Dexamethasone Reduces the Incidence of Postoperative Nausea and Vomiting in Children Undergoing Endoscopic Adenoidectomy under General Anesthesia Without Increasing the Risk of Postoperative Hemorrhage

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Background: Postoperative nausea and vomiting (PONV) is a common complication of pediatric anesthesia, but the overall incidence of PONV in patients undergoing adenoidectomy is unknown. The aim of this controlled study was to compare the effect of dexamethasone administration with placebo to reduce PONV in children undergoing endoscopic adenoidectomy under general anesthesia.

Material/Methods: A randomized placebo-controlled study included 118 pediatric patients who underwent elective endoscopic adenoidectomy under general anesthesia. A dexamethasone-treated (0.15 mg/kg) group (Group D) (n=56) and a placebo group (Group C) (n=62) were randomly assigned. The incidence of nausea and vomiting was recorded on the day of surgery. Postoperative nausea was assessed according to illustrated Baxter Animated Retching Faces (BARF) scale. The Face, Legs, Activity, Cry, and Consolability (FLACC) scale (scores between 0–10) was used to assess pain. Follow-up was performed on the 14th postoperative day by a telephone call.

Results: Overall prevalence of postoperative nausea was 25% (30/118) and postoperative vomiting was 14% (17/118). In the first 24 hours following surgery, in Group D, the incidence of nausea and vomiting was 13% and 7%, respectively, in Group C, without pharmacological prophylaxis, the incidence of postoperative nausea and vomiting was 37%, and 21%, respectively.

Conclusions: A prospective controlled study in children undergoing endoscopic adenoidectomy under general anesthesia showed that dexamethasone (0.15 mg/kg) significantly reduced the incidence of PONV without increasing the risk of postoperative hemorrhage. Dexamethasone is a safe method for the prevention of PONV that may be recommended in pediatric anesthesia.

MeSH Keywords: Adenoidectomy • Dexamethasone • Postoperative Complications • Postoperative Nausea and Vomiting

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Background

Adenoidectomy and tonsillectomy are among the most frequently performed surgical procedures in pediatric patients [1]. These surgical procedures are associated with the second highest incidence of postoperative nausea and vomiting (PONV) in pediatric surgery, being second only to surgery for strabismus [2]. PONV is considered a minor complication in perioperative medicine but is the most frequent cause of morbidity among pediatric patients during the early postoperative period [3–5]. PONV is associated with several medical complications other than the child’s discomfort, including dehydration, metabolic disruptions, the risk of bleeding from the surgical wound, and aspiration of gastric contents [6–8].

Previous clinical studies and reports have shown a significant reduction in postoperative vomiting among patients after tonsillectomy with dexamethasone administration, but the effects of dexamethasone in patients following adenoidectomy has not been assessed [9–11]. Because adenoidectomy is a different surgical procedure to tonsillectomy, in terms of the target surgical site, the anatomical structures involved, the duration and invasiveness of the procedure, it is possible to anticipate differences in the incidence of PONV associated with adenoidectomy when compared with tonsillectomy. Another factor that is important to consider is that adenoidectomy is a surgical procedure that is performed mainly in pre-school children. The young age of most of the patients undergoing adenoidectomy is associated with difficulties in describing the symptoms of postoperative nausea, which is a subjective feeling of discomfort, which is difficult for very small children to verbalize. The overall incidence of PONV among this patient group is likely to be significantly underestimated [6]. PONV is the leading cause of dissatisfaction among pediatric patients and their parents during the course of perioperative care. Postoperative vomiting is associated with increased financial costs required for patient care. PONV is also the leading cause of repeated hospital admissions of patients. Thus, PONV is not only a medical but also an economic problem [12–14].

The exact incidence of PONV following adenoidectomy remains unclear. According to the available literature, the incidence of postoperative vomiting among adult patients reaches 30%, and symptoms of nausea are reported in 50%. Among certain high-risk subgroups of patients (female gender, non-smokers, and a previous history of PONV), the incidence of PONV may reach up to 83% [13]. It is more difficult to determine the exact incidence of PONV in the pediatric patient population, but reports in the published literature report an occurrence varying between 8.9–42% [6]. In cases of high-risk surgical procedures (surgical correction of strabismus and tonsillectomy, with or without adenoidectomy), the prevalence of PONV has been reported to be as high as to 85% [15–17]. The need for an effective prevention and treatment method for PONV in the pediatric population is greater than in the adult population [18–20].

