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A Comparative study of budesonide and lignocaine nebulization in preventing post operative sore throat and cough: A randomized control study

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Introduction

Post operative sore throat (POST), cough and hoarseness of voice are significant problems of General anesthesia following endotracheal intubation and has an incidence of 20-71.8[5]%. Appearance of POST is probably due to the endotracheal tube exerting pressure over the laryngeal and tracheal mucosa causing minor trauma resulting in inflammation of mucosa[3.]

Severity probably depends on many factors like usage of appropriate size of ET tube, type of tube used ,number of attempts, operative time and the type of the lubricant gel used [3.] Low-pressure cuffs may increase the likelihood of sore throat because of larger mucosal contact area[1]. These symptoms lead to dissatisfaction and discomfort after surgery and can delay a patients return to normal routine activities. Conventional treatment include usage of Lozenges, saline gargling, saline nebulization, lignocaine nebulization but they are not so efficacious and not feasible many a times. Budesonide, is an inhaled corticosteroid (potent glucocorticoid and weak mineralocorticoid activities) ,which due to its anti-inflammatory action effectively reduces these symptoms with minimal systemic absorption thus eliminating the risk of side effects[5] . As one of the most commonly used inhaled glucocorticoids which decrease airway hyperactivity, it acts by reducing the number of inflammatory cells and mediators present in the airways, exhibits potent local anti-inflammatory activity with limited systemic exposure. Lignocaine due to local anesthetic properties (suppression of the excitatory sensory C fibers in airways which reduces the amount of neuropeptide release) prevents sore throat.[3] Previous studies were conducted with budesonide administered using MDI but it is difficult for the patient to understand the method of using MDI even after explaining the method. Also it is not cost effective. Hence the present study compares the efficacy of budesonide , lignocaine and saline **nebulization** in preventing post op sore throat.

Aims and Objectives

Aim: To compare the efficacy of budesonide , lignocaine and saline nebulization in preventing post op sore throat.

Objectives

Primary : To compare the efficacy of budesonide, lignocaine and saline nebulization in preventing post op sore throat.

Secondary: To find out incidence of post op sore throat.

Materials and Methods:

Study location and population: Adult patients aged between 18-65yrs scheduled for elective surgery under GA with endotracheal intubation admitted at AJ institute of medical sciences and hospital, Mangalore.

Study design: Randomized double blinded control study.

Institutional ethical clearance obtained

Sample size estimation

$N=2(Z1_{-\alpha/2}+Z_{1-\beta})^2(\bar{p})(1-\bar{p})$ (p 1- p2)^2

Prophylactic Effectiveness of Budesonide Inhalation in Reducing Postoperative Throat Complaints" by **chen at al** in the year 2012 published in the " **Journal of Anesthesia & Clinical Research",**with the two ratios of 72.5% and 87.55% using the formula for calculating the sample size of two proportions ,at an alpha error of 10% power of 80% we arrive at a sample size in total of 118.

Selection Criteria

Inclusion criteria

1. Patients giving informed written consent.
2. ASA physical status I-II.
3. Patients aged between 18years – 65years.
4. Mallampati Grade I-II.
5. Patients scheduled for elective surgery under GA with Tracheal intubation less than 4 hours
6. Laryngoscopy done by same anaesthesiologist and one attempt

Exclusion criteria

1. Prone positions or steep trendelenburg or Anti-Trendelenburg position.
2. ASA 3 and ASA 4
3. MP-3 and MP 4
4. H/o URTI in the previous 2 weeks.
5. H/o Smoking.
6. H/o reactive airway disease & already on bronchodilator nebulization.
7. More than 2 attempts at laryngoscopy & intubation.

Method of collection of data

After institutional ethical committee approval, a comparative randomised two group clinical anaesthesia study will be conducted. A total number of 120 patients, undergoing Elective surgery under GA with Tracheal intubation and satisfying all the inclusion criteria will be enrolled in the study after taking informed consent & will be randomly allocated into 3 study groups with 40 patients in each group.

Group A: Patients receiving 2ml of budesonide (0.5mg)(Budecort respules) nebulization, 10 min prior to tracheal intubation.

Group B: Patients receiving 2ml of lignocaine nebulization, 10 min prior to tracheal intubation.

Group C: Patients receiving 2ml of saline nebulization, 10 min prior to tracheal intubation.

