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Comparison of Benzydamine Hydrochloride Mouthwash and Intravenous Dexamethasone in Reducing Sore Throat and Hoarseness After using i-gel™ Laryngeal Mask Airway

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Abstract

One of complications following surgery under general anesthesia using Laryngeal Mask Airway (LMA) is sore throat (ST) and hoarseness. The aim of this study was to compare 22.5mg Benzydamine HCl (BH) and 0.2mg/kg intravenous (iv) Dexamethasone in reducing postoperative ST and hoarseness in patients underwent elective surgery under general anesthesia (GA) using i-gel™ LMA. A total of 48 adult, ASA PS 1-2, aged 18-65 years old, Mallampati 1 and 2, mouth opening >3 cm, and BMI 18.5-25 kg/cm2 patients who underwent elective surgery with GA using i-gel™ LMA included and randomized into two groups. The first group (group A) received 22.5mg BH 15 ml over 1 minute and the second group (group B) received 0.2mg/kg iv Dexamethasone 30 minutes before inserted i-gel™ LMA. ST and hoarseness were assessed before surgery in preparation room (T0) and at 1 hour (T1), 6 hours (T2), 12 hours (T3), and 24 hours (T4) post LMA exertion. 22.5 mg BH mouthwash was more effective in reducing ST and hoarseness in patients after using i-gelTM LMA compared to 0.2mg/kg iv Dexamethasone at T3 post LMA exertion.

Keywords: Benzydamine HCl; Dexamethasone; Sore throat; Hoarseness; LMA; i-gel™ LMA

Introduction

One of the complications after a surgery using Laryngeal Mask Airway (LMA) is sore throat. Sore throat is a complication that is often found in patients with general anesthesia using LMA that is difficult to control, although surgical pain can be well-controlled using systemic analgesia. The reported incidence of a postoperative sore throat reaches more than 90%. Sore throat is one of the complications that can occur after surgery. Cuff pressure or the insertion of LMA which was forced too deeply can be the cause; this is shown in the study in the form of the incidence of a sore throat 24 hours postoperatively around 9% [1].

Sore throat symptoms and hoarseness better known as postoperative sore throat (POST) are complaints that are rarely complained by patients, but these complications are often found postoperatively [2].

The incidence of sore throat and hoarseness after surgery under general anesthesia from several studies ranged from 12.1-26%. The incidence of sore throat caused by LMA has been reported related to the method and technique of insertion, user experience, LMA size, and balloon pressure [3].

Previous research by [4], examined the comparison of techniques for reducing sore throat after insertion of LMA between lidocaine gel, normal saline, normal saline rinsing and the control group. In the control group, LMA was installed without lubricants. In the lidocaine group, the lidocaine gel was used, and in the saline group, LMA was washed with saline before insertion. In the fourth group, patients rinsed with 20 mL saline before the LMA was removed. Sore throat is most common in the control group (43.3%) and rarely in the rinsing group (25%). The incidence of sore throats in the lidocaine and saline group was the same (35%).

In the use of ETT, [1] conducted a study of the effects of sore throat and hoarseness after surgery with benzydamine HCl (BH) spray, 10% lidocaine and 2% lidocaine in endotracheal tubes. After being observed for 6 hours post-extubation, the incidence of sore throat and postoperative hoarseness was lowest in the benzydamine group (17.0%) versus 10% (53.7%) lidocaine, 2% (37.0%) and saline (40.8%). Benzydamine significantly reduced the incidence of sore throat compared to lidocaine in ETT use. Usage lidocaine spray is very associated with sore throat and post-surgical hoarseness. Lidocaine spray is known to contain addictive such as ethanol and menthol which can cause sore throat and hoarseness.

Another effort to reduce sore throat and hoarseness is through mouthwash. Giving mouthwash is direct to the affected site and making concentration to the maximum there.

BH is an anti-inflammatory drug that is widely used for oral area treatment, including topical non-steroidal anti-inflammatory drugs (NSAIDs). Apart from being anti-inflammatory, BH also has analgesic effects, local anesthetics that do not change the function of the oral mucosa and furthermore BH acts as mucosal protection to reduce the morbidity of sore throat due to mucous damage. BH showed the effect of inhibiting the stimulating effect of TNF-alpha on the production of PGE_2 and PGI_2 prostaglandins in human gingival fibroblasts, so BH inhibits prostaglandin production indirectly [4,5].

