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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Benefits of dexamethasone use in thyroid surgery – a prospective, randomized study

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SUMMARY

Introduction/Objective This study aimed to investigate the effects of preoperative dexamethasone use on the incidence and severity of postoperative nausea and vomiting (PONV), postsurgical pain, and vocal impairment after thyroid surgery.

Methods We performed a prospective, randomized, double-blind study with 50 patients who underwent thyroid surgery. Group A patients (n = 25) received 0.9% NaCl solution (2 ml) before anesthesia, patients in Group B (n = 25) were administered 8 mg of dexamethasone. All the patients preoperatively received 4 mg of ondansetron. During the first 48 hours after surgery, postoperative complications were monitored in defined periods.

Results PONV rate and severity was significantly lower in Group B than in Group A ($p < 0.05$). Patients in Group B reported less pain in resting and in activity ($p < 0.05$) and lower vocal impairment ($p < 0.05$) than patients in Group A in each defined time period.

Conclusion Preoperatively adding dexamethasone to ondansetron is more effective than use of ondansetron alone in the prevention of PONV. Dexamethasone significantly reduces the pain and improves voice function; therefore, we could advise routine single-dose dexamethasone use before thyroid surgery.

Keywords: PONV; postoperative pain; vocal impairment; thyroid surgery; dexamethasone; ondansetron

INTRODUCTION

Common postoperative concerns for patients undergoing thyroid surgery are postoperative nausea and vomiting (usually summarized as PONV), acute postsurgical pain, and vocal impairment. These concerns could, apart from reducing comfort, cause grave local and systemic complications. PONV is defined as nausea and/or vomiting during the first 24 hours after surgery with the incidence among all surgical patients being 20–30% [1]. Patients who undergo thyroid or parathyroid surgery are prone to developing PONV; it occurs in 63–84% of these patients [2, 3].

The etiology of PONV is very complex. Many anesthetic, surgical and individual factors can have a significant impact on the frequency and severity of this complication [4, 5]. Individual risk factors include female sex, young patients, non-smokers, patients with a history of kinetosis and PONV. Apfel et al. [6] developed a simplified risk score as a tool aiming to help the prediction of PONV, according to which there are four main risk factors: female sex, prior history of motion sickness and PONV, non-smoker, and the use of postoperative opioids. According to their results, PONV incidence was 10%, 21%, 39%, 60%, and 78%, in the presence of none, one, two, three, or all four of these risk factors, respectively. Anesthetic risk factors include older volatile anesthetics, nitrous oxide and opioids' use, as well as neostigmine in high doses [7, 8, 9]. Surgical risk factors mainly include duration and the type of surgery [10].

PONV is not caused by a single stimulus or a single cause, so the use of a single antiemetic in PONV prophylaxis is not effective enough. We should use a combination of antiemetic drugs [11–14]. It is not yet known how the combination of dexamethasone and 5-HT_3 receptor antagonists works. Dexamethasone could actually inhibit serotonin central or peripheral production and/or secretion and enhance the antiemetic effects of 5-HT_3 receptor antagonists, or it could sensitize pharmacologic receptors, which leads to potentiating the main effects of other antiemetic drugs [15]. Furthermore, the use of dexamethasone could be effective in prevention of acute postoperative pain and vocal impairment [16, 17, 18].

The objective of this study was to investigate the effects of adding dexamethasone to ondansetron prior to surgery on incidence and severity of PONV, and the effects of dexamethasone on pain and vocal impairment after thyroid surgery.

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METHODS

We performed a prospective, randomized, double-blind clinical study comprising 50 adult patients undergoing elective thyroid surgery (partial or total thyroidectomy) at the Oncology Institute of Vojvodina in Sremska Kamenica, University of Novi Sad, Serbia. Institutional ethics boards approved the study. The inclusion criteria were age ≥ 18 years, patients undergoing thyroid surgery, American Society of Anesthesiologists (ASA) physical status I or II. The exclusion criteria were the use of antiemetic drugs 48 hours before surgery, known contraindication or hypersensitivity to study medications, abnormal levels of serum thyroid hormones, chronic pain, gastrointestinal diseases, BMI < 35, glaucoma, pregnancy, diabetes, and severe cardiovascular, renal, and respiratory diseases.