Method of Study

A prospective, Randomized, comparative, clinical anaesthesia study is planned. Pre anaesthetic evaluation of all patients will be performed by an anaesthesiologist a day before surgery. All patients meeting inclusion criteria after obtaining written informed consent will be randomly allocated into study groups by computer generated tables.

All patients will receive Tab pan (40mg) at night on the previous day of surgery. In the operation theatre intravenous access will be secured using 18 gauge cannula. Monitors will be connected & basal vitals such as Non invasive blood pressure (NIBP), Pulse rate (HR), oxygen saturation (SPO2) & Electrocardiography (ECG) will be noted.

Patients will be pre-oxygenated for 3min, premedicated with Inj. Glycopyrrolate 0.005mg/kg, Inj.Fentanyl 2mcg/kg and induced with Inj.Propofol 2mg/kg after checking for the adequacy of bag and mask ventilation, muscle relaxant Inj.Vecuronium 0.1 mg/kg will be given. Direct laryngoscopy will be done by same anaesthesiologist for all cases with appropriate sized laryngoscope blade,& after visualization of glottis appropriate sized cuffed endotracheal tube will be inserted .Effective ventilation with ET Tube will be confirmed by bilateral chest rise on manual ventilation, 5-point auscultation method, square wave capnogram trace &

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adequate exhaled tidal Volume. The ET tube cuff would be inflated up to 25 cmH2O using a cuff pressure monitor to ensure airtight seal & ET tube would be fixed. Patients will be maintained on volatile anaesthetic with an oxygen & N2O & Inj. Vecuronium at dose of 0.02 mg/kg will be administered on sos basis. The tidal volume & respiratory frequency will be adjusted & intermittent positive pressure Ventilation will be continued by mechanical ventilation to maintain end tidal carbon dioxide level between 25-35mmHg. At the end of surgery all patients will receive Inj.

Ondansetron 4mg iv for prevention of postoperative Nausea & vomiting. Residual Neuromuscular blockade will be antagonized by Inj. Neostigmine 0.05mg/kg & Inj. Glycopyrolate 0.01mg/kg. After surgery gentle oral suctioning will be carried out only once & patient will be extubated awake after confirming adequacy of spontaneous ventilation. Post operatively at 1 Hours, 12 Hours, 24 Hours,48Hours all patients will be assessed for incidence & severity of,

1. Postoperative sore throat
2. Postoperative cough.

Statistical Analysis

All the quantitative variables such as age, attempts of intubation etc. will be summarized in terms of Mean & Standard Deviation / Median & Interquartile range.

Qualitative variables such as presence of POST, cough, will be expressed as percentages. Differences in the mean values will be tested for statistical significance by Student T-test or by Mann - Whitney's test in case of non normality. Differences in the proportions will be tested for statistical significance by Chi - Square test of significance/ Fischer's exact test.

Results

All the patients completed the study, and the results were analysed. Demographic profile in terms of age, weight, ASA physical status and intubation characteristics were comparable in all the groups

Demographic profile of patients in the three groups

Criteria	Group A	Group B	Group C
Male: female	35:5	36:4	32:8
ASA 1 / 2	32/8	34/6	36/4
Age in years (mean+-SD)	42.6 +/- 6.4	43+/-7.2	41+/-6.4
Weight in kg (mean+-SD)	62.6	58.2	64.4

Sore throat at different intervals

Time	Group A(n%)	Group B(n%)	Group C(n%)	P value
1 hour	7 (17.5)	12(30)	18 (45)	0. 12
12 hour	4(10)	10 (25)	16 (40)	0.04
24 hour	3 (7)	6 (15)	11(27)	0.001
48 hour	1 (2)	4 (10)	8 (2)	0.001

Throat at different intervals Sore

Time	Group A(n%)	Group B(n%)	Group C(n%)	P value
1 hour	15(37.5)	16(40)	20(50)	0.04
12 hour	10(25)	7(17)	17(42)	0.02
24 hour	8(20)	3(7)	14(35)	<0.001
48 hour	5(12)	1(2)	4(10)	<0.001

