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**INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES**<http://doi.org/10.5281/zenodo.583739>Available online at: <http://www.iajps.com>**Research Article****RANDOMIZED CLINICAL TRIAL TO EVALUATE THE EFFECT OF
INTRAVENOUS DEXAMETHASONE VERSUS BECLOMETHASONE INHALER TO
REDUCE POSTOPERATIVE SORE THROAT DUE TO INTUBATION DURING
CATARACT SURGERY****Farhad Soltani^{1*}, Mandana Izadpanah², mehrdad maghami³, Shahriar Soltani⁴,
Mohammad Adineh⁵**¹Assistant Professor, Department of Anesthesia and intensive care unit, School of Medicine, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran.² Assistant Professor, Department of clinical Pharmacy, School of Pharmacy, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran. ³Golestan Hospital, Ahvaz Jundishapur University, Ahvaz, Iran.⁴B. SC. Bio-Organic, McGill University, Montreal- Canada.⁵Nursing care Research Center in Chronic Diseases, School of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran.**Abstract:****Introduction**

Postoperative sore throat is among the common consequences of tracheal intubation during surgical operations that is reported for up to 90% of the cases. This research aims to examine the effects of Beclomethasone inhaler versus intravenous Dexamethasone in reducing the sore throat after a tracheal intubation operation.

Material and methods

To conduct this trial 99 patients with an age range of 60 to 65 years who were about to undergo a cataract surgery were included. These subjects were randomly placed into three different groups; the first and second groups received beclomethasone inhaler and intravenous Dexamethasone respectively while the third one was considered as a control group. The medicine was prescribed for the patients before the induction stage of general anesthesia. Moreover, during the recovery phase and while the patients were fully conscious, the examinations were carried out by a doctor 15 hours after the surgery. Finally, a physician asked the questions from the patients face to face.

Results

In the Beclomethasone recipient group, 6% of patients experienced premature sore throat while 64% of them experienced serotinous sore throat. In the group of Dexamethasone recipients, 39% of the patients were reported having premature throat ache and 73% experienced serotinous throat sore. Finally, In the control group, 24% of the patients experienced a premature sore throat (during the recovery) while 76% experienced a different serotinous sore throat (15 hours after the operation). The levels of Dysphonia in the Beclomethasone recipient was significantly lower than those of the other two groups.

Conclusion

The results reveal that considering the local consumption and also the low systemic side effects involved applying Beclomethasone inhaler, it can be applied as an effective solution to control a sore throat after tracheal intubation. However, it is advised to carry out further research and examination with a focus on younger age groups or a specific gender.

Key words: postoperative sore throat, intubation, beclomethasone, dexamethasone

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INTRODUCTION:

Induction phase of anesthesia is often carried out along with laryngoscopy and tracheal intubation (1). Laryngoscopy is an essential and common way to protect the patients' airways. Although this therapy is a common practice, because of its complications it is always regarded as a challenge (2, 3). One of the most common consequences of tracheal intubation is a sore throat (4). A postoperative sore throat is a common complaint of patients that can be very disturbing and even cause sleep disorders and unpleasant memories. The rate of sore throat occurrence from this procedure has been reported in 6.6 to 90% of the patients. Various factors could contribute to this problem including the age of the patients, gender, dryness of anesthesiologic gasses, the reaction to the lubricants, increasing pressure inside the cuff of the tracheal tube, intubation errors, difficult intubation, longer laryngoscopy duration, and repeated intubation (2, 5). Inflammation, as one of the causes of this problem, can be prevented using corticosteroids. A thorough review of the literature shows that beclomethasone inhaler is among the drugs that could be useful in controlling the sore throat and thus is suggested using prior to laryngoscopy and tracheal intubation. Dexamethasone is a strong glucocorticoid and anti-inflammation that is effective in reducing the post-operation sore throat. Considering the significance of the issue and the urge to reduce a post-operation sore throat, this research was carried out to examine the effects of Beclomethasone inhaler and venous Dexamethasone on sore throat after tracheal intubation.

