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Single Prophylactic Dose Of Dexamethasone Antiemetic Versus Ondansteron In Patients Undergoing Middle Ear Surgery: A Comparative Clinical And Experimental Animal Study

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Abstract

This prospective, randomized, double-blinded, placebo-controlled study in which 150 ASA I-II patients scheduled for middle ear surgery were randomized into three equal groups. The dexamethasone group (group D) received a single dose of dexamethasone 10 mg IV at induction of anesthesia, ondansetron group (group O) received 4 mg IV ondansetron and the control group (group C) received 5 ml saline IV as placebo by the same technique. The study demonstrated that the incidence of early postoperative nausea, retching and vomiting (PONV) was significantly greater in the placebo group than the dexamethasone group ($P<0.001$) and the ondansetron group ($P<0.001$), indeed the incidence was comparable in the dexamethasone and ondansetron groups ($P> 0.05$). More over, the severity of late PONV (6-24h) was markedly less in the dexamethasone group than the ondansetron group ($P< 0.05$) and still the incidence of late PONV was markedly less in both dexamethasone and ondansetron groups than the control group ($P< 0.001$). The study also reported that postoperative analgesic requirement was notably lower in the dexamethasone group than the ondansetron and control groups. An experimental animal study was also done to assess the extrapyramidal reaction associated with the use of both dexamethasone and ondansetron. Increasing doses of both drugs were given IV to the rats, up to 5 times the therapeutic dose of each drug. The rats then stimulated for 24h after injection by light, sound and 6 volt electric current in the Rat Conditioning Chamber. No one rat developed akathisa or acute dystonic reaction. In conclusion, dexamethasone and ondansetron were quite effective and have limited side-effects profile when given as single prophylactic antiemetic doses in patients undergoing middle ear surgery. The advantages of dexamethasone over ondansetron were its prolonged antiemetic effect, its analgesic effect and the lower cost.

Introduction

Postoperative nausea, retching and vomiting (PONV) are among the most common complications after anesthesia and surgery, with a relatively high incidence after middle ear surgery (tympanoplasty or mastoidectomy). [1-2]

PONV may lead to serious medical complications such as aspiration pneumonia [3] and dehydration [4]. It may delay discharge from the hospital with obvious economic [5] consequence, and at the very least is distressing to the patient [6].

The concept of using steroids for the prevention of PONV is not a new one [7-10]. Even though the concept is not

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new, many practitioners are hesitant to use steroids on a routine basis for this purpose because of lack of familiarity or due to doubts about the efficacy and safety of this treatment.

The aim of the clinical part of this study was to evaluate the efficacy and safety of a prophylactic single IV dose dexamethasone 10 mg in the prevention of PONV in patients undergoing middle ear surgery (tympanoplasty or mastoid - ectomy) and to compare this to the selective 5-hydroxytryptamine type 3 (5-HT3) receptor antagonist ondanse - tron and saline. Experimental animal study was also done to assess the extrapyramidal reaction associated with both dexamethasone and ondansetron.

