Original research article

Role of Benzydamine Gargling in Reduction of Post Operative Sore Throat Related to Endotracheal Intubation

Supriya Suman[1], Nitish Kumar[2]

[1]Senior resident, Department of Anaesthesiology ANMMCH Gaya

[2]Senior resident, Department of Anaesthesiology ANMMCH Gaya

Corresponding Author: Nitish Kumar

Abstract

Background: General anaesthesia with endotracheal intubation often results in postoperative sore throat, cough and hoarseness of voice. Benzydamine hydrochloride is a topical NSAID with analgesic, local anaesthetic, anti-inflammatory properties. We studied the effect of benzydamine hydrochloride gargling on the incidence and severity of sore throat, cough and hoarseness of voice in patients undergoing elective middle ear surgery under general anaesthesia with endotracheal intubation.

Methods: A prospective randomized placebo controlled double blind study, After institutional ethical committee approval, written informed consent was taken from all the patients after explaining the procedure. 120 patients of either gender scheduled for elective middle ear surgeries under general anaesthesia with endotracheal intubation, who fulfilled the inclusion and exclusion criteria were included. Patients were randomized into two groups - Benzydamine hydrochloride group and control group using sealed envelope method. Patients in Benzydamine hydrochloride group were gargled 0.15% of 20ml benzydamine hydrochloride solution and control group patients gargled 20ml of 0.9% saline for 30secs, 5mins before intubation.

Conclusion: Preoperative benzydamine hydrochloride oral gargle reduces the incidence and severity of sore throat, cough and hoarseness in patients who underwent elective middle ear surgery under general anaesthesia with endotracheal intubation.

Keywords: sore throat, hoarseness, benzydamine hydrochloride.

Introduction

Postoperative sore throat (POST) is a common minor complication after general anaesthesia (GA) with tracheal intubation and laryngeal mask airway (LMA) insertion occurring in 30 to 65% of patients.[1] It leads to patient dissatisfaction, physical discomfort and increased duration of hospital stay.[2,3] The causes of POST is due to several reasons which includes local inflammation of airway,[4] large size of the tracheal tube,[5] increased duration of surgery,[6] movement of tracheal tube and cuff during position change, airway damage during intubation,[7] and prone position.[8] It can be accompanied by cough, laryngitis, tracheitis, dysphagia or hoarseness. Modern anaesthesia is safe, versatile, and indispensable to the patient. Providing quality assurance of anaesthesia is important in improving the postoperative outcome of the patients. Therefore, efforts to decrease the anaesthesia related postoperative complications like postoperative nausea-vomiting and sore throat, including postoperative pain, are going on.[9] It is well recognized that prolonged intubation can have serious consequences, but it is less well recognized that uneventful intubation for routine surgical procedures can also cause pathological changes that may provide an organic basis for patients‟ postoperative throat symptoms. Although in most cases it will resolve

spontaneously, prevention focused on reducing its frequency and severity are recommended to better patient satisfaction and quality of postoperative care. Numerous non-pharmacological and pharmacological measures have been used for attenuating POST with variable success. Among the non-pharmacological methods, smaller sized tracheal tubes, careful airway instrumentation, minimizing the number of laryngoscopy attempts, intubation after the full relaxation of the larynx, gentle oropharyngeal suctioning, filling the cuff with an anaesthetic gas mixture, minimizing intracuff pressures <20 mm Hg, and extubation when the tracheal tube is fully deflated, have shown to decrease the incidence of POST. In most cases, postoperative throat complaints resolve spontaneously without specific treatment. In moderate to severe cases it may be beneficial to treat pain and dysphagia. BH is approved for the symptomatic treatment of acute sore throat pain. It has an alkaline pH, which means that it becomes concentrated in inflamed tissue and has minimal systemic absorption. This study was designed to compare the effect of Benzydamine oral gargling before surgery in patients who underwent ear surgeries under GA with endotracheal intubation.

Objectives

To compare the effect of gargling of 0.15% Benzydamine hydrochloride solution for 30 seconds, five minutes before endotracheal intubation on postoperative sore throat, cough and hoarseness of voice in patients operated under general anaesthesia with endotracheal intubation for middle ear surgeries.

Material and Method

A prospective randomized placebo controlled double blind study, Patients scheduled for elective middle ear surgeries under general anaesthesia with endotracheal intubation at Anugrah Narayan Magadh Medical College and hospital Gaya, Bihar. Study duration of two years , A total of 120

American patients (60 patients in each group) with below mentioned inclusion and exclusion criteria were enrolled for the study.

Inclusion criteria

Society of Anaesthesiologists (ASA) class 1-11

Age 20-60 years of either sex

Elective middle ear surgical procedures under general anaesthesia with oral- tracheal intubation

Duration of surgery <4hrs

Exclusion criteria

Patients with history of preoperative sore throat, More than one attempt at intubation ,Mallampati grade >2, Known smoker/allergies to BH, Patients on treatment with NSAIDs ,Morbidly obese (BMI >35)

A thorough preoperative evaluation was done for all the patients on the previous day of surgery and were explained about the procedure. All patients were kept nil per oral for 8 hrs for solid foods and 4 hrs for clear fluids.