MATERIAL AND METHODS:

This research was a clinical study conducted in 2016 at Imam Khomeini Hospital, Ahvaz Jundishapur University of Medical Sciences. The study was performed on 60-65 years old cataract eye surgery patients who were examined to later undergo general anesthesia and did not have a contraindication to administration of steroids. For this purpose, 99 patients were randomly placed into three groups of beclomethasone inhaler recipients, intravenous Dexamethasone recipients, and the control group. In accordance with the Mallampati classification of American Society of Anesthesiologists (ASA) on the respiratory airway structure, all patients were classified as type 1. Moreover, they were informed of the research in person and the examination started following their consent. The patients having a history of smoking, sore throat in the past 14 days prior to the ones with a history of asthma or allergies, the patients with a history of analgesic or steroid drug

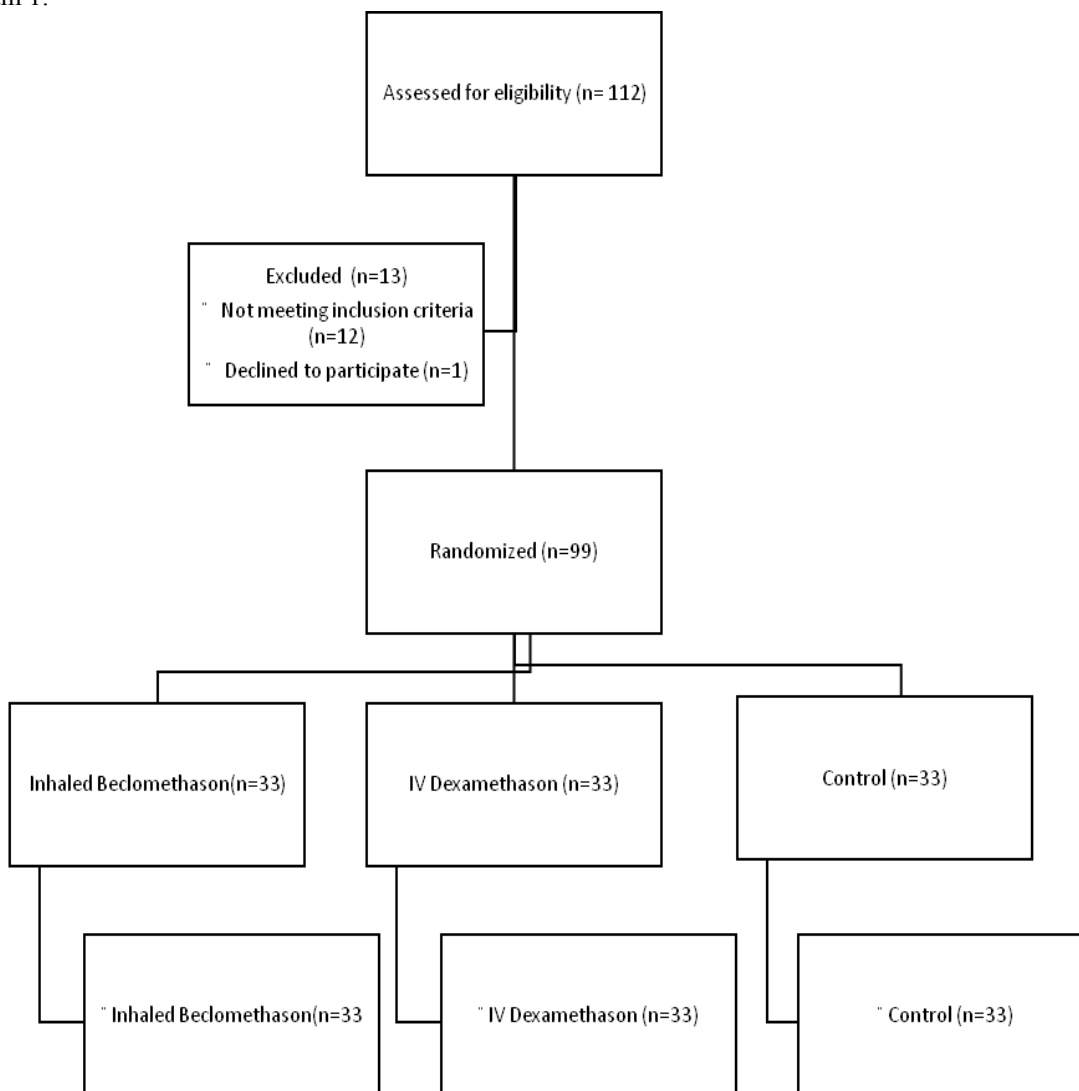
usage in past week, a history of respiratory infection, and neck or head surgery were omitted from the project. As mentioned, the patients were randomly assigned to 3 groups of 33 people. In Group 1, two puffs of beclomethasone inhaler were given right before the intubation, without using steroid during anesthesia or during the operation. In Group 2, 8 mg intravenous Dexamethasone was injected prior to the injection of anesthetic drugs. Finally, Group 3 was considered as the control. Only the anesthesiologist doctor was aware of the group divisions and none of the patients or the questioners (data collectors) were informed of the group divisions and whether one has received steroids or not. In order to record the data, a questionnaire was designed to collect information on the occurrence of potential side effects such as respiratory disorders, coughing, nausea, Laryngitis, premature sore throat (during recovery), and sore throat. During recovery and while the patient was fully conscious, 15 hours after the operation, the patients were asked by the questioners about their symptoms. For general anesthesia, cuffed tracheal tube was used for both groups using a Macintosh laryngoscope. Patients who received intubation for more than 15 seconds or the ones who received more than one intubation trial (more than one attempt) were removed from the study. The oxygenation process duration before laryngoscopy with pure oxygen was considered and recorded for all the three groups. A pulse oximeter was used to measure the oxygen saturation of arterial blood gas (ABG) throughout the patient's presence in the operation room. The room temperature was kept constant for all patients on the interval of 22-25°C. The medicine used for general anesthesia were Midazolam by a dose of 0.1-0.2 mg/kg, Fentanyl by a dose of 2-5 µg/kg, Sodium thiopental by a dose of 2.5-4.5mg/kg, Atracurium by a dose of 0.5 mg/kg, Ringer's lactate solution, Dextrose 3.33%, and sodium chloride 0.3%. For the anesthetic reverse process, Neostigmine was used by a dose of 50-70 µg/kg and Atropine by a dose of 20 µg/kg. During anesthesia, the average dosage of the medicine received was identical for both groups. Endotracheal tube cuff pressure in all patients was maintained between 20 to 30 cm of water.