Patients and Methods

150 patients ASA physical class I and II adult male or female patients, aged 17 - 65 years scheduled to undergo middle ear surgery (tympanoplasty or mastoidectomy) under general anest - hesia were enrolled in the study. A written informed consent was obtained from all patients to participate. The study was approved by the hospital Ethical committee. Exclusion criteria included patients who were ASA grade three or higher, patients with significant medical diseases, the presence of conv - ulsions Parkinson's disease, pregnancy, menstruation or breast feeding, patients with gastro-intestinal diseases or requi - ring intragastric tube, recent history of drug or alcohol abuse and patients who had received any antiemetic medication or corticosteroids within 48h before surgery. Also patients who were elder than 65 years or weighing more than 100 kg were excluded from the study. Using the double blind technique the 150 patients were randomized into three equal groups: group D (50 patients) were received a single dose of dexamethasone 10 mg at 5 ml saline given as slow intravenous injection (over 60 seconds) immediately prior to induction of anesthesia; group 0 (50 patients) were received 5 ml saline as placebo by the same technique. The general anest -hesia regimen consisted of premedication (if required) with midazolam 3 mg IV given prior to surgery or at induction of anesthesia. Induction was with thiopentone 4-7 mg/kg IV and fentanyl 2 μg/kg IV. Atracurium 0.6 mg/kg IV was used to facilitate endotracheal intubation. Anesthesia was maintained with 1-2.5% isoflurane (inspired concentration) and 66% nitrous oxide (which was replaced by air before closing the tympanic membrane) in oxygen. Ventilation was controlled mechanically and adjusted to maintain end-tidal carbon dioxide concentration at 4.6-5.2 kpa throughout the surgery. Fluid replacement was in the form of normal saline or 5% dextrose. Monitoring of vital signs (heart rate, blood pressure, electrocar - diogram tracing, oxygen saturation and end-tidal Co_2) was done using Datex cardioscope. Atracurium may be supplemented during general anesthesia guided by nerve stimulator (TOF). At the end of surgery, residual neurom - uscular blockade was antagonized by atropine 0.02 mg/kg IV, neostigmine 0.04 mg/kg IV and all patients were extubated in the operative room. The time of cessation of anesthetic adminis - tration and the time of recovery from anesthesia (defined as patient's first response to spoken command) were recorded. From that, the awakening time (emergence and recovery from anesthesia) was calculated. After the surgery, the patients received indome - thacin 50 mg rectally for postoperative analgesia. For 24h, the patients were continuously monitored (pulse oxim - eter, ECG monitor, non invasive blood pressure and respiratory rate); 2h in

post-anesthesia care unit (PACU) till stabilization of vital signs, then in the wards. Laboratory safety tests (full blood count, chemistry, renal and liver function tests) were undertaken at base line and 24h postoperatively.

The efficacy and safety data were collected for 24h post operatively. Vital signs, nausea, reaching, emetic episo - des, pain score and adverse events were recorded by blinded observer every 2h during the first 24h after giving the study drugs. The relevant and points of the study were prevention of early PONV (0 to 6h) post operatively, late PONV (6 to 24h), adverse effects and the requirement for postoperative anal- gesic supplements. Nausea was defined as the unpleasant sensation associated with awareness of the urge to vomit. Retching was defined as labouredly, spasmodic rhythmic contraction of respiratory muscles without expulsion of gastric contents. Vomiting was defined as the forceful expulsion of gastric contents from the mouth. An emetic episode was defined as a single vomit or retch. The blinded observers (nurses) asked the patients if retching or vomiting had occurred and if they felt nauseated, with only two possible ans - werers (yes, no). A complete response was defined as no PONV and no need for rescue antiemetic medication. A prophylactic failure was defined as one or more emetic episodes or the receipt of a rescue antiemetic. A rescue antie - metic (metoclopyramide 10 mg IV) was allowed at the request of the patient, upon physician determination, or after 15 minutes of severe nausea or two emetic episodes.

Animal study

Ondansetron (3-30μm) was found to be weakly active as antagonist at the dopamine receptors [(11)]. Dexamethasone and other steroids in chronic use have mental health effects including insom - nia, nervousness, euphoria, confusion and hallucination [(12)].

The aim of the animal work was to assess the extrapyramidal reaction associated with both dexamethasone and ondansetrone which was not clearly assessed in previous studies [(13)].

Two groups of rats were studied, group O (ondansetron group) and group D (dexamethasone group). Group O included 5 subgroups, each subgroup composed of 6 rats (subgroup O1, O2, O3, O4 and O5). Also group D included 5 subgroups (subgroup D1, D2, D3, D4 and D5) and each subgroup composed of 6 rats .The average weight of each rat included in the study was 200 gm (180-220 gm).

Subgroup O1 was given an average 0.07-0.1 mg ondansetron I.V. equivalent to the therapeutic dose of the rat [(14-15)]. Subgroups O2, O3, O4 and O5 were given respectively double, triple, 4 times and 5 times the rat therapeutic dose.

