



An Evaluation of The Efficacy of Aspirin And Benzzydamine Hydrochloride Gargle for Attenuating Postoperative Sore Throat

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ABSTRACT

Aim: The present study was carried out to compare the efficacy of preoperative Aspirin and Benzzydamine Hydrochloride gargle for attenuating POST in patients undergoing elective surgery (e.g. mastoidectomy, modified radical mastectomy, fibroadenoma excision etc.) under GA with oral endotracheal intubation.

Material and methods: The present study was carried out on in a tertiary care teaching hospital in 90 patients. Patients were randomly allocated into 3 group of 30 patients each. Group AS-Aspirin, Group BH-Benzzydamine Hydrochloride, Group C-control. Patients were asked to do gargle the study drug for 30 secs 5 mins prior induction of anesthesia. POST was assessed at 0, 2, 4 and 24 hours post surgery.

Results: The results were collected tabulated and analyzed using the chi square, Mann Whitney test and Kruskal Wallis Test. The overall incidence of POST in C group (80%) was reduced to (23.33%) in AS group and (20%) in BH group. This was statistically significant.

Conclusion: In conclusion, both Aspirin and Benzzydamine Hydrochloride gargles are safe, simple and effective means of reducing the incidence and severity of POST; but benzzydamine hydrochloride gargle is more effective than Aspirin gargle in reducing POST for longer duration.

KEYWORDS : POST, Gargles, Benzzydamine , Aspirin , Sore throat

INTRODUCTION

The etiology of postoperative sore throat (POST) is considered the result of damage to airway mucosa after insertion of a laryngeal mask airway device or endotracheal tube. Numerous nonpharmacological and pharmacological measures have been used for attenuating POST with variable success. Endotracheal intubation is a rapid, simple, safe and non-surgical technique that achieves all goals of airway management and thus remains the gold standard procedure for airway management. However, pharyngo-laryngeal discomfort, dysphonia, dysphagia, and POST are well known following the use of an endotracheal tube (ETT).¹The combined incidence of this ranges between 5.7 and 90%

POST although a minor complication contributes to postoperative morbidity and patient dissatisfaction. The incidence of POST varies from 40 to 100 % in intubated patients.^{2,3,4} POST has been rated by patients as the 8th most undesirable outcome in the post-operative period⁵. POST may be caused by pharyngeal, laryngeal or tracheal irritation and may occur even in the absence of endotracheal intubation (with the use of a laryngeal mask airway or face mask)^{6,7,8}. There are a multitude of potential factors associated with POST which may be patient related, surgery related or anaesthesia related^{8,9,10}

The present study was carried out to compare the efficacy of preoperative Aspirin and Benzzydamine Hydrochloride gargle for attenuating POST in patients undergoing elective surgery (e.g. mastoidectomy, modified radical mastectomy, fibroadenoma excision etc.) under GA with oral endotracheal intubation.

MATERIALS AND METHODS:

Prospective, randomized, single-blind, placebo-controlled study was conducted in a tertiary care teaching hospital after approval from the institute's ethics committee and with well informed, written informed consent from the patients. We considered patients for inclusion if they were aged between 18 and 60 years, ASA physical status I and II, of either sex and undergoing elective surgery under GA with oral en-

dotracheal intubation and with Surgery duration between 1- 4 hours. During the preoperative visit by an anesthesiologist patients with a history of preoperative upper respiratory tract infection , sore throat or who received GA in previous 2 weeks of surgery, gastroesophageal reflux, regurgitation, known allergy to Aspirin or Benzzydamine Hydrochloride, patients with recent NSAIDS, smokers. pregnancy, anticipated difficult intubation, and MPC grade II , Nasogastric tube (NG tube) and/or throat pack use intraoperatively and when number of attempts for placing ETT was more than 2 were excluded from study.

Patients were randomized into 3 groups with 30 patients in each group with the help of a computer generated table of random numbers. The Group AS (Aspirin): 350 mg dispersible Aspirin tablet in distilled water. Group BH (Benzzydamine Hydrochloride): 15 ml Benzzydamine Hydrochloride in distilled water. GROUP C (control): 30 mL of distilled water. All the medications were made into 30 mL with distilled water.

Patients were asked to gargle the study medication for 30 secs, 5 min before induction of anesthesia. Patients were clearly instructed to gargle with this solution and none of the patients swallowed it. Medications for gargle were placed in an opaque container by a by an anesthesiologist who was not involved in further postoperative evaluation of the patient. Surgery was conducted in general anaesthesia by intubating the patient. On arrival in PACU (0 h) and thereafter at 2, 4, and 24 hours, POST was assessed by chief investigator who was unaware of the group allocation.

POST was graded on a 4-point scale (0–3):

- 0- no sore throat,
- 1- mild sore throat (complains of sore throat only on asking),
- 2- moderate sore throat (complains of sore throat on his/her own),
- 3- Severe sore throat (change of voice or hoarseness, associated with throat pain).

Side effects, if any, were also noted.