Dexamethasone is very effective for preventing PONV in pediatric patients, especially when it is administered during the induction of general anesthesia rather than towards the end, due to a delayed onset of effect [21]. The exact mechanism of action of dexamethasone is not known, but its anti-emetic effect is attributed to the antagonism of the effects of prostaglandins [22]. Several authors have noted the ability of dexamethasone to reduce the concentration of tryptophan, a precursor of 5-hydroxytryptamine (5-HT) (or serotonin), in the neural tissue and to influence the release of serotonin in the intestine, resulting in an anti-inflammatory effect [23,24]. Currently, only a few studies have been performed that have evaluated the antiemetic effect of dexamethasone for preventing PONV in children following tonsillectomy. These studies are somewhat limited by the very small numbers of patients studied and by the absence of a standardized anesthetic protocol [25–27]. Therefore, it is difficult to compare the results in patients who underwent general anesthesia with different medications and methods of anesthesia management [25–27]. The results of placebo-controlled clinical trials investigating the antiemetic effect of dexamethasone in pediatric patients after tonsillectomy are inconclusive, as some of the studies have shown a clear effect, but others have not [10,28–30]. Another limitation is that these previous studies have primarily investigated postoperative vomiting, which is a side effect of general anesthesia that is easy to document objectively, while postoperative nausea is a side effect of general anesthesia that remains poorly studied. The incidence of PONV in adenoidectomy in pediatric patients remains unknown, and no study evaluating the effect of dexamethasone on decreasing the incidence of PONV in these patients has been currently performed.

Because nausea is difficult to assess in small children in terms of onset, severity, and duration, due to the difficulty in verbalizing subjective symptoms, the use of pictorial scales appears to have better reliability and validity in young children. The illustrated Baxter Animated Retching Faces (BARF) scale was developed using a series of cartoon faces with expressions of increasing nausea [31]. Currently, there have been no previously published studies that have used the BARF scale in diagnosing postoperative nausea in children, but this approach appears to be a logical way to overcome the limitations of evaluating nausea in a patient group for whom this adverse postoperative effect has been previously overlooked.

Following tonsillectomy, the postoperative complication of hemorrhage is the most serious postoperative complication, with a reported incidence varying between 0.1–8.1% [32]. Although there is evidence of the efficacy of dexamethasone in the context of tonsillectomy, the evidence of its safety is less
well established [32,33]. The use of dexamethasone to prevent PONV has been reported to be associated with an increased risk of postoperative hemorrhage in patients after tonsillectomy [27]. A recently published meta-analysis did not prove a relationship between the administration of dexamethasone and postoperative hemorrhage [33]. Currently, there have been no studies to evaluate whether or not dexamethasone administration is associated with an increased risk of hemorrhage following adenoidectomy.

Therefore, the aim of this prospective clinical study was to design and implement a randomized, placebo-controlled evaluation of the efficacy and safety of the use of dexamethasone on the incidence of PONV following endoscopic adenoidectomy. The primary endpoint was the incidence of any nausea or vomiting within the first 24 hours after surgery with the aim of determining the efficacy of dexamethasone for reducing PONV. The secondary endpoint was to assess the incidence of nausea in children using the BARF scale. The tertiary endpoint was to detect postoperative hemorrhage within 14 days after surgery and to compare the incidence of postoperative hemorrhage between the dexamethasone-treated group and the placebo control group.

**Material and Methods**

**Study design**

This prospective, double-blind, placebo-controlled clinical trial was approved by the Ethics Committee of the University Hospital of Ostrava. Each patient was enrolled into the study with informed consent from both parents. Between January 2017 and October 2017, a total of 118 pediatric patients of both sexes, with an American Society of Anesthesiology (ASA) classification of between I and II, aged between 3–9 years, who were undergoing endoscopic adenoidectomy under general anesthesia were enrolled into the study. Indications for the procedure were as follows: repeated infections of the upper and lower respiratory tract, mechanical obstruction of the nasopharynx, sleep apnoea syndrome, or conductive hearing loss.

