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Research Article

Preventive Effect of Two Different Doses of Intravenous Dexamethasone on Sore Throat after Caesarean Section

Mitra Jabalameli, Reihanak Talakoub, Atefeh Ghosouri, Fatemeh Dadvar*

Department of Anesthesiology and Critical Care, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran.

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ABSTRACT

Background: Sore throat after tracheal intubation is one of the unpleasant experiences of patients under general anesthesia, which can affect the patient's recovery and postoperative satisfaction. It is more common in the female sex after gynecological and obstetric surgeries. Physiological and anatomical changes during pregnancy result in intubation difficulty and subsequent sore throat. One of the prevention methods of this condition is the use of dexamethasone, which is a glucocorticoid with anti-inflammatory properties. This study aims to compare the effectiveness of two different dexamethasone doses (4 mg and 8 mg) in reducing post-operative sore throat after caesarean section.

Methods: In a double-blinded randomized controlled trial (RCT), 90 candidates of caesarean section under general anesthesia were randomized to three groups receiving 8 mg of dexamethasone IV (Group I), 4 mg of dexamethasone IV (Group II), and 2 ml of normal saline (Group III) as a control group after the umbilical cord clamp. Then, through the VAS questionnaire, the rates of sore throat at one, 6, 12, and 24 hours after extubation were recorded and compared in three groups.

Results: The average time of extubation in the 8 mg IV dexamethasone receiving group was significantly shorter than the normal saline receiving group (1.59 ± 5.13, P=0.007). The average severity of the sore throat at 6, 12, and 24 hours postoperatively was significantly different between the three groups. The severity of the sore throat in a group receiving 8 mg and 4 mg dexamethasone was significantly less than in the normal saline group (0.59 ± 0.19, P= 0.003 and 0.41 ± 0.19, P=0.036), respectively. Patient satisfaction was higher in the 8 mg dexamethasone-receiving group than in the other groups.

Conclusion: Two doses of 8 and 4 mg of intravenous dexamethasone are effective in reducing the rate and severity of post-intubation sore throat after cesarean section under general anesthesia, and the dose of 8 mg is more effective than 4 mg, but this difference was not statistically significant.

Introduction

Post-intubation sore throat is a significant discomfort for patients undergoing general anesthesia [1]. This unpleasant experience is particularly common in females and during gynecological and obstetric surgeries, including Caesarian sections (CS), and many other factors, such as a history of smoking or lung disease, intubation trauma, and a large-sized tracheal tube, contribute to the increased risk of this condition [2-5]. Various methods have been explored to prevent this complication, such as using low-pressure tracheal tubes, topical lidocaine, and corticosteroids applied to the airway [6-13].

The increasing rate of CS worldwide necessitates further research into patient comfort during these procedures [14]. Physiological and anatomical changes in

The authors declare no conflicts of interest.
*Corresponding author.
E-mail address: atefehghosouri@med.mui.ac.ir
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the airway of pregnant women make intubation more challenging. Therefore, identifying effective methods to prevent post-intubation sore throat in this population is crucial since congestion of the capillaries of the airway causes swelling of the nasopharynx, oropharynx, larynx, and trachea [15-16]. Also, increased estrogen and increased blood volume during pregnancy can cause airway mucosal edema. These changes can be exacerbated by a mild upper airway infection and preeclampsia-related edema [17]. Therefore, it is important to study efficient methods to prevent a sore throat after intubation in pregnant women undergoing CS.

While numerous studies have investigated methods and medications to reduce sore throat after tracheal intubation [18-26], no single ideal method has been established specifically for CS. This present study aims to compare the preventive effect of two different intravenous doses of dexamethasone (4mg and 8mg) on the severity of post-intubation sore throat in patients undergoing CS under general anesthesia.

Methods

The present study is a double-blinded randomized prospective controlled trial. After receiving the Ethics Committee approval and obtaining informed and written consent from all participants and registering in the IRCT system (IRCT20230716058799N1), this study was performed on 90 candidates of caesarean section under general anesthesia.

The inclusion criteria included pregnant women, ASA I, age over 18, with gestational age between 37 and 42 weeks, candidates for caesarean section surgery under general anesthesia. Those patients with colds or sore throats before anesthesia, patients with a BMI of more than 40, users of painkillers and sedatives before surgery, recipients of corticosteroids during pregnancy, patients with allergies to the studied drug, patients with a history of lung diseases and asthma, and patients with laryngoscopic grades of 3 and 4 (difficult intubation) did not enter the study. During the study, patients who were reluctant to continue the study and who developed an allergy to the drug or any complications and unusual prolonged surgery were excluded from the study.