Subgroup D1 was given an average 0.1-0.2 mg dexamethasone IV which was equivalent to the therapeutic dose of the rat. Subgroups D2, D3, D4, and D5 were given respectively double, triple, 4 times and 5 times the therapeutic dose.

The rats were put inside Rat Conditioning Chamber. They were stimulated by light, sound and 6 volt electric current. The stimuli were applied 15 min., 30 min., 1h, 2h, 3h, 4h, 8h and 24h after injection. Akathisa and acute dystonic reaction were recorded.

Statistical Evaluation

Statistical analysis was by Kruskal-Wallis ANOVA, the Mann Whitney U test employed for further pair wise comparison, chi-squared test was used for comparison of proportions. P-value of 0.05 or less was considered

significant. All values are expressed as mean (SD, range) or number (%).

Results

Demographics

The three groups were comp - arable. There were no significant differences between the groups with regard to patients' demographics and relevant details of the procedure performed (table 1).

Efficacy

The study demonstrated that the incidence of early PONV(0-6h) was significantly greater in the placebo group than the dexamethasone (P<0.001) and ondansetron group (P<0.001), indeed the incidence was comparable (P<0.05) in the dexamethasone and ondansetron groups (table 2).

Moreover, the severity of late PONV (6-24h) was markedly less in the dexamethasone group than the ondan - setron group (P<0.05) and still the incidence of late PONV was markedly less in the dexamethasone and ondansetron groups than the control group, P<0.001 (tables 2). Also the requirement for postoperative analgesic supplements in the first 8h after surgery was notably lower in the dexamet - hasone group than the ondansetron and control groups (table 3).

Safety

The mean awakening time was similar between the three groups (table 1). Also no differences were seen between the three groups with respect to vital signs (heart rate, blood pressure, respiratory rate and oxygen saturation) recorded for the first 24h after surgery (2h in PACU then in the wards). Analysis of laboratory parameters (hematology, blood chemistry and liver enzymes) revealed no significant differences between the groups when postoperative values were compared with those observed at baseline. The most frequently adverse events were demonstrated in table 4, but there were no difference between groups.

Animal study

No one rat developed extrapyr - amidal reaction in both dexamethasone and ondansetron groups.

Table (1): Patient demographics and operation details.

	Group-D (n=50)	**Group-O (n=50)**	**Group-C (n=50)**
Age (yr)	46 (10)	44 (11.5)	45 (11)
Sex (M/F)	26 / 24	27 / 23	25 / 25
Weight (kg)	65 (7)	64 (8)	62 (9)
Height (cm)	166 (6)	165 (7)	163 (8)
Physical status (n)			
ASA I	32 (64)	33 (66)	32 (64)
ASA II	18 (36)	17 (34)	18 (36)
Operation type (n)			
Tympanoplasty	37 (14)	39 (76)	39 (76)
Mastoidectomy	13 (26)	12 (24)	12 (24)
Duration of operation (min)	232 (43)	229 (45)	230 (46)
Duration of anesthesia (min)	245 (44)	243 (47)	244 (42)
Awakening time (min)	10.7 (2.3)	10.5 (1.6)	10.4 (1.8)

Values are mean (SD) except number (%). No significant differences.

Tables (2): Number (%) of patients with complete response (no PONV, no rescue); incidence of nausea, retching, vomiting and rescue antiemetic during the first 6h (0-6h) and the next 18h (6-24h) postoperatively. P1 values = dexamethasone vs. placebo, P2 values = ondansetron vs. placebo, P3 values = dexamethasone vs. ondansetron. Sig = significant, NS = not significant.