On the day of surgery, after arrival to the operation theatre, the patients were shifted to anaesthesia preparation room. Patients were randomized into two groups namely BH group (intervention group) and control group using sealed envelope method. Patients in BH group received oral gargle of 20 ml of 0.15% Benzydamine solution for 30 seconds.

Patients in control group received oral gargle of 20 ml of 0.9% saline for 30 seconds.

The solutions were prepared by a pharmacist in our pharmacy department so that the different solutions had the same external appearance. After 5 minutes of gargle, patients were shifted to

operation table. 18G IV cannula was secured in left upper arm and Ringer‟s Lactate was started. ECG, NIBP, SpO_2 monitors were connected and baseline readings were noted. Injection midazolam 1mg IV, injection glycopyrrolate 0.2mg IV was given. All patients were preoxygenated for 3 minutes and anaesthesia was induced with injection propofol 2.5mg/kg body weight and fentanyl 2mcg/kg. Neuromuscular blockade was achieved with injection vecuronium bromide 0.1mg/kg. Once adequate depth was achieved, gentle laryngoscopy was done and the trachea was intubated in all patients, by a single anaesthesiologist who was blinded to the study drug with a 7.5mm tube in females and an 8.0mm tube in males. Successful intubation was confirmed by bilateral symmetrical chest expansion on manual ventilation, square waveform on capnography, stable oxygen saturation, no audible leak of the gases and lack of gastric insufflations. The endotracheal tube cuff was inflated with room air to a cuff pressure of 20 to 25 cm H_2O. The cuff pressure was intermittently measured after endotracheal tube intubation using a manometer (VBM, Sulz, Germany) and then once in every 60 minutes after intubation. Anaesthesia was maintained with Oxygen, Nitrous oxide and Sevoflurane and ventilated with intermittent positive pressure ventilation. At the end of surgical procedure, anaesthesia was discontinued and patients was reversed with injection neostigmine 0.05 mg/kg and injection glycopyrrolate 0.01 mg/kg. Once the patient was awake and breathing adequately, gentle oral suctioning was done and endotracheal tube was removed after deflating the cuff. Blood staining of the endotracheal tube or any presence of blood in suction catheter was noted. All the patients were shifted to the recovery room.

A sample size of 55 patients was calculated considering a decreased incidence of POST from 40% to 20% with a power of 90% and a significance level of 0.05. To compensate for potential dropouts, we enrolled 60 patients in each group. A total of 120 Patients were enrolled in the study.

Results

A sample size of 55 patients was calculated considering a decreased incidence of POST from 40% to 20% with a power of 90% and a significance level of 0.05. To compensate for potential dropouts, we enrolled 60 patients in each group. A total of 120 Patients were enrolled in the study**,** The data was analysed in using STATA 12.0 and SPSS 20.0 software. Continuous variables like age, weight, height, body mass index, and duration were reported as mean (SD). Categorical variables such as gender, type of surgery, ASA status, smoking, blood stain, postoperative parameters (sore throat, cough and hoarseness of voice), groups (intervention and control group) and side effects (nausea, vomiting, local tingling or numbness of the throat and mouth and dry mouth) were reported as proportions. The association between continuous variables and the groups (intervention and control) were assessed using unpaired t test and the association between categorical variable and groups were assessed using Chi Square test or Fisher‟s exact test based on the cell values. The difference between overall presence of postoperative parameters (sore throat, cough and hoarseness of voice), and side effects (nausea, vomiting, local tingling or numbness of the throat and mouth and dry mouth) between groups were assessed using difference between proportions test. p value of <0.05 was considered for statistical significance.

Table 1: Age distribution

Age in years	Intervention group (Benzydamine) N (%)	Control group (Normal Saline) N (%)	p value
Mean (SD)	31.1 (7.8)	32.1 (8.1)	0.465*

Unpaired t test

Table 2: Gender distribution

Gender	Intervention group (Benzydamine) N (%)	Control group (Normal Saline) N (%)	p value
Male	29 (48.3)	31 (51.7)	0.855[#]
Female	31 (51.7)	29 (48.3)	
Total	60 (100)	60 (100)	

Chi square test

The number of male and female participants in intervention (benzydamine) group are 29 (48.3%) and 31 (51.7%) respectively. In the control group 31 (51.7%) were male and 29 (48.3%) were females respectively. There is no statistically significant difference in gender of the participants in both the groups (p = 0.855)

Table 3: Duration of anaesthesia among the study participants

Duration	Intervention group (Benzydamine) Mean (SD)	Control group (Normal Saline) Mean (SD)	p value
Duration ofanaesthesia (min)	61.7 (7.0)	60.9 (8.4)	0.589*

Unpaired t test

Mean duration of anaesthesia (in mins) for subjects in benzydamine group and control group was 61.7 and 60.9 respectively. There was no statistically significant difference between the groups. (p = 0.589).