After admission to the hospital, patients underwent physical examination and were given explanation of the research and the purpose of the study. After the written informed consent had been obtained from the patients, a random division into two groups of patients was done. Randomization was carried out by permuted-block randomization where the block size was six, with sex as the stratification factor.

The enrolling anesthesiologist prepared the group assignment in sealed opaque envelopes. The treating and the enrolling anesthesiologist were different persons. Fifteen minutes before induction of anesthesia the envelopes were opened and an independent nurse, who was not participating in any other part of the study, prepared the drugs.

Ingestion of solid food is discontinued eight hours prior to the scheduled beginning of surgery, and ingestion of clear liquids is discontinued two hours prior to surgery. Both groups of patients received 2.5 mg of midazolam IV 30 minutes prior to anesthesia, and antiemetic drugs 10 minutes before anesthesia. Group A patients (n = 25) received 4 mg of ondansetron and placebo (2 mL of 0.9% NaCl solution), while patients in Group B (n = 25) were administrated 4 mg of ondansetron and 8 mg of dexamethasone (2 mL).

The same team of surgeons performed all the operations. The patients received standardized general anesthesia. For the induction we used propofol 2 mg/kg, fentanyl 2 μg/kg, and atracurium 0.5 mg/kg for tracheal intubation. All the intubations were conducted by experienced anesthesiologists using video laryngoscopy. After intubation, tracheal tube cuff pressure was measured with manometer and then adjusted to 20–30 cm H_2O. Anesthesia was maintained with sevoflurane titrated to achieve minimal alveolar concentration (MAC) 1 and 50% nitrous oxide in oxygen. Ventilation was mechanically controlled and adjusted to maintain the partial pressure of the end-tidal concentration of CO_2 of 35–40 mmHg. Intermittent doses of atracurium were given during anesthesia to maintain adequate muscle relaxation throughout the procedure. Neuromuscular blockade was monitored using train-of-four monitoring and reversion were provided with 0.01 mg/kg of atropine and 0.02 mg/kg of neostigmine. Electrocardiography, heart frequency, blood pressure, blood oxygen saturation, and inspiratory and expiratory concentration of O_2, CO_2, nitrous oxide, and sevoflurane were monitored during anesthesia.

Postoperative pain control was managed with ketorolac 30 mg IV every eight hours. Paracetamole 1 g IV was administered when visual analogue scale (VAS) was ≥ 5. Metoclopramide 10 mg IV was administered to patients who had more than three episodes of vomiting.

During the first 48 hours after surgery, postoperative complications were monitored in defined periods (first, sixth, 12th, 24th, and 48th hour) by the third anesthesiologist. All the data were collected using anesthesia charts, a survey, and observation.

The total PONV rate, incidence, and severity of PONV in Group A and Group B, as well as the incidence of PONV among smokers were the primary end points of this study. The secondary end points were the acute postsurgical pain and vocal impairment. All the data were collected within the first 48 hours following the anesthesia.

A four-point scale was used to assess the presence and severity of PONV: Grade 1 – absence of nausea, Grade 2 – very mild nausea, Grade 3 – moderate nausea and retching (a retroperistalsis of the stomach and esophagus without vomiting), Grade 4 – vomiting (a forceful discharge of stomach contents).

Postsurgical pain was assessed using a 10-point VAS (0 – no pain to 10 – the worst pain imaginable). Pain scores were measured at the state of rest (no coughing) and with activity (coughing).

Analysis of voice quality included the patient's own subjective evaluation of voice according to the Voice Visual Analog Scale (VVAS, 10 – normal voice, 0 – worst voice imaginable).

Statistical evaluation was carried out using SPSS® for Windows®, Version 16.0 (SPSS Inc., Chicago, IL, USA). Statistical significance was defined for p-value less than 0.05.

RESULTS

Our study involved six (12%) male and 44 (88%) female patients. Statistically significant differences between the groups were not found in patients' demographic characteristics, ASA score, indications for surgery, and type of thyroid surgery (Table 1).

