

The Effect of Postoperative Single-Dose Intravenous Dexamethasone on Common Complications After Tonsillectomy in Children: A Randomized Controlled Trial

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Abstract

Background: Tonsillectomy is associated with early and late postoperative complications in the children. Previous studies have shown some effects of dexamethasone; however, there has been a lack of studies that evaluate its effects on other complications, including odynophagia and otalgia.

Objectives: We aimed to investigate the effects of dexamethasone on odynophagia and otalgia after surgery.

Patients and Methods: In this randomized clinical trial, 100 patients who underwent adenotonsillectomy were divided into two groups: one group received 0.1 mg/kg of dexamethasone (case) and the other received Ringer serum as a placebo (control). Intravenous (IV) dexamethasone was prescribed to be administered by a nurse on the ward. The incidence of bleeding, nausea and vomiting, odynophagia, voice change, acetaminophen intake, halitosis and otalgia, and activity were evaluated at 24 h and during the first 7 days after surgery.

Results: The mean ages of patients were 7.1 ± 2.8 and 6.5 ± 2.4 years in the control and case groups, respectively. The overall proportions of females and males were 41% and 59%, respectively. No significant difference in demographic data was seen between the two groups ($P > 0.05$). There was a significant difference in terms of odynophagia and nausea and vomiting between the case and control groups after 24 h ($P = 0.001$). There was no significant difference between the case and control groups in terms of bleeding, voice change, halitosis, or nausea and vomiting after 7 days ($P > 0.05$). Meanwhile, there were a significant difference in the incidence of acetaminophen intake (60% vs. 30%, $P = 0.002$), odynophagia (24% vs. 6%, $P = 0.011$), otalgia (20% vs. 4%, $P = 0.014$), and activity (80% vs. 98%, $P = 0.004$) of patients after 7 days between the groups.

Conclusions: In children undergoing adenotonsillectomy, dexamethasone has a significant antiemetic effect and decreases odynophagia, otalgia, and the need for analgesia.

Keywords: Tonsillectomy, Children, Dexamethasone Complications

1. Background

Tonsillectomy and adenoidectomy are among the most commonly performed surgical procedures in children (1-3). Recurrent throat infection and sleep-disordered breathing, halitosis, and tonsil hypertrophy are included in the indications for surgery, as they affect the health status and life quality of child (2). Common complications of tonsillectomy are postoperative pain, nausea and vomiting, bleeding, delayed feeding, voice change, and rarely, death (2-4). It has been stated that effective management of postoperative pain can prevent morbidity, facilitate early oral intake, and decrease the risk of bleeding (5-7). Nonsteroidal anti-inflammatory drugs (NSAIDs) have been administered for their analgesic effects. However, they increase the risk of postoperative bleeding, as they inhibit platelets (8, 9). Glucocorticoids such as dexamethasone have antiemetic and anti-inflammatory effects that may decrease postoperative edema (10, 11). It has also been reported that based on its effects, it can improve oral intake after ton-

sillectomy (10, 11). It has been demonstrated in previous studies that dexamethasone is administered to children undergoing a variety of surgical procedures, particularly tonsillectomy, as it reduces postoperative pain, nausea and vomiting, and airway swelling, while increasing oral intake (12, 13). However, there is a lack of studies that have investigated the effects of this drug on other common complications like otalgia, odynophagia, and halitosis.

2. Objectives

As other effects of this drug have not been established, more studies are needed for further investigation. Thus, in this randomized controlled clinical trial, we aimed to investigate the effects of dexamethasone on postoperative pain, bleeding, nausea and vomiting, odynophagia, voice change, activity or healthiness, halitosis, and otalgia at 24 h and for 7 days after surgery.

3. Patients and Methods

In this randomized clinical trial, we enrolled 100 patients referred to the ear, nose, and throat (ENT) department of Khalili Hospital, a governmental hospital, who underwent adenotonsillectomy between February 2011 and March 2013.

3.1. Ethical Considerations

Informed consent was obtained from all patients prior to surgery. This study was approved by the ethics committee of the Shiraz university of medical sciences (ethical approval code number: ir.sums.rec.1394.100). The IRCT code for this study was IRCT2015080522889N2. Study population, intervention, and protocol. We recruited study participants from the Khalili hospital, Shiraz, Iran. Children aged 4 - 10 years scheduled for elective adenotonsillectomy for recurrent tonsillitis or sleep apnea and adenotonsillar hypertrophy were eligible to enter the study. Children were excluded if they had a history of convulsion, prematurity, allergy or hypersensitivity to dexamethasone, syndromic disease (e.g., Down syndrome), coagulation disorder, systemic disease, developmental problems, congenital heart disease, nutritional deficiencies like SDP or G6PD, and poor follow-up. Written informed consent was obtained from parents; it was also obtained from children if they were able to read and sign a specifically designed information sheet. The exact number of cases lost to follow-up and mortalities was $n = 0$.