The number of participants who had blood either in the suction catheter or the endotracheal tube at the extubation in the intervention group are 5 (8.3%) and that in control group are 6 (10%). There is no statistically significant difference between the groups in the blood stain during extubation (p = 0.764). At the end of 4 hrs post operatively, only 10 patients in Benzydamine group had sore throat which was minimal as compared to 31 patients in the control group (p <0.001). In control group one patient had severe sore throat, 4 patients had moderate and remaining had minimal sore throat. At the end of 6 hrs post operatively, only 6 patients in Benzydamine group had sore throat which was minimal as compared to 25 patients in the control group (p <0.001).

In control group 4 patients had moderate and remaining had minimal sore throat. Immediately after extubation, 10 patients in the benzydamine group had cough which was moderate in 2 patients and minimal in the remaining as compared to the control group 18 patients had cough among which 4 patients had moderate and remaining had minimal cough. (p > 0.05), In the postoperative period, 12 patients had nausea and vomiting in the benzydamine group as compared to 11 patients in the control group. Local tingling was observed in 6 patients in benzydamine group which was clinically not significant.

Table 4: Satisfaction of patients at 24 hours among the study participants

Time point	Patient's Satisfaction	Intervention group (Benzydamine) N=60 n (%)	Control group (Normal Saline) N =60 n (%)	p value
24 hours	Satisfied	60 (100.0)	52 (86.7)	0.006[†]
	Not satisfied	0 (0.00)	8 (13.3)	

Fisher‟s exact test

At 24 hrs after surgery and extubation, all the patients in benzydamine group were satisfied and comfortable as compared to 52 patients in control group.

Discussion

This study showed that preoperative gargling with Benzydamine hydrochloride solution for 30 seconds, five minutes before orotracheal intubation was effective in reducing the incidence and severity of sore throat, cough and hoarseness of voice in the postoperative period without any complications as compared to placebo group in patients undergoing elective middle ear surgeries under general anaesthesia. POST may be caused by pharyngeal, laryngeal, or tracheal irritation and may occur even in the absence of endotracheal intubation.[10] It is difficult to differentiate whether POST is secondary to laryngoscopy alone, or is caused by insertion of an endotracheal tube, or is a combined effect of the two.[6] Numerous pharmacological and non-pharmacological approaches to prevent or minimize the incidence and severity of POST have been tried with conflicting results.[4] Among them benzydamine hydrochloride which possesses pluripotent actions has been proposed as an agent for the prevention of POST. Not much literature is available about the use of benzydamine hydrochloride (BH) gargling on POST. Benzydamine hydrochloride (BH) is a topical NSAID that has analgesic, local anaesthetic, anti-inflammatory and antimicrobial properties with a terminal half-life of approximately 8 hours.[11] Although local drug concentrations are relatively large, the systemic absorption of mouthwash-gargle of benzydamine is relatively low compared to oral doses, this lower absorption should greatly diminish the potential for any systemic drug side effects when BH is administered by gargling. [12] Hence we chose to administer Benzydamine in form of gargle for the intervention group. The contributing factors for POST include sex, age, use of succinylcholine, larger tracheal tubes, cuff design, and intracuff pressures.[3] In our study, no correlation was observed between age, gender, duration of surgery. We had chosen ASA 1 or 2 group of patients for the study who underwent surgeries on middle ear like tympanoplasty and mastoidectomy which lasted less than 4 hrs. The duration of anaesthesia in both the groups were similar. It is shown that the duration of surgery can also contribute to the incidence and severity of POST.[13] Biro P et al found that the patients who had history of smoking had higher incidence and severity of POST.[6] We excluded the patients with history of smoking. Brimacombe et al, explained that pressure exerted by the tracheal tube cuff on the mucosa may exceed capillary perfusion pressures and is a major cause of morbidity in intubated patients.[14] Jensen et al, found that frequency and severity of POST after short-term intubation was significantly greater after the use of high-pressure, low- volume cuffs, than after the use of a mask or of low-pressure, high-volume cuffs.The incidence of sore throat varies with the use of different lubricants, degree of intra- cuff pressures, and number of attempts of airway device insertion.[15] In our study the intracuff pressure was maintained by intermittently checking of the pressure and keeping it below 25 mmHg and in all the patients we used high volume low pressure cuffs. The side effects of topical use of benzydamine hydrochloride include local numbness or burning, stinging sensation, nausea or vomiting, cough and hoarseness.We did not observe any statistically significant difference among the intervention group and the control group in side effects. Biro P et al studied the effect of coughing and bucking during extubation on the incidence of POST. They observed that coughing and bucking can increase the incidence and severity.[6] We avoided the frequency of patient coughing and bucking during extubation by gentle oral suctioning and smooth extubation. We did not evaluate the correlation between the frequency of coughing or bucking at the time of extubation and the incidence of POST.

Conclusion

Preoperative gargling with benzydamine hydrochloride solution for 30 seconds, five minutes before intubation, reduces the incidence and severity of sore throat in patients who underwent elective middle ear surgery under general anaesthesia with endotracheal in the postoperative period. The incidence and severity of cough and hoarseness were also reduced in the postoperative period.

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