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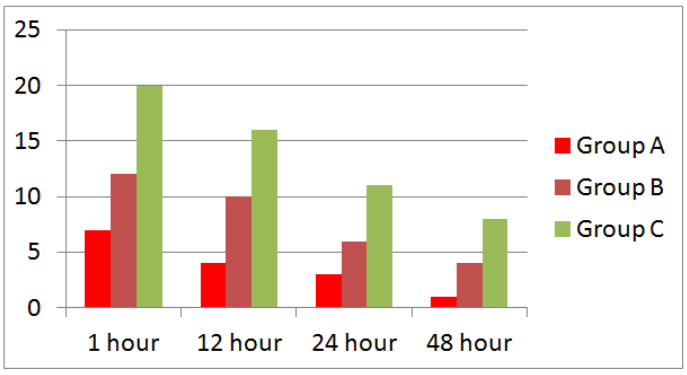
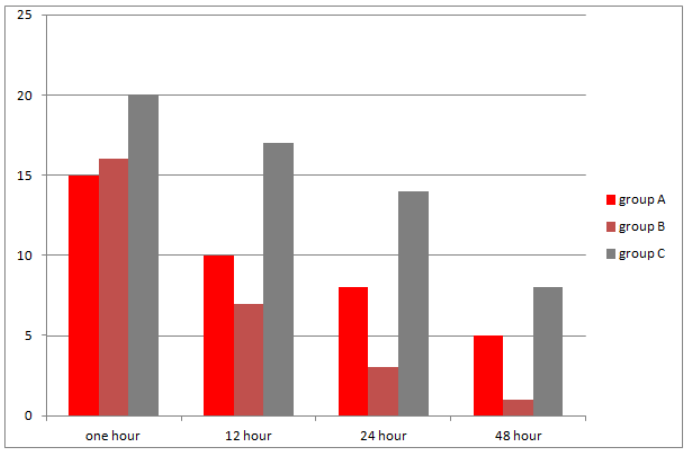
Cough at different intervals





Cough at different intervals

Discussion

Although considered as a minor self-limiting complication, POST accounts for one of the major reasons of patient dissatisfaction and delay in discharge following ambulatory surgery.[2] It results from an aseptic inflammatory process caused by irritation of the pharyngeal mucosa during laryngoscopy, and tracheal mucosa due to endotracheal tube cuff.[5,6] Trauma during laryngoscopy and intubation is another major contributing factor. Prophylactic management of Post-Operative Sore Throat (POST) is recommended to improve the quality of post anaesthesia care.

Various drugs like Ketamine, Lidocaine and Magnesium Sulphate administered either by nebulisation or gargling, which have some efficacy in reducing the symptoms. Budesonide is an anti-inflammatory corticosteroid with potent non- halogenated glucocorticoid and weak mineralocorticoid It was the first and only inhaled corticosteroid that could be delivered by atomization inhalation.[8,9]

Budesonide has a stronger lipophilicity, When compared with other systemic corticosteroids and it can shorten the anesthesia recovery time and alleviates post operative anaesthesia related complications. Budesonide enhances the vascular tension of throat and also causes reduction of capillary permeability as well as can also cause inhibition of edema formation and inflammatory reactions of the local tissues.[9]

In our study, the incidence and severity of sore throat decreased with passage of time. In present study the incidence of sore throat was 17.5%, 10%, 7%, 2% at 1, 12, 24, 48 hours respectively in budesonide group and that in lignocaine group was 30%, 25%, 15%, 10% at 1 , 12, 24 , 48 hours respectively and the difference was significant .In the study conducted by rajan at el showed significantly lower incidence of sore throat at 2, 6 ,12 ,24 hours in budesonide group compared to control group ($p<0.001$) In the present study The incidence of cough was 20%,15%, 5% , 0% at 1 , 12, 24 , 48 hours respectively in budesonide group and that in lignocaine group was 25%, 20%, 10%, 5% at 1 , 12 , 24 , 48 hours respectively with p value significant at 12,24, 48 hours. In study conducted by rajan et al cough was significantly lower in 2,6,12 hrs but not significant at 24hrs ($p=0.346$). In the study conducted by sheersha malhotra et al. The incidence and severity of sore throat at 1hr was higher in the patients who received lignocaine . Budesonide was most effective at 48 hrs Lignocaine was found to be better than ketamine at 24 hrs, difference being statistically significant, With passage of time, the overall incidence of sore throat and cough also decreased in all the groups . Lowest incidence of cough

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was found in the lignocaine group at 1 and 24 hrs postoperatively.

Conclusion

Budesonide and lignocaine nebulisation are effective agents in reducing POST and cough when given preoperatively but budesonide has the better outcome compared to lignocaine Incidences of POST and cough reduces with passage of time .

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