Data analysis was performed using SPSS version 20. To estimate the prevalence and incidence of a sore throat, the demographic data of descriptive analysis (i.e., frequency distribution, mean, and standard deviation) were used. A chi-square (χ^2) test was performed to compare the occurrence of a sore throat amongst the groups. The statistical significance was set at $P < 0.05$.

RESULTS:

Initially, 112 people were scheduled to be examined for the study. Next, 12 of which were excluded from Diagram 1:

the study based on as previously explained criteria and one person did not consent to be part of the study (Diagram 1).



The remaining 99 patients were randomly divided into 3 groups, with their demographic data presented in Table 1.

Table 1: Demographic Data and characteristics of study population

Characteristic	Group 1: Inhaled Beclomethason (n= 33)	Group 2: IV Dexamethason (n=33)	Group 3: Control (n=33)
Age (years)	61/15±14/59	66.45 ± 10.17	62/91±12/80
Sex (male) n (%)	15 (48.5%)	15 (48.5%)	17 (51.5%)
Data have been presented as mean ± SD or number (%) as indicated.			

Table 2: incidence of sore throat and dysphonia

	Group 1: Inhaled Beclomethason (n= 33)	Group 2: IV Dexamethason (n=33)	Group 3: Control (n=33)
sore throat after recovery	2 (6.06%)	13 (%39/39)	8 (24/24%)
sore throat After 15 hours	22 (63/63%)	24 (%72/72)	25 (75/75%)
Dysphonia	9 (27/27%)	19 (%57/57)	17 (54/54%)

In Group 1, which received beclomethasone nasal inhaler, 37.5% of the patients were male with an average age of $59.14 \pm 15.61\%$. In this group, 6.06% of the patients experienced a sore throat during recovery. The occurrence rate of a serotinous sore throat was 63.63%. In addition, 27.27% of the patients experienced Dysphonia.