Table 1. Patient characteristics and surgical treatment

Patient characteristics	Group A (n = 25)	Group B (n = 25)	p
Mean age, years	53.3	48.9	0.575
ASA status, No. (%)			
I	0 (0)	3 (12)	0.067
II	25 (100)	22 (88)	0.077
Smokers, No.	11	9	0.564
Type of surgery			
Subtotal thyroidectomy	9	11	0.564
Lobectomy	9	7	0.544
Lobectomy with resection of the isthmus	4	3	0.682
Total thyroidectomy	3	4	0.682

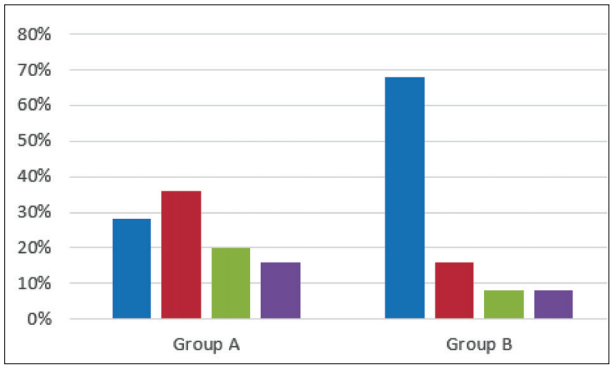

Figure 1. The presence and severity of postoperative nausea and vomiting in Group A and Group B during the period of 48 hours

Table 2. Mean values of postoperative nausea and vomiting (PONV) severity in Group A and Group B; the presence and severity of PONV were assessed using a four-point scale; Grade 1 – no nausea, Grade 2 – very mild nausea, Grade 3 – moderate nausea and retching, Grade 4 – vomiting

Time periods	Group A (n = 25)	Group B (n = 25)	PONV severity p
0–1 h	1.2	0.5	0.034
1–6 h	0.3	0.1	0.214
6–12 h	0.3	0.1	0.18
12–24 h	0.4	0.12	0.138
24–48 h	0.1	0.1	1

The mean duration of anesthesia was 84.5 minutes. No significant difference was found between the groups in the mean duration of anesthesia, which could influence PONV incidence (Group A = 88 minutes, Group B = 81 minutes, p = 0.124). All the patients were hemodynamically stable in the perioperative period.

The total PONV (including very mild nausea) incidence in both groups up to 48 hours after anesthesia was 52% (26/50 patients). In Group A, 72% of patients reported PONV. In Group B, the PONV rate was significantly lower (32% of patients, $p < 0.05$). There were no significant differences in the administered dose of metoclopramide (80 mg in Group A for four patients, 20 mg in Group B for two patients).

PONV severity was also significantly lower in Group B compared to Group A ($p < 0.001$, Figure 1). Very mild nausea (Grade 2) was reported by 16% of patients in Group B and in 36% of patients in Group A. Moderate nausea and retching (Grade 3) were reported by 8% of patients in Group B and in 20% of patients in Group A. Only 8% of patients in Group B had vomiting (Grade 4), compared with 16% of patients in Group A.

During the first hour following surgery, intense vomiting (Grade 4) occurred among 8% (2/25) of patients in Group A, whilst not a single patient in Group B reported intense vomiting, which is statistically lower (p = 0.034). In the following defined periods there was no statistically significant difference between the groups regarding the severity of PONV (Table 2).

Twenty patients were smokers and 30 were nonsmokers. Significant difference in PONV incidence between smokers and nonsmokers was found in the period between the first and the sixth hour (p = 0.004) and the sixth and the 12th hour (p = 0.013), while there was no difference in other defined time intervals.

Regarding the intensity of acute postoperative pain, we found significant difference between the groups in each determined time period following surgery. Patients in Group B reported significantly less pain at the state of rest and on coughing in all the periods than patients in Group A (Table 3). In accordance with this, five patients in Group A received paracetamol (8 g in total), while in Group B paracetamol was administered in only one patient (1 g) ($p < 0.05$).

Our research showed that the development of vocal impairment was significantly lower in Group B compared to Group A ($p < 0.05$) in each defined time period during the first 48 hours after the surgery (Table 3).

DISCUSSION

The most prominent perioperative concerns from the patients' point of view are the ones causing him the biggest discomfort – pain, nausea, and vomiting. PONV happens to be one of the most common causes of dissatisfaction among patients after undergoing anesthesia. Despite the fact that serious complications caused by PONV are rare, nausea and vomiting are still a disagreeable and common complications following the surgery [1]. Fortunately, this unpleasant complication can be effectively managed [4].