STATISTICAL ANALYSIS:

The data obtained from the study was analysed as follows: Analysis between the groups, for sex of patients was done with the Pearson Chi-square test and analysis for age of patients, weight of patients and duration of surgery was done with the ANOVA test. Association of sex and age of patients, duration of surgery and type of surgery with incidence of POST was tested with Chi- square test; analysis between three groups for POST grade was done with Kruskal Wallis Test and analysis between two groups for POST grade was done with Mann Whitney test. (Statistical significance: p value < 0.05 and Statistical insignificance: p value > 0.05).

OBSERVATIONS AND RESULTS:

| Type of surgery | | POST | | To- tal | POST | | To- tal | POST | | To- tal |
|--------------------------|--------------|----------|-------|------------|-------|-------|------------|----------|-------|------------|
| | | No | Yes | | No | Yes | | No | yes | |
| Mas- toidec- tomy | Count | 10 | 5 | 15 | 10 | 4 | 14 | 2 | 10 | 12 |
| | Per- cent | 66.67 | 33.33 | 100 | 71.43 | 28.57 | 100 | 16.67 | 83.33 | 100 |
| Breast surger- ies | Count | 13 | 2 | 15 | 14 | 2 | 16 | 4 | 14 | 18 |
| | Per- cent | 86.67 | 13.33 | 100 | 87.5 | 12.5 | 100 | 22.23 | 77.77 | 100 |
| Total | Count | 23 | 7 | 30 | 24 | 6 | 30 | 6 | 24 | 30 |
| | Per- cent | 76.67 | 23.33 | 100 | 80 | 20 | 100 | 20 | 80 | 100 |
| Chi square | | 0.745 | | 0.41 | | | | 0.009 | | |
| P value | | 0.388 | | 0.522 | | | | 0.926 | | |
| Association is | | Not sig. | | Not sig. | | | | Not sig. | | |

Table 1: Types of surgery in each group and the incidence of POST

TABLE 2: Mean rank of POST at all points of time in study groups.

| Time | Group (N=30) | Mean rank | Kruskal Wallis Test | df | p value | Significance |
|--------------|--------------|-----------|---------------------|----|-----------|--------------|
| 0 hr. POST | AS | 35.60 | 34.1873 | 2 | 3.77 E-08 | Significant |
| | BH | 35.60 | | | | |
| | C | 65.30 | | | | |
| 2 hrs. POST | AS | 39.68 | 16.04391 | 2 | 0.000328 | Significant |
| | BH | 38.30 | | | | |
| | C | 58.52 | | | | |
| 4 hrs. POST | AS | 42.27 | 9.46306 | 2 | 0.008813 | Significant |
| | BH | 39.33 | | | | |
| | C | 54.90 | | | | |
| 24 hrs. POST | AS | 44.40 | 7.801602 | 2 | 0.020226 | Significant |
| | BH | 41.50 | | | | |
| | C | 50.60 | | | | |

Table 3: Overall incidence of POST among study groups.

| Groups | | POST | | Total | Chi- square | p value | Significance |
|--------|---------|-------|-------|-------|----------------|---------------|--------------|
| | | Yes | No | | | | |
| C | Count | 24 | 6 | 30 | 28.18 | 7.6 E - 07 | Significant |
| | Percent | 80 | 20 | 100 | | | |
| AS | Count | 7 | 23 | 30 | | | |
| | Percent | 23.33 | 76.67 | 100 | | | |
| BH | Count | 6 | 24 | 30 | | | |
| | Percent | 20 | 80 | 100 | | | |

DISCUSSION:

Numerous nonpharmacological and pharmacological measures have been used for attenuating POST with variable success. Among the nonpharmacological methods smaller sized ETT⁹, lubricating the endotracheal tubes with water soluble jelly, careful airway instrumentation, intubation after full relaxation, gentle oropharyngeal suctioning, minimizing intra-cuff pressure and extubation when the ETT cuff is fully deflated have been reported to decrease the incidence of POST³. Tracheal intubation (ETT) is associated with a greater incidence of sore throat than laryngeal mask airway (LMA) or facemask.¹¹

The pharmacological measures including beclomethasone inhalation and gargling with azulene sulphonate have been reported to decrease the incidence of POST. ¹². Tenoxicam [hydrophilic nonsteroidal anti-inflammatory drug (NSAID)] from an impregnated gauze pack has been shown to be effective in reducing moderate or severe POST. ¹³The perioperative use of beclomethasone inhaler, betamethasone gel, ¹⁴ inj. dexamethasone (0.2mg/kg)¹⁵, inj. lignocaine (1-1.5mg/kg) intravenously¹⁶, alkalized lignocaine in the ETT, ketamine gargle, ¹⁷licorice gargle¹⁸, dexpanthenol pastilles,¹⁶. Some of these pharmacological measures are used pre-emptively. Pre-emptive analgesia is an anti- nociceptive treatment modality that prevents the central hypersensitivity that causes postoperative pain.²¹

Aspirin gargles are reportedly effective in relieving pain of oral lesions²²and pre-emptive topical benzydamine hydrochloride (a topical NSAID having analgesic, local anesthetic, anti-inflammatory and anti-microbial properties) has been reported to decrease the incidence of POST resulting from laryngeal mask airway use⁶.Sore throat and hoarseness are the most common complications after endotracheal intubation, with the incidence ranging from 6.6 to 90%.²³ Postoperative sore throat, while usually self-limiting, was rated by patients as one of the top 10 most undesirable postoperative outcomes.⁵ POST, although a minor complication contributes to postoperative morbidity and patient dissatisfaction. POST might be a consequence of localized trauma, leading to inflammation of pharyngeal mucosa secondary to either laryngoscopy or endotracheal intubation or both. It is difficult to differentiate whether POST is secondary to laryngoscopy alone, is caused by insertion of an endotracheal tube, or is a combined effect of the two². There are a multitude of potential factors associated with POST which may be patient related, surgery related or anaesthesia related^{8,9,10}.