The sample size required for this study by using the sample size estimation formula to compare the means and with a confidence level of 95%, a test power of 80%, the standard deviation of the severity of sore throat, which was estimated at 1.7 in one study, and the minimum meaningful difference between the two groups, which was considered 0.8, The number of 30 people in each group was considered. Then, 90 pregnant women were selected for the caesarean section under general anesthesia and distributed in 3 groups of 30 patients. Patients entered the study after obtaining written and informed consent and explaining the study. Group One: 8 milligrams of dexamethasone, Group Two: 4 milligrams of dexamethasone, and Group Three received a similar volume of 2 ml of normal saline after the umbilical cord clamp. Due to the small sample size and to ensure that the number of people in each group was balanced, a restricted randomization method was used from the permuted block randomization type. Thus, it consisted of 15 blocks of 6 consisting of 2 A's, 2 B's, and 2 C's.

The studied drugs were prepared and numbered by the first anesthesiologist in similar syringes.

Before induction of anesthesia, VAS was explained to all patients by a graded ruler from 0 to 10.

Preoperative preparation, fluid therapy, and the anesthetic drugs were the same in all three groups. Induction of anesthesia was performed with injections of fentanyl (50 micrograms), sodium thiopental (5 mg/kg), and succinylcholine (1 mg/kg). Due to the fact that the skill of the anesthesiologist affects the results, all patients were intubated with a tracheal tube of size 7 by one anesthesiologist. The tracheal tube cuff was filled with air with a pressure of 20 cm/H_2O for all patients. Maintenance of anesthesia was performed with isoflurane 5/0-1 percent and 0.5 mg/kg of Atracurium, and fluid therapy was performed with Ringer serum at 10 ml/kg/h speed. After the umbilical cord clamp, the studied drugs were injected by the second anesthesiologist slowly.

All patients underwent standard monitoring during and after surgery, and the duration of intubation and extubation was also measured.

After completing the procedure and patients entering the recovery room, the severity of the sore throat in the hours of one, 6, 12, and 24 after extubation was measured by the VAS scale and recorded by an anesthesiologist unaware of the studied groups. In this study, all the participants, healthcare providers, other caregivers, and outcome assessors were blinded and not aware of the type of substance injected.

Sore throat was considered positive if the patient's sore throat score (VAS) was 4 or more, and then one gram of Apotel in 100 ml normal saline was given within 15 minutes. Moreover, possible side effects of dexamethasone, such as nausea, vomiting, headache, confusion, and rash, were investigated and recorded.

In addition, the duration of intubation and extubation was measured and recorded. The duration of intubation was determined from the time of insertion of the endotracheal tube to the time of extubation. Also, the duration of extubation is considered from the time of closing the anesthetic drugs until the time of endotracheal tube removal. Airway classification was carried out based on the size of the tongue and the visible structure of the throat. To perform this examination, the patient is in a sitting position and, while holding his head in a neutral position, opens her mouth as wide as possible and expels

his tongue as much as possible. The patient should not say "A" during the examination. This preoperative examination is performed to predict the ease of intubation. Accordingly, the airway is divided into four classes:

Class I: soft palate, anterior and posterior tonsillitis and small tongue are visible.

Class II: tonsillitis and small tongue tips are hidden by the rule of the tongue.

Class III: only soft palate and small tongue rule are visible.

Class IV: not even the soft palate is visible.

Finally, the collected data is entered into the SPSS software version 26 and is analyzed with K-Square statistical tests, one-way variance analysis, variance analysis with repeated observations, and independent T-tests. Significance was set at $P< 0.05$.

Results

In this study, 90 candidates of CS in three groups of 30 people were studied. Each group received 8 mg of dexamethasone, 4 mg of dexamethasone, and normal saline intravenously after the umbilical cord clamp, respectively. In this study, no patient was excluded due to withdrawal criteria and/or the occurrence of unwanted side effects. The data analysis was carried out on 90 patients. The three study groups did not differ significantly in terms of the demographic distribution and basic variables (age, gestational age, number of previous pregnancies, and number of births) (Table 1).