In our study, demographic and clinical characteristics, duration of anesthesia, type of surgical intervention, anesthetic and perioperative analgesic use were similar between the two groups. None of the patients in both groups required opioids in the postoperative period. In addition, patients with obesity and previous postoperative emesis and history of sickness while driving had been excluded from the study. There were no difficult intubations. Therefore, the difference in incidence of PONV between the groups could only

Table 3. Mean values of visual analogue scale (VAS) at rest and on coughing and voice visual analog scale (VVRS) in Group A and Group B; VAS – 10-point scale: from 0 – no pain to 10 – the worst pain imaginable; VVAS: from 10 – normal voice to 0 – the worst voice imaginable

Time periods	VAS at rest			VAS on coughing			VVAS		
	Group A (n = 25)	Group B (n = 25)	p	Group A (n = 25)	Group B (n = 25)	p	Group A (n = 25)	Group B (n = 25)	p
0–1 h	3	1.75	**0.002**	4	3	**0.027**	7.5	9	**0.000**
1–6 h	1.75	0.8	**0.002**	3.2	2	**0.001**	8.7	9.3	**0.025**
6–12 h	1.9	0.75	**0.003**	3.5	1.75	**0.000**	8.5	9.5	**0.001**
12–24 h	0.5	1.25	**0.009**	2.6	1.5	**0.002**	8.7	9.8	**0.000**
24–48 h	0.25	0.9	0.001	1.9	0.9	0.001	9	10	0.000

be explained by different antiemetic drugs administered before surgery. One of the main causes of PONV, especially during the early postsurgical recovery period, is certainly the use of inhalational drugs [6, 7, 19]. Nitrous oxide is well known and recognized as the risk factor for PONV. Myles et al. [20] concluded that the use of antiemetic drugs before surgery could eliminate the risk of severe PONV caused by nitrous oxide. We designed our study to show prophylactic effectiveness of dexamethasone and ondansetron on PONV in case of anesthesia with nitrous oxide.

Among 50 patients in the study, 26 had PONV including very mild nausea, moderate nausea, and vomiting, which represents 52% of patients.

We found that the total incidence of PONV after preoperative use of dexamethasone in combination with ondansetron (32% of patients) was significantly lower in comparison to ondansetron alone pretreatment (72% of patients). This is confirmed in some other studies [21–24]. The PONV incidence in our study was higher compared to the mentioned studies, probably because we considered very mild nausea (Grade 2), which patients have described more as an inconvenience. Excluding very mild nausea, the total PONV incidence was 26% (36% in the ondansetron alone group, 16% in the dexamethasone with ondansetron group). Dexamethasone combined with others drugs could significantly reduce the incidence of PONV in postoperative 24 hours [25]. Ahsan et al. [22] and Song et al. [23] compared ondansetron and dexamethasone combination effectiveness with ondansetron alone in preventing postoperative nausea and vomiting. Their results showed that the combination therapy was more effective.

The commonly used dexamethasone doses were 8–10 mg IV. No side effect related to single dose of 8 mg dexamethasone was found in our study and there was no prolonged hospital treatment due to the use of dexamethasone. Our results suggest that the combination of ondansetron and dexamethasone is more effective for control of nausea and vomiting.

Severity of PONV was in our study lower in patients who were pretreated with dexamethasone and ondansetron than with ondansetron only. We found that the difference in the severity of the PONV between the groups is significant only in the first hour following surgery. Although this difference failed to maintain significance during the overall period (0–48 h), the combination of medications is more beneficial than individual ondansetron use according to the trend of 95% confidence intervals.

Although the fact that smoking has antiemetic effect is confirmed by many studies, the etiology of its action is not completely known yet [26, 27]. There is a possibility that people who smoke have a lower incidence of PONV because they are more tolerant to anesthetic gases and other toxins than nonsmokers. According to our results, PONV was more frequent in smokers; we found a marked difference in the incidence of PONV in smokers compared to nonsmokers in the period between the first and the 12th hour after anesthesia. The small number of patients included in the study could be the cause of this result.

Postsurgical pain and PONV are two separate outcomes, but it is known that pain causes anxiety, which could be associated with nausea [16].