Dexamethasone is a potent glucocorticoid with analgesic and anti-inflammatory properties [6]. Stated in his research article that the use of intravenous (IV) dexamethasone 0.2 mg/kg can reduce the incidence of sore throat after surgery [7]. Examined the local effects of

dexamethasone in sore throat after surgery using LMA. Dexamethasone was given to LMA balloons while the control group used aquadest. The incidence of sore throat for 24 hours after surgery was 8% in the dexamethasone group and 22% in the aquadest group [8]. Concluded in their study that dexamethasone 10 mg/IV was more effective in reducing sore throat after surgery when used before intubation compared to after intubation.

From the description above, there are incidents of sore throat and postoperative hoarseness mainly due to the installation of LMA i-gel™. The airway device such as i-gel™ LMA is currently often used in surgery using general anesthesia. Based on this, the aim of this study was to determine the comparison of the effect of benzydamine hydrochloride mouthwash 22.5 mg with dexamethasone 0.2 mg/kg intravenously in preventing sore throat and hoarseness due to the installation of LMA i-gel™.

Patients and Methods

Location and Time of Research

The study was conducted at the Dr. Wahidin Sudirohusodo Hospital and its network hospital in Makassar, starting September 2018 until samples are enough.

Research Design and Variables

This study used a double-blind randomized trial design. The research variables consisted of: independent variables (group A, group B), dependent variables (sore throat, hoarseness), control variables (ASA PS, age, BMI, mallampati score, open mouth), and intermediate variables (installation of Laryngeal Mask Airway).

Population and Samples

The population included in this study was patients who would undergo general anesthesia procedures using LMA in the central operating theatre of Dr. Wahidin Sudirohusodo Hospital and its network hospital in Makassar. Samples were selected consecutively randomly from all populations that met the inclusion criteria, exclusion and agreed to participate in this study.

Method of collecting data

The assessment of sore throat and hoarseness was carried out 4 times, first (T1) in the recovery room 1 hour after the LMA i-gel™ exertion, the second (T2) was 6 hours after the LMA i-gel™ exertion, the third (T3) 12 hours after exertion the LMA i-gel™, and the last one (T4) was 24 hours after the LMA i-gel™ exertion, was assessed by an examiner who did not know the treatment given to the patient. Observations and interviews of patients were conducted carefully about the presence of sore throat and hoarseness which was assessed using pain scale with values 0 to 3.

Data analysis technique

The collected data will be re-examined about its completeness before tabulation and processing and then analyzed with the SPSS program and presented in the form of tables, sentences and graphs. The collected data is tabulated into the master table using Microsoft Office Excel software. Numerical data is displayed in mean values ± standard deviation, while categorical data is displayed in numbers (percentages). The research hypothesis was tested using the Chi Square method. The confidence interval used: 95% with a value of p <0.05 was considered statistically significant. At the end of the study, analysis will be separated between sore throat and hoarseness.

Results

A double-blind randomized trial was conducted to compare the effect of 22.5mg benzydamine hydrochloride mouthwash with intravenous dexamethasone 0.2 mg/kg in preventing sore throat and hoarseness due to the insertion of LMA i-gel™. Research began in September 2018 until the number of samples was fulfilled. The study was conducted on 48 people who underwent general anesthesia procedures using the LMA i-gel™ in the central operating theatre of the Dr. Wahidin Sudirohusodo Hospital and its network hospital in Makassar.

Sex comparisons were tested using the Chi square test, the results obtained p=0.773 where p <0.05 was stated as significant. In addition, there were no significant differences in age between the two groups (p=0.159). The mean ± SD age of each group was 41.92 ± 14.231 years for the dexamethasone group and 36.39 ± 12.514 years for the benzydamine group. Likewise, for BMI, no significant difference was found (p=0.390) between the two groups. The mean ± SD BMI in each group was 22.05 ± 2.28 kg/m^2 for the dexamethasone group and 22.62 ± 2.27 kg/m^2 for the benzydamine group. Therefore, the three groups can be considered homogeneous based on the characteristics of age and BMI. Age and BMI were tested using independent t-test, where p <0.05 was stated as meaningful (Appendix, Table 1).