**Study groups, inclusion and exclusion criteria**

Of the 118 pediatric patients undergoing elective endoscopic adenoidectomy under general anesthesia, the two study groups included a dexamethasone-treated group (Group D) (n=56) and a placebo group (Group C) (n=62). The subjects were randomized using a computer with a binary code into two study arms: interventional arm with a group that was administered dexamethasone (Group D) and a control group that was administered a placebo of physiological saline solution (Group C). A total of 200 identical vials were prepared, with 100 containing dexamethasone, and the other 100 were filled with placebo (physiological saline). The content of each vial was determined by a random number generator using binary code. An anesthesiology nurse, who was not a part of the investigation team, randomly selected a vial prior to the enrolment of each patient into the study, and the vial contents were subsequently administered to the patient; the number of the vial was identical to the number of the patient in the study. The exclusion criteria were as follows: the use of corticosteroids as a chronic medication; mental retardation; ASA classification of III or more; and patients with known coagulation disorders or malignant disease.

**General anesthesia procedure and treatment with dexamethasone or placebo**

General anesthesia was administered to each pediatric patient according to a standardized anesthesiology protocol. Each study subject received premedication with oral midazolam at a dose of 0.5 mg/kg of body weight 45 minutes prior to the surgical procedure. Anesthesia was induced with sevoflurane with a vaporizer setting of 8% in a carrier mixture of O₂ and air in a 1:1 ratio. After the induction of general anesthesia, peripheral venous access was secured, and opioids were subsequently administered (sufentanil at a dose of 0.2 µg/kg of body weight, as a single dose), and the study drug, dexamethasone, was administered intravenously at a dose of 0.15 mg/kg of body weight, with a maximum dose of 4 mg. The airway was secured according to the usual practice of the department with a reinforced laryngeal mask. In cases of any air leakage or other problems associated with the laryngeal mask, the airway was secured via orotracheal intubation and hypopharyngeal tamponade.

**Patient monitoring during general anesthesia**

General anesthesia was maintained with sevoflurane, aiming for an anesthesia minimum alveolar concentration (MAC) value of 1.2–1.5. Fluid therapy was guided by the rule of 4/2/1 ml/kg of body weight/hr with Ringer’s solution. Each study subject received standard analgesia for the early postoperative period with paracetamol at a dose of 15 mg/kg of body weight administered intravenously 10 minutes within the surgical procedure. Additionally, each patient was monitored in a standard way with an electrocardiogram (ECG), non-invasive blood pressure measurement, pulse oximetry, capnometry, and inspiratory and expiratory sevoflurane concentrations. In all cases, the surgical procedure lasted approximately 10 minutes. After completion of the surgical procedure, the patient recovered from general anesthesia, the laryngeal mask was removed upon reaching sufficient spontaneous ventilation, and the patient was subsequently moved to the post-anesthesia care unit (PACU).
Evaluation of postoperative nausea and vomiting (PONV) and pain

Each study subject was monitored in the PACU, and their vital functions were recorded at regular intervals. Each vomiting episode was carefully recorded in the PACU medical records. After sufficient recovery from anesthesia, each subject was assessed with the illustrated Baxter Animated Retching Faces (BARF) scale, and the postoperative value was recorded (early BARF score). In cases of active vomiting, rescue therapy with ondansetron was administered intravenously, at a dose of 0.15 mg/kg of body weight, with a maximum dose of 4 mg. A trained nurse assessed the patients’ postoperative pain according to the Face, Legs, Activity, Cry, Consolability (FLACC) scale (scale scores ranged between 0–10). In cases in which the FLACC score exceeded 4, the study subject received further analgesia with intravenous tramadol at a dose of 1 mg/kg of body weight, following consultation with a physician. Patients were discharged from the PACU on the basis of predefined criteria. After fulfilling the standard criteria of our department, the criteria for the discharge of children younger than 6 years of age, the patient was transferred to a standard ward of the ear, nose, and throat (ENT) department.