3.2. Procedures

After monitoring, patients were randomly assigned to one of two groups via a computer-generated randomization list, as follows: a group administered dexamethasone 0.1 mg/kg (case) and one given Ringer serum as a placebo (control). Children were permitted to eat solid food until 12 a.m. on the day before the operation and drink clear fluids until 3 h before the surgery. Anesthesia was induced with sevoflurane or propofol and was maintained using a volatile anesthetic. A standardized anesthetic was used. All patients were tracheally intubated. The amount of intravenous (IV) fluid administered was 25 - 30 mL/kg of lactated Ringer's solution during the intraoperative period. The same surgeon used the blunt dissection and electrocautery technique for all patients. Patients were tracheally extubated in the operating room when fully awake. After surgery, children were transferred to the post-anesthesia care unit and moved to the 2 hours later, where they stayed overnight. On the ward, analgesia was administered via oral acetaminophen (10 - 15 mg/kg/day every 6 hours). IV dexamethasone was prescribed and administered via nurse in the ward. Children were free to eat a cold soft diet and drink as soon as the surgeon confirmed the absence of bleeding from the tonsillar bed through visual examination. One day after surgery, the

incidence of bleeding, nausea and vomiting, odynophagia, voice change, and activity were evaluated. Children were discharged home the day after surgery. If they had pain, analgesia at home was identical to that on the ward. All patients were also sent home with an oral antibiotic, namely amoxicillin (10 - 20 mg/kg/day for 5 - 7 days). Parents were given a patient care diary to record the time and number of further episodes of vomiting, time and dose of analgesia (acetaminophen), time to soft food intake, and time to hard food intake. Within 7 days after surgery, patients were examined by a physician again to monitor bleeding, nausea and vomiting, odynophagia, voice change, activity or healthiness, acetaminophen intake, halitosis, and otalgia. Two different questionnaires were used to collect data; one was filled out 24 h after the surgery and the other within 7 days of the surgery.

3.3. Statistical Analysis of the Data

The t-test from Statistical Package for Social Sciences (SPSS 18) was used to compare the mean age between two groups. To check the normality of quantitative variables, the one-sample K-S test was used. In addition, to compare amounts of bleeding 24 hours after the surgery, Fisher's exact test was used. Chi-square tests for similarity of populations were performed to identify any significance of variation of the results within the groups. A $P < 0.005$ was considered to be statistically significant.

4. Results

One-hundred patients were enrolled in this study; they were randomly divided into case ($n = 50$) and control ($n = 50$) groups. Based on the results of our study, there was no significant difference between the control and case groups in terms of age or gender (Table 1).

It should be mentioned that all patients received acetaminophen until 24 hours after surgery. The number of patients who exhibited activity 24 hours after the surgery was greater than in the case group ($n = 41$). However, this result was not statistically significant ($P = 0.108$). In addition, the number of patients who experienced a voice change after 24 hours after the surgery was lower in the case group, but this difference was not statistically significant ($P = 0.140$). Based on Table 2, there was no difference in the incidence of bleeding, voice change, acetaminophen intake, and activity of patients after 24 hours between the case and control groups ($P > 0.05$). Time to first liquid intake was not significantly different between the groups ($P > 0.05$). There was no difference among the treatment groups in time to first pain rescue ($P > 0.05$). However, there were significant differences in terms of odynophagia and nausea and vomiting between the case and control groups after 24 hours ($P = 0.001$).

The analgesic demand in patients who did not receive dexamethasone was higher than that of patients who received dexamethasone at 48 - 72 hour after discharge from hospital ($P = 0.002$). Based on the results of this

study, the numbers of patients who had nausea and vomiting, voice change, and halitosis were lower in the case group. However, this difference was not statistically significant ($P = 0.332, 0.082, 0.094$). As shown in Table 3, there was no significant difference between the case and control groups in terms of bleeding, voice change, halitosis, and nausea and vomiting after 7 days ($P > 0.05$). Meanwhile, there were a significant difference in the incidence of patients' acetaminophen intake ($P = 0.002$), odynophagia ($P = 0.011$), otalgia ($P = 0.014$), and activity ($P = 0.004$) between groups after 7 days.

Table 1. Demographic Characteristics of Patients in the Case and Control Groups^a

	Control	Case	P Value
Age	7.1 ± 2.8	6.5 ± 2.4	0.826
Gender			0.547
Female	22 (44)	19 (38)	
Male	28 (56)	31 (62)	

^aValues are expressed as mean ± SD or No. (%).

Table 2. Incidence of Bleeding, Nausea, Vomiting, Odynophagia, Voice Change, Acetaminophen Intake, and Activity of Patients After 24 hours in the Case and Control Groups^a

	Control	Case	P Value
Bleeding	1 (2)	2 (4)	0.562
Nausea and vomiting	20 (40)	6 (12)	0.001
Odynophagia	22 (44)	7 (14)	0.001
Voice change	9 (18)	4 (8)	0.140
Acetaminophen intake	50 (100)	50 (100)	> 0.999
Activity	35 (70)	41 (82)	0.108

^aValues are expressed as No. (%).