Parameter	Dexamethasone Group (n=24)	Benzydamine Group (n=24)	p
Sex {n (%)}*			
Male	13 (54, 2%)	11 (45, 8%)	0,773
Female	11 (45, 8%)	13 (54, 2%)	
Age {mean(years) ± SD}**	41,92 ± 14,231	36,39 ± 12,514	0,159
BMI {mean(kg/m2) ± SD}**	22,05 ± 2,28	22,62 ± 2,27	0,390

Table 1: Characteristics of both groups.

Sample distribution based on *sex tested by Chi square test,** age and BMI tested by independent t-test p<0,05 was declared homogenous.

T0 measurements in both groups did not find sore throat in all samples. In the T1 measurement, the Dexamethasone group obtained 1 sample with first degree of sore throat, while in the benzydamine group no sore throat was found in all samples. Based on statistical analysis, no significant difference in pain scores was found between the two groups with a value of p=0.500. In the measurement of T2, the dexamethasone group obtained 9 samples with first degree of sore throat while the benzydamine group obtained 6 samples with first degree of sore throat. Based on the statistical analysis, no significant difference in pain scores was found between the two groups with a p value 0.267. In the T3 measurement the dexamethasone group obtained 7 samples with first degree of sore throat. While in the benzydamine group there were no samples with sore throat. Based on statistical analysis, there were significant differences in pain scores

between the two groups with a value of p=0.005. In the measurement of T4 in both groups no sore throat was found in all samples so no statistical tests were carried out (Appendix, Table 2).

	Sore throat	Dexamethasone Group	Benzydamine Group	p
T0				
	Score 0 (n/%)	24/100%	24/100%	-
	Score 1 (n/%)	0/0%	0/0%	
	Score 2 (n/%)	0/0%	0/0%	
	Score 3 (n/%)	0/0%	0/0%	
T1				
	Score 0 (n/%)	23/95,8%	24/100%	0,500
	Score 1 (n/%)	1/4,2%	0/0%	
	Score 2 (n/%)	0/0%	0/0%	
	Score 3 (n/%)	0/0%	0/0%	
T2				
	Score 0 (n/%)	15/62,5%	18/75%	0,267
	Score 1 (n/%)	9/37,5%	6/25%	
	Score 2 (n/%)	0/0%	0/0%	
	Score 3 (n/%)	0/0%	0/0%	
T3				
	Score 0 (n/%)	17/70,8%	24/100%	0,005*
	Score 1 (n/%)	7/29,2%	0/0%	
	Score 2 (n/%)	0/0%	0/0%	
	Score 3 (n/%)	0/0%	0/0%	
T4				
	Score 0 (n/%)	24/100%	24/100%	-
	Score 1 (n/%)	0/0%	0/0%	
	Score 2 (n/%)	0/0%	0/0%	
	Score 3 (n/%)	0/0%	0/0%	

T0 measurements in both groups did not get any degree of hoarseness in all samples. In the measurement of T1, the dexamethasone group found that 1 sample had second degree of hoarseness while the benzydamine group did not get hoarseness in all samples. Based on the statistical analysis, there were no significant differences in hoarse voice scores between the two groups with a value of p=0.500. In the measurement of T2, the dexamethasone group found 8 samples had first degree of hoarseness and 1 with second degree of hoarseness while in the benzydamine group, 6 samples with first degree of hoarseness were obtained with p value=0.459. Whereas in the measurement of T3, the Dexamethasone group found 7 samples had first degree of hoarseness and 1 sample with second degree. While the Benzydamine group did not get samples with hoarseness. Based on statistical analysis, it was found that the difference in hoarseness score was significant between the two groups with a value of p=0.008. The measurement of T4 in the Dexamethasone group obtained 1 sample with first degree of hoarseness. While the Benzydamine group did not get hoarseness in all samples so that no statistical tests were carried out (Appendix, Table 3).