Postoperative care

Further postoperative care was provided in a standard ward of the ENT department. A trained nurse again assessed the patients’ postoperative pain using the FLACC scale. In cases in which the FLACC value exceeded 3, paracetamol was administered as an analgesic medication, in the form of flavored syrup (pediatric paracetamol, 24 mg/ml), at a dose of 15 mg/kg of body weight every six hours. All postoperative analgesic medication received by the study subjects during the day was recorded in the study. The incidence of postoperative nausea and vomiting during the course of hospitalization at the standard ward was continuously monitored and recorded by the accompanying parent, who was hospitalized with the child. Each parent was given a questionnaire on hospital admission and on enrollment of the child into the study, and the parent recorded the presence of vomiting (time and number of episodes), the presence of nausea and the BARF score. Rescue therapy for treatment of vomiting at the standard ward was not defined in the study. Every parent was contacted via telephone or email two weeks after the surgical procedure and was questioned about the incidence of any complications, particularly regarding any postoperative hemorrhage.

Data collection on postoperative nausea and vomiting (PONV)

The anesthesiology team consisted of an anesthetist and a nurse who were responsible for the administration of general anesthesia and the management of the study according to the standardized protocol, recorded the data regarding the administration of dexamethasone or placebo into a standardized form prepared for the study, which contained the identification of the patient and the number of the study preparation. The form was handed over with the patient to the PACU, where the PACU nurse and the parent recorded the presence of PONV, together with the first BARF (early BARF) value. The form for PONV monitoring at the standard ward was handed to the parent, who was present at the child’s bedside during the whole period, until hospital discharge. The parent recorded the number of vomiting episodes and the BARF score eight hours after surgery (late BARF score), and the parent was further instructed to ask the child about the presence of nausea every two hours. In cases of vomiting, the time and number of vomiting episodes were recorded. The questionnaire also contained information regarding the first intake of fluids and solid food following the end of the surgical procedure.

Statistical analysis

The patient cohort consisted of 118 children aged 3–9 years. From this group, 62 children who were in the control group (C) were given a placebo of a physiological saline solution, and 56 children were in the active arm of the study (D) and were treated with dexamethasone. In both arms, patients with homogenous characteristics of basic demographic data were randomized. Boys represented 59% of the study group, and no statistically significant difference in gender distribution was observed between the groups (p=0.504). The average age of the children in Group D was 4.2 years, and in Group C was 4.1 years. The body height of the children varied between 90–137 cm. The body weight was between 10–54 kg. For all these parameters, no statistically significant differences were observed between the interventional and control groups (Table 1). Basic statistical methods were used for data description. Qualitative signs were statistically analyzed using the chi-squared (χ²) test. In cases in which the conditions for the use of this test were not met, Fisher’s exact test was used. In the analysis of quantitative values, the data were evaluated for normal distribution. If the obtained data did not have a normal distribution, the Wilcoxon signed rank test was used. Stata software, version 13 was used for statistical analysis. A p-value <0.5 was considered to be statistically significant.

Results

Findings in the study groups: Dexamethasone-treated group (Group D) and placebo group (Group C)

Initially, a total of 122 pediatric patients of both sexes were enrolled in the study. Four patients were excluded due to loss of...
contact with their parents and due to insufficiently completed study forms and insufficient follow-up. Of the 118 pediatric patients undergoing elective endoscopic adenoidectomy under general anesthesia, the two study groups included a dexamethasone-treated group (Group D) (n=56) and a placebo group (Group C) (n=62). For all patients enrolled in this study, the overall incidence of postoperative nausea and vomiting (PONV) was 25% for nausea (30/118) and 14% for postoperative vomiting (17/118) within the first 24 hours after surgery. To evaluate the incidence of PONV, we divided the time from surgery into two periods. The early stage was when the patient was transferred from the operating theatre and was monitored in the post-anesthesia care unit (PACU), which was a period of approximately two hours, prior to discharge to the inpatient ward. The late stage included the remaining stay in the inpatient ward until the patient was discharged to home care.