Table 3. Incidence of Bleeding, Nausea, Vomiting, Odynophagia, Voice Change, Acetaminophen Intake, and Activity of Patients Within 7 days of Surgery in the Case and Control groups^a

	Control	Case	P Value
Bleeding	4 (8)	5 (10)	0.730
Nausea and vomiting	12 (24)	8 (16)	0.332
Odynophagia	12 (24)	3 (6)	0.011
Voice change	7 (14)	2 (4)	0.082
Acetaminophen intake	30 (60)	15 (30)	0.002
Activity	40 (80)	49 (98)	0.004
Halitosis	5 (10)	1 (2)	0.094
Otalgia	10 (20)	2 (4)	0.014

^aValues are expressed as No. (%).

5. Discussion

Tonsillectomy is not comparable with most other surgical interventions because the wound created by the excision of the tonsils is neither sutured nor covered by sealing or hemostatic material. It remains a large wound surface that is covered by crusting and exposed to food, inhaled air, and saliva (14). In the tonsillectomy procedure, muscle and surrounding tissue damage may occur; this leads to activation of an acute inflammatory response in the surrounding tissues and consequently causes spasm of pharyngeal muscles, irritation of nerve endings, and in some cases, disruption of the mucosa (15). Finally, the tissue damage results in an imbalance in the mechanisms of swallowing, incoordination, dysphagia, and pain. A review of the above events has shown that if the tissue damage could be prevented, the normal physiological mechanisms could be reestablished (16). In previous studies, dexamethasone administered has been administered for the children underwent a variety of surgical procedures, especially tonsillectomy, as it reduces postoperative pain, nausea and vomiting, and airway swelling, while increasing oral intake (12, 13). However, there is a lack of studies that have investigated the effects of this drug on other common complications like otalgia, odynophagia, and halitosis. Thus, in this randomized controlled clinical trial, we investigated the effects of dexamethasone after adenotonsillectomy in terms of postoperative nausea and vomiting, pain, and bleeding, as in previous studies, as well as odynophagia, otalgia, halitosis, voice change, and activity or healthiness, which were not evaluated in previous research. Faiz et al. compared the effects of intravenous acetaminophen or dexamethasone in their randomized controlled trial study. They concluded that dexamethasone had more advantages in comparison to acetaminophen for inhibiting postoperative pain and nausea and vomiting following tonsillectomy in children (13). They also showed that glucocorticoids like dexamethasone decrease the degree of inflammation via the inhibition of bradykinin, prostaglandin, and leukotrienes, leading to a decrease in accompanying signs and symptoms, including pain (16). We can state that the reductions in postoperative pain, odynophagia, and otalgia may be attributed to the anti-inflammatory effect of dexamethasone, which may decrease local edema and pain. The association of paediatric anaesthetists of great Britain and Ireland concluded that in patients undergoing tonsillectomy, dexamethasone 15 mg/kg provided good reduction in postoperative vomiting with no adverse effects (17). In addition, in 2013, Muhammad et al. designed a study to compare the effectiveness of gastric suction and a single dose of dexamethasone in reducing post-tonsillectomy vomiting in children. Their results indicated that a single dose of dexamethasone can decrease the frequency of postoperative vomiting in children (11). Dexamethasone exerts its antiemetic effect through the inhibition of serotonin,

release of endorphins, and antagonism of prostaglandin (15). In accordance with the previous studies, our results indicated that dexamethasone decreased the incidence of postoperative nausea and vomiting in adenotonsillectomy. In a study conducted by Czarnetzki et al. their results indicated a significant and dose-dependent decrease in the incidence of postoperative nausea and vomiting in children undergoing tonsillectomy with administration of dexamethasone. Dexamethasone also decreased the need for rescue analgesia with ibuprofen. However, it was associated with a significant increase in the risk of postoperative bleeding (1). The results of our study and those of Czarnetzki et al. research revealed that dexamethasone increases the risk of bleeding (1). The most convincing biological explanation for this might be related to the inhibition of the wound healing process by glucocorticosteroids (18). Dexamethasone inhibits factors that regulate the healing process, such as epidermal and basic fibroblast growth factors (19, 20). In addition, dexamethasone decreases the deposition of collagen, epithelization, and fibroblast content of surgical wounds (21). In contrast, our results indicated that the difference in the incidence of bleeding between the case and control groups was not significant. Thus, further randomized trials that are specifically designed to confirm or refute our findings are needed, although it may be difficult to perform adenotonsillectomy trials in children. Finally, this study showed that dexamethasone significantly decreased the incidence of postoperative nausea and vomiting, pain, odynophagia, and otalgia in children undergoing tonsillectomy. In addition, it decreased the need for analgesia with acetaminophen. However, dexamethasone was associated with an increase in the risk of postoperative bleeding. It should be mentioned that the limited number of patients represents a limitation of our study. We suggest more research to compare dexamethasone with other drugs and evaluate their effects on postoperative complications after tonsillectomy in children. In conclusion, in children undergoing adenotonsillectomy, dexamethasone has a significant antiemetic effect and decreases odynophagia, otalgia, and the need for analgesia.

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Footnotes

Authors' Contribution:All authors contributed in the surgical procedures and writing and revising manuscript.

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