	Hoarseness	Dexamethasone Group	Benzydamine Group	p
T0				
	Score 0 (n/%)	24/100%	24/100%	-
	Score 1 (n/%)	0/0%	0/0%	
	Score 2 (n/%)	0/0%	0/0%	
	Score 3 (n/%)	0/0%	0/0%	
T1				
	Score 0 (n/%)	23/95,8%	24/100%	0,500
	Score 1 (n/%)	0/0%	0/0%	
	Score 2 (n/%)	1/4,2%	0/0%	
	Score 3 (n/%)	0/0%	0/0%	
T2				
	Score 0 (n/%)	15/62,5%	18/75%	0,459
	Score 1 (n/%)	8/33,3%	6/25%	
	Score 2 (n/%)	1/4,2%	0/0%	
	Score 3 (n/%)	0/0%	0/0%	
T3				
	Score 0 (n/%)	16/66,7%	24/100%	0,008*
	Score 1 (n/%)	7/29,2%	0/0%	
	Score 2 (n/%)	1/4,2%	0/0%	
	Score 3 (n/%)	0/0%	0/0%	
T4				
	Score 0 (n/%)	23/95,8%	24/100%	1,000
	Score 1 (n/%)	1/4,2%	0/0%	
	Score 2 (n/%)	0/0%	0/0%	
	Score 3 (n/%)	0/0%	0/0%	

Table 3: Comparison of Hoarseness Score in Both Groups. Comparison of pain scores between the two groups was tested by the Fisher Exact Test, * p <0.05 was stated as meaningful.

Discussion

This study showed that mouthwash BH 22.5 mg was more effective than intravenous 0.2 mg/kg dexamethasone in reducing sore throat and hoarseness after the use of LMA i-gelTM at 12 hours after LMA exertion.

The study was conducted on 48 people who underwent general anesthesia procedures using LMA in the central operating theatre of Dr. Wahidin Sudirohusodo Hospital and its network hospital in Makassar and fulfilled the inclusion criteria. The sample was divided into 2 groups, 24 samples in Group A who got 15 ml of 15 mL mouthwash for 1 minute and 24 samples in Group B who received 0.2mg/kgBB of dexamethasone intravenously 30 minutes before LMA i-gel insertion. Data obtained on gender, age and BMI. No samples were excluded or dropped out.

The results of the sample homogeneity test based on the characteristics of the study sample on sex characteristics between the two groups was p=0.773. Based on these results it was concluded that there were no significant differences in sex characteristics between the two groups. Age characteristics showed no significant differences in age between the two groups (p=0.159). The mean ± SD age of each group was 41.92 ± 14.231 years for the dexamethasone group and 36.39 ± 12.514 years for the benzydamine group.

Similarly for BMI, no significant difference was found (p=0.390) between the two groups. The mean ± SD BMI in each group was 22.05 ± 2.28 kg/m^2 for the dexamethasone group and 22.62 ± 2.27 kg /m^2 for the benzydamine group. That is, both groups can be considered homogeneous based on sex characteristics, age and BMI.

From the results of the analysis showed that the measurement of T0 time in both groups did not get sore throat in all samples. At the time measurement of T1, the Dexamethasone group obtained 1 sample (4.2%) having first degree of sore throat. While in the benzydamine group no sore throat was found in all samples. Based on statistical analysis, no significant difference in pain scores was found between the two groups with a value of p=0.500.

Clinically in the measurement of T2, the dexamethasone group found 9 samples (37.5%) had first degree of sore throat. While in the benzydamine group there were 6 samples (25%) with first degree of sore throat. Based on statistical analysis no differences in pain scores were found significant between the two groups with a value of p=0.267.

Whereas in the measurement of T3, the dexamethasone group found 7 samples (29.2%) had first degree of sore throat. While in the benzydamine group there were no samples with sore throat. Based on statistical analysis, there were significant differences in pain scores between the two groups with a value of p=0.005. The results of the analysis showed that in the T4 measurements in both groups no sore throat was found in all samples.

The low incidence of sore throats of all groups at the time of T1 when compared with the incidence of T2 sore throat, it is possible at T1 the influence of analgesic drugs used during surgery is still there so that disguises discomfort in the throat, whereas in T2 the analgesic effect has decreased. When T3 and T4 are possible there has been spontaneous healing of trauma that causes sore throat in accordance with the ability to work anti-inflammatory drugs.