(Table 2) shows that there was no meaningful difference in the mean duration of intubation between three groups (P=0.56), but the difference in the mean duration of extubation between three groups was significant (P=0.005). In a two-to-two comparison of groups with the LSD follow-up test, there was a difference between the two receiving groups of 8 and 4 mg of dexamethasone in the mean time of extubation, but this difference was not statistically significant (1.59 ± 3.67, P=0.07). There was also no significant difference between the groups receiving dexamethasone 4 mg and normal saline (1.59 ± 5.13, P=0.65). But the difference between the groups receiving dexamethasone 8 mg and normal saline was significant (1.59 ± 5.13, P=0.007). (Table 2).

(Table 3) shows the mean and standard deviation of sore throat severity from one to 24 hours after the extubation between the three groups. According to the one-way ANOVA test, the average severity of sore throat at 6, 12, and 24 hours after the extubation was significantly different between the three groups. With the analysis of variance test with repeated observations, within all three groups, the trend of changes in sore throat severity from 1 to 24 hours after surgery had a meaningful difference ($P< 0.001$) (Table 3).

The mean sore throat severity until 24 hours after surgery had a significant difference among groups (P=0.009). According to the LSD follow-up test, the mean sore throat severity between the two dexamethasone 8 mg and 4 mg groups did not differ significantly (0.19 ± 0.18, P = 0.34), but there was a significant difference between the dexamethasone 8 mg and normal saline groups (0.19 ± 0.59, P = 0.003), and between the two dexamethasone 4 mg and normal saline groups (0.19 ± 0.41, P = 0.036) (Figure 1).

The mean patient satisfaction score in the three groups receiving 8 mg dexamethasone, 4 mg dexamethasone, and normal saline was 0.93 ± 9.03, 0.98 ± 9, and 1.47 ± 8.37, respectively, and the difference between the three groups was meaningful (P = 0.047). In comparing the two groups, satisfaction between the two dexamethasone groups of 8 ml and 4 ml did not differ significantly (0.3 ± 0.03, P=0.91). But there was a significant difference between the two groups of dexamethasone 8 ml and normal saline (0.3 ± 0.67, P = 0.028), while there was also a significant difference between the two groups of dexamethasone 4 ml and normal saline (0.3 ± 0.63, P = 0.036).

In this study, 10 patients received Apothel, of whom 2 (6.7%) of them were from the dexamethasone 8 mg group, one (3.3%) was from the dexamethasone 4 mg group, and 7 (23.3%) were from the normal saline group, and the difference was three meaningful groups (P=0.031).

Also, during the study, 10 patients developed drug complications, with 1 (3.3%) of the dexamethasone group 8 mg, 3 (10%) of the dexamethasone group 4 mg, and 6 (20%) of the normal saline group. This difference was significant between the three groups (P=0.031).

(Table 4) shows the distribution of the prevalence of drug side effects in three groups. According to the table, there was no significant difference in the type of side effects among groups (Table 4).

Table 1- Distribution of demographic and basic variables in three groups

Variable	Groups			P
	Dexamethasone (8mg) (n=30)	Dexamethasone (4mg) (n=30)	Normal saline (n=30)	
age (year)	30.33±8.17	32.33±7.04	30.67±4.67	0.48
weight (Kg)	68.7±6.96	72.67±7.65	71.57±8.06	0.12
gestational age (week)	37.73±1.05	38.0±1.26	37.73±1.02	0.57

Number of previous pregnancies	1	12(40)	12(40)	11(36.7)	0.48
	2	7(23.3)	7(23.3)	5(16.7)	
	3	9(30)	4(13.3)	7(23.3)	
	4 and more	2(6.7)	7(23.3)	7(23.3)	
Number of previous births	0	12(40)	12(40)	17(46.7)	0.51
	1	10(33.3)	13(43.3)	8(26.7)	
	2	7(23.3)	2(6.7)	6(20)	
	3 and more	1(3.3)	3(10)	2(6.7)	

Table 2- Mean and standard deviation of intubation and extubation duration in three groups

Variable	Groups			P
	Dexamethasone (8mg) (n=30)	Dexamethasone (4mg) (n=30)	Normal saline (n=30)	
Mean intubation duration (minutes)	85.93±23	96.10±56.69	89.23±19.1	0.56
Mean extubation duration (minutes)	10.67±4.11	14.33±8.22	15.80±5.35	0.005

Table 3- Mean and standard deviation of sore throat severity up to 24 hours after surgery in three groups