The results of meta-analysis conducted by De Oliveira et al. [28] support the fact that steroids have an analgesic effect. Since numerous effects of corticosteroids require gene expression and protein production, it is expected for them to have a delayed onset, which is uncommon for most analgesics. Expectedly, preoperative dosing turned out more effective than intraoperative administration. In the present study we found that patients receiving prophylactic dexamethasone rated postoperative pain significantly lower on the VAS scale at state of rest and on coughing than patients who were not pretreated with dexamethasone throughout the observation period.

Doksrød et al. [24] concluded that the incidence of PONV could be reduced effectively with dexamethasone; there were no differences in effectiveness between the medium (0.15 mg/kg) and the higher dose (0.3 mg/kg). According to their results, dexamethasone had no opioid sparing or analgesic effect after thyroid surgery. The results of a meta-analysis performed by Li et al. [29] were similar.

Worni et al. [17] studied the effects of corticosteroids on voice impairment related to thyroidectomy, and showed improved postoperative voice function, reduced nausea, vomiting, and pain during the first 48 hours after surgery in the group of patients who were pretreated with dexamethasone. Our results also confirmed the benefits from the use of dexamethasone in regard to voice function. We found significantly lower rate of vocal impairment in dexamethasone and ondansetron group in each defined time period within the first 48 hours after surgery.

In a study conducted by Lee et al. [30], effects of ramosetron and dexamethasone were compared with ramosetron alone in patients who undergo thyroid surgery. The PONV incidence, need for additional antiemetics, intensity of postsurgical pain and incidence of shivering were the primary end points of the study. They concluded that combining ramosetron with dexamethasone significantly decreases the incidence of PONV, the need for additional antiemetic treatment, pain intensity immediately after surgery, ketorolac consumption, as well as the incidence of shivering.

In spite of the fact that currently used antiemetics, such as ondansetron and granisetron, have shown their effectiveness, the solution is in better prevention [23, 24].

The second generations of 5-HT_3 antagonists' price is very high, which limits clinical application especially in low-income economies. On the other hand, dexamethasone's clinical use is common due to its low price.

CONCLUSION

According to our findings, preoperatively adding dexamethasone to ondansetron provides much better prevention of PONV than using ondansetron alone. Significant reduction of pain intensity and improvement of the voice function within the first 48 hours after thyroid surgery may

be achieved by applying a single dose of dexamethasone prior to surgery.

Using dexamethasone is a safe and simple method for reducing the incidence and severity of PONV, pain, and vocal impairment; hence, dexamethasone use could reduce the total treatment cost. Therefore, we advise the routine use of a single dexamethasone dose before thyroid surgery.

Conflict of interest: None declared.

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Предности примене дексаметазона код болесника који се подвргавају операцијама штитасте жлезде – проспективно, рандомизовано истраживање

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САЖЕТАК

Увод/Циљ Истраживање је спроведено са циљем да се испита утицај преоперативно примењеног дексаметазона на учесталост и интензитет постоперативне мучнине и повраћања, интензитет постоперативног бола и вокалну дисфункцију после операције штитасте жлезде.

Методе Проспективно, рандомизовано, двоструко слепо истраживање обухватило је 50 болесника код којих је изведена операција штитасте жлезде. Пре увода у анестезију болесници групе А ($n = 25$) примили су 0,9% *NaCl* (2 *ml*), а болесници групе Б ($n = 25$) 8 *mg* дексаметазона (2 *ml*). Сви болесници су преоперативно примили и 4 *mg* ондансетрона. Постоперативне компликације су праћене 48 сати после операције у дефинисаним временским интервалима.

Резултати Постоперативна мучнина и повраћање су били значајно ређи и мањег интензитета ($p < 0,05$) код болесника групе Б у поређењу са болесницима групе А. Болесници групе Б су постоперативно осетили значајно слабији бол у миру и у напору ($p < 0,05$) и имали су мање изражену вокалну дисфункцију ($p < 0,05$) у поређењу са болесницима групе А.

Закључак Преоперативна примена комбинације дексаметазона и ондансетрона је ефикаснија у превенцији постоперативне мучнине и повраћања у поређењу са применом само ондансетрона. С обзиром на то да дексаметазон значајно смањује и интензитет постоперативног бола и унапређује вокалну функцију, можемо предложити рутинску примену појединачне дозе дексаметазона пре операција штитасте жлезде.

Кључне речи: постоперативна мучнина и повраћање; постоперативни бол; вокална дисфункција; хирургија штитасте жлезде; дексаметазон; ондансетрон