due to its high efficacy in controlling and preventing symptoms with reduced systemic side effects compared to other corticosteroids therapy. The risk-benefit ratio of ICSs is determined by multiple factors. Beneficial properties include low oral bioavailability, high systemic clearance, and sufficient receptor binding affinity. Since ICSs inhalation possesses these beneficial properties, it has been considered a more secure treatment.

Budesonide inhalation suspension (BIS) is the first and only nebulized ICS. It has been proved that BIS is effective and well tolerated in patients with asthma [21] and rhinitis [22,23]. In addition, the efficacy and safety of BIS has been well verified [24-26]. Volovitz B and colleagues reported that high dose of inhaled budesonide was not associated with a decrease in cortisol plasma concentration [27]. De Benedictis and colleagues reported that 10 days of administration of 500 mcg nebulized budesonide or 250 mcg fluticasone was not associated with hypophysial pituitary axis suppression [28].

In the present study, the treatment of BIS inhalation was well tolerated by all patients and exhibited significant effects in reducing postoperative symptoms of POST and hoarseness. In addition, our data also suggested that the addition of a BIS administration prior to the tracheal intubation further boosted the beneficial effects of the post-intubation administration. Our study also indicated that the BIS inhalation seemed more effective in improving hoarseness than reducing POST. However, the results of POST might be less accurate since the wound pain after thyroid surgery might interfere with the estimation of POST.

Conclusion

In conclusion, our study indicated that administration of BIS inhalation both before and after tracheal intubation could significantly prevent and reduce the occurrence of throat complaints in patients receiving thyroid surgery under general anesthesia.

References

1. Tazeh-Kand NF, Eslami B, Mohammadian K (2010) Inhaled fluticasone propionate reduces postoperative sore throat, cough, and hoarseness. Anesth Analg 111: 895-898.
2. Park SY, Kim SH, Lee AR, Cho SH, Chae WS, et al. (2010) Prophylactic effect of dexamethasone in reducing postoperative sore throat. Korean J Anesthesiol 58:15-19.
3. Christensen AM, Willemoes-Larsen H, Lundby L, Jzkobsen KB (1994) Postoperative throat complaints after tracheal intubation. Br J Anaesth 73: 786-787.
4. Al-Qahtani AS, Messahel FM (2005) Quality improvement in anesthetic practice-incidence of sore throat after using small tracheal tube. Middle East J Anesthesiol 18: 179-183.
5. Kadri IA, Khanzada TW, Samad A (2009) Post-thyroidectomy sore throat: a common problem. Par J Med Sci 25: 408-412.

6. Jung TH, Rho JH, Hwang JH, Lee JH, Cha SC, et al. (2011) The effect of the humidifier on sore throat and cough after thyroidectomy. Korean J Anesthesiol 61: 470-474.

7. Park SH, Han SH, Do SH, Kim JW, Rhee KY, et al. (2008) Prophylactic dexamethasone decreases the incidence of sore throat and hoarseness after tracheal extubation with a double-lumen endobronchial tube. Anesth Analg 107: 1814-1818.

8. Sumathi PA, Shenoy T, Ambareesha M, Krishna HM (2008) Controlled comparison between betamethasone gel and lidocaine jelly applied over tracheal tube to reduce postoperative sore throat, cough, and hoarseness of voice. Br J Anaesth 100: 215-218.

9. Maruyama K, Sakai H, Miyazawa H, Toda N, Iinuma Y, et al. (2004) Sore throat and hoarseness after total intravenous anaesthesia. Br J Anaesth 92: 541-543.

10. Biro P, Seifert B, Pasch T (2005) Complaints of sore throat after tracheal intubation: a prospective evaluation. Eur J Anaesthesiol 22: 307-311.

11. Hisham AN, Roshilla H, Amri N, Aina EN (2001) Post-thyroidectomy sore throat following endotracheal intubation. ANZ J Surg 71: 669-671.