Time	Groups			P*	P**
	Dexamethasone (8mg) (n=30)	Dexamethasone (4mg) (n=30)	Normal saline (n=30)		
1 hr after surgery	1.33±1.18	1.50±1.38	2.07±1.39	0.09	0.009
6 hrs after surgery	1.57±0.82	1.70±0.75	2.27±0.98	0.005	
12 hrs after surgery	0.80±0.66	0.97±0.77	1.30±0.92	0.049	
24 hrs after surgery	0.20±0.41	0.47±0.68	0.63±0.62	0.017	
P***	<0.001	<0.001	<0.001		

* P-value Intergroup
** P-Value between groups
***P-Value Intergroup

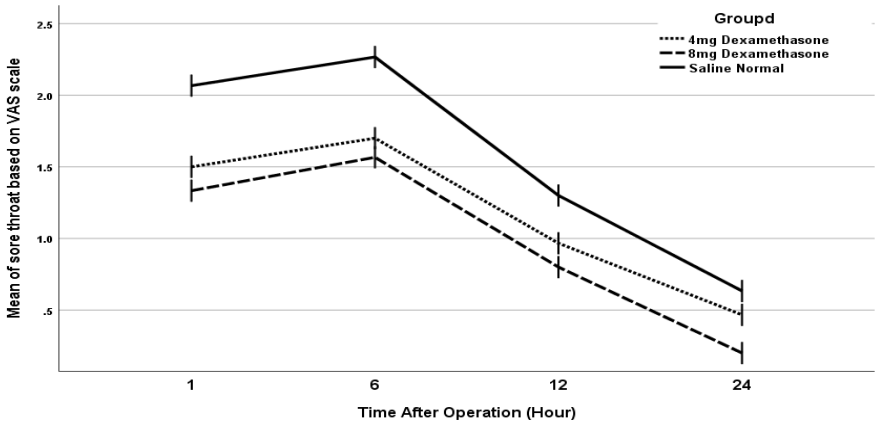

Figure 1- Mean sore throat severity from 1 to 24 hours after surgery in three groups

Table 4- Distribution of the prevalence of drug side effects in three groups

Variable	Groups			P
	Dexamethasone (8mg) (n=30)	Dexamethasone (4mg) (n=30)	Normal saline (n=30)	
Headache	1(3.3)	2(6.7)	3(10)	0.87
Nausea	0(0)	0(0)	2(6.7)	0.33
Vomiting	0(0)	0(0)	1(3.3)	>0.97

Confusion	1(3.3)	3(10)	3(10)	0.69

Discussion

This study is the first, to our knowledge, to compare the effect of two intravenous dexamethasone doses (4mg and 8mg) on post-intubation sore throat severity in C-section patients. Our findings demonstrated that both doses of dexamethasone significantly reduced the rate and severity of sore throat compared to the control group, without affecting hemodynamic variables. Notably, the 8mg dose may have shortened the duration of extubation, although this difference was not statistically significant. Additionally, patient satisfaction was significantly higher in the 8mg dexamethasone group.

Three groups were similar in the distribution of demographic and basic variables, including age, gestational age, weight, number of pregnancies, and previous births.

Our results also showed that the use of 8 mg of dexamethasone reduced the duration of extubation when compared to the normal saline group, while the consumption of 4 mg of dexamethasone did not significantly reduce the duration of extubation when compared to the normal saline group.

These results are consistent with previous studies that showed a positive association between intravenous dexamethasone administration and a lower incidence of postoperative sore throat [10-13, 19].

Postoperative sore throat has been reported in the literature after the use of an endotracheal tube, supraglottic devices, or even a face mask. The underlying cause might be trauma to the oropharynx, base of tongue, or posterior pharyngeal wall, or inflammation secondary to an allergy to any component of the airway device used. Further trauma to epithelial or deeper layers of vocal cords may cause inflammation and edema, which can affect voice quality and hoarseness, which usually resolves spontaneously (< 6 weeks). An inflammatory reaction sets in after the initial insult. It is this early stage of inflammation that is inhibited by the corticosteroids. Dexamethasone is a potent corticosteroid that has 26.6- and 6.6-times stronger anti-inflammatory and immunosuppressant effects than cortisol and prednisone, respectively. It has anti-inflammatory properties and is reported to be effective in the treatment of sore throat and decreasing edema in the airway after traumatic intubation. Further, it is used in the perioperative period as an antiemetic and also to potentiate analgesic effects. It has a rapid onset and a short duration of action. It is cheap, so it can be considered a good option. It reduces the production of inflammatory mediators, prostaglandins, and leukotrienes. Post-extubation laryngeal edema is caused by infiltration of fibrinous exudates and polymorphonuclear cells.