In Group 2, which received venous Dexamethasone, 48.5% of the patients were male with an age average of $17.10 \pm 45.66\%$. In this group, 39.39% of the patients experienced a sore throat during recovery. The occurrence rate of a serotinous sore throat was 72.72%. In addition, 57.57% of the patients experienced Dysphonia 12 hours after the operation, which was significantly higher than that in Group 1. The obtained data for this group are presented in Table 2.

Among three groups, there was no significant difference in the occurrence of a sore throat. However, looking at Dysphonia statistics, the patients receiving beclomethasone nasal inhaler had a significantly lower occurrence rate than the other groups ($p=0.001$). Additionally, there was no significant difference on Dysphonia occurrence between the patients receiving venous Dexamethasone (Group 2) and the control group (Table 2)

DISCUSSION:

One of the common side effects of general anesthesia followed by tracheal intubation is the sore throat symptoms after the operation, which could lead to damaging the neurons, tissues, and larynx. Dexamethasone is a corticosteroid that is used to prevent a sore throat after intubation. In this study, there was no significant difference in the occurrence of a premature sore throat between the group receiving venous Dexamethasone (Group 2) and the control group. This result, therefore, agreed with the results of Eydi et al. (2014) [12] in Iran who investigated the sore throat occurrence after intubation operation. In addition, this study was relatively contrary to the study performed by Sun et al. (2013)[13] in China who concluded that venous Dexamethasone could be useful to deal with the

occurrence of a postoperative sore throat. In contrast, this study was rather contrary to the results of the meta-analysis performed by Zhao et al. (2013) [14] who determined a positive role for venous Dexamethasone in controlling the sore throat after operations.

In this study, beclomethasone nasal inhaler proved to significantly reduce the occurrence of a premature sore throat, compared to the other two groups. However, it yet did not show to have a significant impact on serotinous sore throat occurrence. In this regard, Bani Hashem et al. (2015)[15] examined the effects of beclomethasone on the postoperative sore throat and concluded that beclomethasone, both in short-term and up to 24 hours after intubation, could reduce the severity of a sore throat. This result is consistent with our result upon the short-term effects on the sore throat; however, on the long-term effects of serotinous, the results are relatively contrary. Another study by Honarmand and Safavi (2008) [16] also showed a positive role for beclomethasone nasal inhaler to relieve pain after the operation. In the current study, beclomethasone nasal inhaler proved to be useful in reducing the levels of Dysphonia after the operation, a conclusion that is contrary to that of Bani Hashem, et al (2015)[15]. Additionally, in the current study, venous Dexamethasone did not show a significant impact on reducing the levels of Dysphonia, which is in agreement with the result reported by Eydi et al (2014). But, it is contrary to results of Park et al. (2008)[17], who completed a research in South Korea in order to determine the effect of Dexamethasone on voice roughness and Dysphonia and eventually concluded a positive role for Dexamethasone in this case.

Today, anesthesiologists are looking for ways to control the respiratory channel during general anesthesia, to minimize the tension and risks in the channel; for example, using LMA instead of a tracheal tube or implementing specific Local anesthesia techniques. However, considering the current conditions, it is inevitable to use a tracheal tube and hence it becomes necessary to examine the effects of tracheal intubation on a patient's health during and after the operation. The findings of this

study and multiple other studies showed different results on the effects of venous Dexamethasone and beclomethasone nasal inhaler. Thus, reaching consensus amongst the results requires further research. Moreover, there is a need to take necessary steps toward controlling the potential reasons that could lead to a sore throat.

CONCLUSION:

The suggestion by the researchers in this study is to attempt further clinical research on various age groups. Another suggestion would be to do a full examination of mouth and pharynx structure in order to make sure the participants in a study have similar general conditions. Additionally, studying younger age groups and gender-specific studies (male or female) on patients is recommended.

CONFLICT OF INTEREST :

The authors had not any financial or personal relationships with other people or organizations during the study. So there was no conflict of interests in this article.

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