12. Brimacombe J, Holyoake L, Keller C, Brimacombe N, Scully M, et al. (2000) Pharyngolaryngeal, neck, and jaw discomfort after anesthesia with the face mask and laryngeal mask airway at high and low cuff volumes in males and females. Anesthesiology 93: 26-31.

13. Keijzer C, Buitelaar DR, Efthymiou KM, Srámek M, ten Cate J, et al. (2009) A comparison of postoperative throat and neck complaints after the use of the i-gel and the La Premiere disposable laryngeal mask: a double-blinded, randomized, controlled trial. Anesth Analq 109: 1092-1095.

14. Kim DK, Rhee KY, Kwon WK, Kim TY, Kang JE (2007) A heated humidifier does not reduce laryngo- pharyngeal complaints after brief laryngeal mask anesthesia. Can J Anaesth 54:134-140.

15. Selvaraj T, Dhanpal R (2002) Evaluation of the application of topical steroids on the endotracheal tube in decreasing postoperative sore throat. J Anaesthesial Clin Pharmacol 18: 167-170.

16. Honarmand A, Safavi M (2008) Beclomethasone inhaler versus intravenous lidocaine in the prevention of postoperative airway and throat complaints: a randomized, controlled trial. Ann Saudi Med 28: 11-16.

17. Suissan S, Barnes P J (2009) Inhaled corticosteroids in COPD: the case against. Eur Respir J 34: 13-16.

18. Calverley PM, Anderson JA, Celli B, Ferguson GT, Jenkins C, et al. (2007) Salmenterol and fluticasone propionate and survival in chronic obstructive pulmonary disease. N Engl J Med 356: 775-789.

19. Loke YK, Singh S (2009) Inhaled corticosteroids in patients with COPD. JAMA 301: 1432-1434.

20. Wei JL, Kasperbauer JL, Weaver AL, Boggust AJ (2002) Efficacy of single-dose dexamethasone as adjuvant therapy for acute pharyngitis. Laryngoscope 112: 87-93.

21. Szefler SJ, Baker JW, Uryniak T, Goldman M, Silkoff PE (2007) Comparative study of budesonide inhalation suspension and montelukast in young children with mild persistent asthma. J Allergy Clin Immunol 120: 1043-1050.

22. Zhang PH, Chen XH, Zhang MY (2010) Inhalation of pulverized budesonide suspension in infantile rhinitis. Chinese general practice 13: 1906-1907.

23. Jiang YM, Jiang XC, Li JP, Zhang C, Wang JD (2010) Influence of nebulized Pulmicort Respules inhalation after endoscopic sinus surgery on expression of ENaC protein. Journal of Shanghai Jiaotong University 30: 80-83.

24. Leflein JG, Baker JW, Eigen H, Lyzell E, McDermott L (2005) Safety features of budesonide inhalation suspension in the long-term treatment of asthma in young children. Adv Ther 22: 198-207.

25. Berger WE, Qaqundah PY, Blake K, Rodriguez-Santana J, Irani AM, et al. (2005) Safety of budesonide inhalation suspension in infants aged six to twelve months with mild to moderate persistent asthma or recurrent wheeze. J Pediatr 146: 91-95.

26. Szefler SJ, Lyzell E, Fitzpatrick S, Cruz-Rivera M (2004) Safety profile of budesonide inhalation suspension in the pediatric population: worldwide experience. Ann Allergy Asthma Immunol 93: 83-90.

27. Volovitz B, Amir J, Malik H, Kauschansky A, Varsano I (1993) Growth and pituitary-adrenal function in children with severe asthma treated with inhaled budesonide. N Engl J Med 329: 1703-1708.

28. De Benedictis FM, Del Giudice MM, Vetrella M, Tressanti F, Tronci A, et al. (2005) Flic 12 Study Group Nebulized fluticasone propionate vs. budesonide as adjunctive treatment in children with asthma exacerbation. J Asthma 42: 331-336.