The potential mechanism by which dexamethasone reduces sore throat is presumably based on its anti-inflammatory activity, which includes inhibition of leukocyte migration and maintenance of cell membrane integrity. In addition, this effect may be increased when dexamethasone is administered before laryngeal trauma. In more detail, dexamethasone inhibits phospholipase A2 through the production of calcium-dependent phospholipid-binding proteins known as annexins and cyclooxygenase.

Dexamethasone, when used in treating sore throat by different routes, is found to be effective, intravenous being most commonly studied, but it has some undue side effects.

However, there are studies that show that a single dose of dexamethasone has no systemic adverse effects like adrenal suppression, gastritis, glucose intolerance, osteoporosis, and high blood pressure. Also, glucocorticoids do not increase the risk of postoperative infection [27-28].

In our study, patient satisfaction was significantly higher in the group receiving 8 mg of dexamethasone. This increase in satisfaction corresponded to the observed decrease in sore throat and discomfort, which is likely to lead to a more positive postoperative experience. Moreover, the decrease in prevalence and severity of sore throat and duration of extubation in patients receiving intravenous dexamethasone is consistent with the results seen in many studies that have evaluated patients undergoing other surgical procedures [15].

However, some studies reported no significant effect. For example, Singh and colleagues studied the effect of a single dose of 8 mg of intravenous dexamethasone on reducing sore throat, nausea, and vomiting after caesarean section surgery and reported that the prevalence and severity of postoperative sore throat was significantly lower in the group receiving dexamethasone at 1, 2, 6, 12, and 24 hours after surgery. The prevalence of nausea and vomiting in the dexamethasone group was also lower at 6, 12, and 24 hours after surgery [29]. Ruangsin and his colleagues reported that 8 and 4 mg intravenous dexamethasone had no significant effect on post-operative sore throat reduction after various elective surgeries [30]. The above studies are not consistent with our study. Variations in surgical procedures, patient populations, and dexamethasone dosage regimens might explain these discrepancies.

Dabir and his colleagues reported that the duration of extubation is more reduced by dexamethasone in comparison with bupivacaine [31]. In another study conducted by Amuzadeh and his colleagues on 110 patients undergoing head and neck surgery, it was shown that in the group receiving 8 mg of intravenous dexamethasone three times a day in the first 24 hours and

then 4 mg twice a day in the second 24 hours, the duration of extubation was shorter than in the control group, who did not receive corticosteroids [32].

Cardoso and colleagues studied the effect of 10 mg of dexamethasone on nausea, vomiting, and pain after cesarean section surgery and reported that the prevalence of nausea and vomiting was significantly lower in the study group than in the control group. The prevalence of pain during rest and movement in the study group was also lower in the dexamethasone-receiving group [33].

In spite of the fact that there have been studies on the effect of various drugs on sore throats after extubation in patients undergoing Caesarean section, two different intravenous doses of 4 and 8 mg dexamethasone on the severity of sore throats have not been studied and compared in these patients.

The results of our study showed that the 8 mg of the intravenous dexamethasone is not associated with the occurrence of significant side effects compared to its 4 mg dose and the control group. These findings also coincide with the results of the Cardoso study. Our study also showed that 8 mg of dexamethasone was associated with greater patient satisfaction in the postoperative period. In other words, patients receiving 8 mg of dexamethasone had less cough and sore throat during the postoperative period. So given the results, the cost-effectiveness of using dexamethasone for this purpose, the absence of significant drug complications, and the need to control the sore throat after a caesarean section, it seems that the single dose of 8 mg dexamethasone is more appropriate in these patients.

Despite the promising findings, limitations exist. The sample size was relatively small, since most caesarean section surgeries are performed under spinal anesthesia. Further studies with larger sample sizes are warranted to confirm the optimal dose of dexamethasone in CS using spinal anesthesia. The other limitation was its short follow-up period, which could be beneficial to assess longer-term effects.

Conclusion

Our study suggests that both 4mg and 8mg of intravenous dexamethasone effectively reduce post-intubation sore throat severity after CS under general anesthesia. While the 8mg dose may shorten extubation time and improve patient satisfaction, this difference requires further investigation. So, it seems that the use of an 8 mg intravenous dexamethasone is preferable in these patients.

Ethical approval

The study obtained the approval of the institutional review board at the School of Medicine, Isfahan (code: IR.MUI.MED. REC.1402.012). All patients provided informed consent before participation in this study.

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