In accordance with our study, the Benzydamine group did not find patients with sore throat after 12 and 24 hours of LMA exertion. Previous studies have suggested that the use of benzydamine in endotracheal tubes and spraying of the mucosa of the oropharynx can reduce the incidence of throat and hoarseness in patients with endotracheal tube and laryngeal mask airway (LMA) [9].

In addition, the results of the analysis showed that in the T0 measurements in both groups no hoarseness was found in all samples. In the T1 measurement, the Dexamethasone group obtained 1 sample (4.2%) having a second degree of hoarse voice while the benzydamine group did not get hoarseness in all samples. Based on the statistical analysis, there were no significant differences in hoarse voice scores between the two groups with a value of p=0.500.

In the measurement of T2, the dexamethasone group obtained 8 samples (33.3%) having first degree of hoarseness and 1 sample (4.2%) with second degree of hoarseness. While in the benzydamine group 6 samples (25%) had first degree of hoarseness. Based on the statistical analysis, there was no significant difference in hoarse voice scores found between the two groups with a p value of 0.459.

Whereas in the measurement of T3, the dexamethasone group found 7 samples (29.2%) had first degree of hoarseness and 1 sample (4.2%) with a degree of hoarseness. While the benzydamine group did not get samples with second degree of hoarseness. Based on statistical analysis, it was found that the difference in hoarseness score was significant between the two groups with a value of p=0.008. The measurement of T4 in the Dexamethasone group obtained 1 sample (4.2%) with first degree of hoarseness while the benzydamine group did not get hoarseness in all samples.

The use of steroid prophylaxis is known to reduce the frequency of sore throat and cough during the recovery phase because it can affect the inflammation process due to tissue injury. Steroids inhibit the movement of leukocytes to the site of inflammation and inhibit the release of cytokines by maintaining cell integrity. Intravenous dexamethasone can also inhibit arachidonic acid metabolism and the production of leukotriene-B4 thereby inhibiting interleukin-2 formation [10]. Getting the use of intravenous dexamethasone prophylaxis at a dose of 0.2 mg/kg can reduce the rate of postoperative sore throat in the first 1 hour post-extubation of about 30% and extubation in prevention of sore throat by about 60%. Intravenous dexamethasone has an average length of action of 6 hours; this can explain in some studies the rate of postoperative sore throat is greater in the dexamethasone group than in the benzydamine group. There was a statistically significant difference in the incidence of sore throat and hoarseness at 12 hours after the LMA i-gelTM exertion. So the use of BH mouthwash before insertion of the LMA i-gelTM can be recommended. It is necessary to do further research on how the effect of repetitive BH mouthwash after the patient is awake after surgery on anesthesia using the LMA i-gelTM.

Side effects of BH mouthwash include nausea, vomiting, headache, while local effects include local numbness, burning, pain, dry mouth, irritation of the throat and coughing. But in this study there were no side effects of BH mouthwash. In this study the side effects of dexamethasone which can increase blood sugar postoperatively by examining postoperative blood sugar were not carried out because patients with uncontrolled diabetes mellitus were excluded from the study.

Intravenous dexamethasone and BH mouthwash are both easily available at the hospital. However, the use of BH mouthwash can reduce the side effects that can occur due to systemic corticosteroid use such as intravenous dexamethasone. Another advantage compared to intravenous dexamethasone was that there were no side effects in this study, and the price was cheap, not traumatic, and easy to administer.

Conclusions and Recommendations

The researchers concluded that the mouthwash BH 22.5 mg was more effective than intravenous 0.2 mg/kg dexamethasone in reducing

sore throat and hoarseness after the use of the LMA i-gelTM at 12 hours after LMA exertion. The researcher suggested that further research be conducted using BH mouthwash before LMA insertion and after the patient was awake, to reduce the incidence of sore throat and hoarseness. Further research is needed by using the next generation of other types of LMA that use balloon development to determine the effect of BH on the incidence of sore throat and hoarseness. Further research is needed by using other types of pharmacological therapy to compare with BH on the incidence of sore throat and hoarseness.

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