### Postoperative vomiting in the two study groups

During the stay in the inpatient ward, a total of 17 children experienced postoperative vomiting: 7% in Group D (4/56) and 21% in Group C (13/62). There was a statistically significant difference in the incidence of vomiting between both groups (p=0.033) (Table 2, Figure 1). Among patients affected with vomiting, no difference was observed regarding the number of vomiting episodes (Mann-Whitney test: p>0.999). The median number of episodes of vomiting within 24 hours was approximately three, and the maximum number of episodes of vomiting was eight episodes within 24 hours.

### Postoperative nausea in the two study groups

A statistically significant difference was also found in the incidence of postoperative nausea (p=0.002) between the interventional (D) and control (C) groups. In Group D, 13% of patients (7/56) experienced postoperative nausea, whereas...
The incidence in the control group was 37% (23/62) (Table 3, Figure 2). The late illustrated Baxter Animated Retching Faces (BARF) scale score values (measured 8 hours after surgery) were higher in the control group (C) when compared with the interventional group (D), which indicated a higher degree of nausea in these patients. Although the control group experienced more episodes of postoperative nausea, this fact was not reflected in a delay in oral intake of fluids and solid food (p=0.6387 and p=0.7911, respectively) (Table 4).

Early and late postoperative PONV in the two study groups

No differences were observed between the D and C groups in terms of early PONV and early BARF scores (within two hours after surgery). Early postoperative vomiting was recorded in a total of 5 children from the entire patient cohort: 5% in Group D (3/56) and 3% in Group C (2/62). No statistically significant difference was observed in the incidence of vomiting in the PACU (p=0.566) between both groups. Each of the children who experienced vomiting during the early postoperative period had only one vomiting episode, and one child received rescue therapy with ondansetron. The feeling of early postoperative nausea was recorded in 9 children, and no statistically significant difference was observed between the D and C groups (p>0.999). In accordance with previous results, the early BARF scores did not differ between both groups (Table 5).

Postoperative pain in the two study groups

The assessment of postoperative pain at PACU and the inpatient department using the Face, Legs, Activity, Cry, Consolability (FLACC) scale (scores between 0–10) did not show a statistically significant difference between both arms of the study. No study subject reached a FLACC value exceeding 4 while at PACU, that is why the rescue therapy with tramadol was not administered. The total consumption of analgesics required for permanent FLACC value below 3 in the course of 24 hours from the surgery was identical in both groups. No statistically significant difference was observed in postoperative pain and the need for its treatment.
Follow-up showed no cases of postoperative hemorrhage

The children’s parents were contacted via telephone or email two weeks after the surgical procedure, with questions regarding the presence of any complications in the child, enquiring particularly about the presence of postoperative hemorrhage. The authors did not record any cases of postoperative hemorrhage among the entire group of study subjects.

Discussion

This prospective, double-blind, placebo-controlled clinical trial included 118 pediatric patients who underwent elective endoscopic adenoidectomy under general anesthesia and included two study groups, a dexamethasone-treated group (Group D) (n=56) and a placebo group (Group C) (n=62). The findings showed that the incidence of postoperative vomiting was 14% in the entire study group. As far as the authors are aware, this is the first study investigating the incidence of postoperative nausea and vomiting (PONV) exclusively among patients undergoing adenoidectomy. Previously, published studies evaluated the incidence of PONV among patients undergoing tonsillectomy, with or without adenoidectomy [28,34]. According to the findings of the study, endoscopic adenoidectomy was a procedure with a much lower risk of PONV than tonsillectomy, which has been reported to be associated with postoperative vomiting in up to 85% of patients [15,35]. Although adenoidectomy is a much less emetogenic surgical procedure, it still has the potential to cause nausea. Therefore, it might be misleading to evaluate and compare the incidence of PONV in patients undergoing tonsillectomy and adenoidectomy with those undergoing surgery without adenoidectomy. The precise cause of the observed differences in the incidence of PONV between both surgical procedures remains unknown, but one of the possible explanations is that tonsillectomy requires a longer surgical time with an increased requirement for treatment with opioids for pain.