Aspirin is a NSAID analgesic that is rapidly converted in the body to salicylic acid with a t1/2of the anti-inflammatory dose being 8 –12 hours. Aspirin gargle has been reported to be effective for relieving pain of oral lesions²⁰and in attenuating POST ²²

Benzydamine is a locally acting nonsteroidal anti-inflammatory drug(NSAID) with local anaesthetic, antimicrobial and analgesic properties providing both rapid and extended pain relief as well as a significant anti-inflammatory treatment for the painful inflammatory conditions of the mouth and throat²². BH has been suggested for the symptomatic treatment of acute sore throat pain by Mc Hardy and Chung. It has been reported that local tissue concentrations of BH are larger after topical application than after systemic administration. There may, therefore, be advantages to local application of the drug where the desired target site is accessible.¹¹Pre-emptive topical BH has been reported to decrease the incidence of sore throat resulting from endotracheal intubation²²and laryngeal mask airway use⁶.

In present study, the 3 groups were comparable with respect to sex, age and weight of the patients. There was no significant difference in the age factor of the patient except in the C group where POST was more common in patients having age > 36 years. This was comparable with Chen KT et al⁹and Kloub R ²³.POST was more common in females (30.43 %) than males (0 %) in AS group but no significant difference was seen in BH and C group. This was comparable with Biro P et al², Chen KT et al⁹ and PP Higgins et al¹⁸.The 3 groups were comparable with respect to duration and type of surgery. The mean duration of surgery in AS group was 2.55 hours, in BH group it was 2.45 hours and in C group it was 2.55 hours; which is not statistically significant (p value = 0.669)..

In our study, the patients were divided into 2 groups depending on the type of surgery, those who underwent mastoidectomy and those

who underwent breast surgery. This difference in incidence of POST among the two type of surgery groups was not statistically significant. The overall incidence of POST in C group (80%) was reduced to (23.33%) in AS group and (20%) in BH group. This was statistically significant.

All the patients were intubated in a single attempt and other anaesthesia related factors were standardised and controlled. As can be seen from the above discussion, in our study, the type of surgery didn't have a statistically significant association with the incidence of POST in all the 3 groups. For association of other factors viz. sex of patient, age of patient and duration of surgery with POST, the results were variable among the 3 groups. This might be due to a smaller sample size and different interventions among the 3 groups in our study as compared with studies conducted by Chen K T et al⁹ (sample size : 7541 patients), PP Higgins et al⁸ (sample size: 5264 patients), Biro P et al³ (sample size : 809 patients) and Kloub R²³ (sample size : 266 patients). These studies were conducted to simply determine the patient related, surgery related and anaesthesia related factors with POST and no attempt was made to reduce POST by any intervention.

When the 3 groups were compared with each other, it showed that the incidence and severity of POST in C group was more at all points of time when compared with AS and BH groups .

When AS and C groups were compared, it was found that the difference between the mean ranks of POST grade at 0, 2, 4 & 24 hours of AS & C groups were statistically significant. This shows that Aspirin is effective in reducing the incidence and severity of POST till 4 hours as compared with distilled water. This is comparable with Agarwal's results.¹⁷

When BH and C groups were compared, it showed that the difference between mean ranks of POST grade at 0, 2, 4 & 24 hours of BH & C groups were statistically significant. This shows that Benzydamine Hydrochloride is effective in reducing the incidence and severity of POST till 24 hours as compared with distilled water.

When AS and BH groups were compared, the difference in incidence and severity of POST between AS & BH groups at all points of time were not statistically significant. However, when the individual number of patients as per grade of sore throat at all points of time were compared; it showed that at 24 hours, 2 patients in the AS group had POST (grade 1) while not a single patient in the BH group had POST. This difference even though was statistically insignificant, but clinically it can be said that BH gargle was more effective than Aspirin gargle in reducing POST for longer duration.

CONCLUSION

- Gargling with Aspirin and benzydamine hydrochloride preoperatively reduced the incidence and severity of postoperative sore throat (POST).
- Aspirin gargle was effective for reducing POST for 4 hours.
- Benzydamine Hydrochloride gargle was effective for reducing POST for 24 hours.
- In conclusion, both Aspirin and Benzydamine Hydrochloride-gargles are safe, simple and effective means of reducing the incidence and severity of POST; but benzydamine hydrochloride gargle is more effective than Aspirin gargle in reducing POST for longer duration.

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