The findings of this study have shown that dexamethasone reduced the incidence of postoperative nausea and vomiting in patients undergoing endoscopic adenoidectomy. A single dose of dexamethasone administered after the induction of general anesthesia resulted in a statistically significant decrease in the incidence of PONV.
in the incidence of vomiting at the inpatient ward (two hours after surgery). Early PONV that occurs in the post-anesthesia care unit (PACU) (within 2 hours after surgery) was similar in both groups. The observed result is in accordance with the presumed late onset of effect of corticosteroids, which has been shown in a number of previously published studies. Therefore, it is logical to administer dexamethasone at the beginning of the surgical procedure, in order to ensure the onset of effect as early possible after the child recovers from general anesthesia [22].

It is very difficult to evaluate postoperative nausea in patients undergoing adenoidectomy, as this surgical procedure is performed mostly in pre-school children. It is also very difficult to estimate the true incidence of nausea in children who are too young to be able to express their degree of discomfort associated with this subjective feeling. These factors explain why antiemetic studies in children have evaluated postoperative vomiting rather than PONV [6]. However, as the present study showed, the problem of communicating symptoms of nausea by very young children can be solved with the use of the illustrated Baxter Animated Retching Faces (BARF) scale, which helps children to express their feelings of nausea using pictograms. Most pediatric patients with postoperative vomiting also feel postoperative nausea. However, it is possible to assume that a number of children suffer only from postoperative nausea without vomiting. In this study, dexamethasone effectively reduced the incidence of postoperative nausea, which was also reflected by the late BARF score obtained eight hours after surgery. However, the early BARF score obtained in the PACU did not differ between the interventional and control groups. The decrease in postoperative nausea occurred, similarly to the decrease in postoperative vomiting, only two and more hours after surgery.

The safety of the use of dexamethasone in pediatric patients has also been discussed in the literature. The most serious complication following tonsillectomy is hemorrhage, which may be life-threatening. The study by Czarnetzki et al. to investigate the effect of dexamethasone in children undergoing tonsillectomy was prematurely terminated due to the increased risk of postoperative bleeding observed in the group of patients who were treated with dexamethasone to prevent PONV [27]. However, other authors have questioned the study methodology and the findings and three recent meta-analyses did not find any statistically significant increase in the risk of post-tonsillectomy hemorrhage associated with the use of dexamethasone [35–37]. Another systematic review evaluating the effect of dexamethasone on post-tonsillectomy hemorrhage found no influence of this drug but noted that further prospective research was needed [33]. As far as we are aware, currently, no previous study has been performed to evaluate the influence of dexamethasone on the incidence of hemorrhage following adenoidectomy. In the present study, no postoperative hemorrhage was observed in any patient during follow-up performed during the two weeks after surgery.

This study had several limitations. First, despite the careful monitoring of patients after surgery and the use of the BARF score, there was no objective way to detect postoperative nausea in all pediatric patients, which is why the study findings on the prevalence of postoperative nausea results may be underestimated. Further prospective clinical trials, including the use of new picture scoring systems, are necessary to clarify the incidence of postoperative nausea and the treatment of this condition. Second, in this study, there were no reported cases of postoperative hemorrhage following the adenoidectomy procedure but the patient cohort might have been underpowered. Larger controlled studies with longer patient follow-up should be planned in the future, particularly to resolve the controversy regarding the use of dexamethasone and the risk of postoperative hemorrhage.

Conclusions

Adenoidectomy, which is one of the most frequently performed surgical procedures among pediatric patients, is associated with a significant risk of postoperative nausea and vomiting (PONV). The findings of this placebo-controlled study of pediatric patients undergoing elective endoscopic adenoidectomy under general anesthesia showed that dexamethasone effectively reduced the incidence of postoperative PONV and was not associated with postoperative hemorrhage in any of the cases in the study. Therefore, following further controlled clinical studies, dexamethasone has the potential to be included as a routine part of anesthesiology care for pediatric patients undergoing adenoidectomy.

Conflict of interest

None declared.
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