	Group-D (n=50)	Group-O (n=50)	Group-C (n=50)	P1	P2	P3
0-6h postoperative complete response (no PONV, no rescue)	42 (84%)	43 (86%)	11 (22%)	Sig	Sig	NS
Nausea	7 (14%)	6 (12%)	32 (64%)	Sig	Sig	NS
Retching	2 (4%)	3 (6%)	9 (18%)	Sig	Sig	NS
Vomiting	5 (10%)	4 (8%)	18 (36%)	Sig	Sig	NS
Rescue	1 (2%)	1 (2%)	16 (32%)	Sig	Sig	NS
6-24h Postoperative						
Complete response (no PONV, no rescue)	44 (88%)	38 (76%)	12 (24%)	Sig	Sig	Sig
Nausea	3 (6%)	7 (14%)	31 (62%)	Sig	Sig	Sig
Retching	2 (4%)	2 (4%)	8 (16%)	Sig	Sig	NS
Vomiting	3 (6%)	6 (12%)	16 (32%)	Sig	Sig	Sig
Rescue	0 (0%)	0 (0%)	10 (20%)	Sig	Sig	NS

Table (3): Number (%) of patients needed analgesic supplements (added to rectal indomethacin given at the end of the surgery) guided by pain scale during the first 8h (0-8h) postoperatively.

	Group-D (n=50)	Group-O (n=50)	Group-C (n=50)
(0-8h) postoperative Acetaminophen (65mg rectally)	2*	12	13

*P significant compared to saline.

Table (4): Adverse events profile Number (%).

	Group-D (n=50)	Group-O (n=50)	Group-C (n=50)
Headache	5 (10%)	6 (12%)	5 (10%)
Dizziness	8 (16%)	7 (14%)	9 (18%)
Drowsiness / sedation	4 (8%)	3 (6%)	4 (8%)
Constipation	1 (2%)	1 (2%)	1 (2%)
Injection site reaction	0 (0%)	1 (2%)	1 (2%)

No significant differences.

Discussion

Several factors including age, sex, obesity, menstruation, pregnancy, surg - ical procedure, anesthetic technique and postoperative pain are considered to affect the incidence of PONV in patie - nts undergoing middle ear surgery[16-17]; in this study, however, these factors were well balanced between the groups. During surgery, an increased middle ear pressure caused by nitrous oxide is also one of the surgical factors contributing to PONV [1].As middle ear pressure was measured in this study, no pressure was generated in the middle ear from diffu - sion of nitrous oxide, which was repla - ced by air before closing the tympanic membrane. Therefore, the difference in complete response between the groups might be attributed to differences in the antiemetic drug administered.

This study used 10 mg dexameth - asone which was the adult most frequent dose tested in other studies [18]. Also the tested drug was given just prior to induction of anesthesia. Wang in his study [19] found that dexamethasone 10 mg given one minute before induction of anesthesia worked better than when given after extubation and batter than placebo.

The precise mechanism of action of dexamethasone in prevention of PONV remains unclear; it may act via prostaglandin antagonism [20] endorphin release [21] and serotonin inhibition [22]. Ondansetron is a highly potent and selective antagonist at 5-HT3 receptors [23]. It is hypothesized that ondansetron blocks nausea and vomiting by 5-HT3 receptors antagonisms centrally in the area postrema, nucleus tractus solitarius (NTS) and peripherally on vagus nerve terminals[24].

The present study revealed that both dexamethasone and ondansetron significantly decreased the total incidence of PONV and the proportions of patients requiring rescue antiemetics after middle ear surgery. The differ - ences between dexamethasone group and ondansetron group were not signif - icant in the early postoperative period (0-6h); concluded that single dose intravenous 10 mg dexamethasone given prior to induction of anesthesia of middle ear surgery was effective as 4 mg ondansetron given by the same technique and was more effective than placebo. Moreover, the severity of late PONV (6-24h) was markedly less in the dexamethasone group than ondansetron group but still the incidence in both groups was markedly less than the placebo group. The prolonged antiem - etic efficacy of dexamethasone was not surprising given its biological half life or 36-72h [25].

This study reported also another finding that postoperative analgesic requirement was notably lower in the dexamethasone group. This finding was consistent with Aasboe et al. investi - gation which showing that betame - thasone prophylaxis decreased postop - erative pain and late PONV [26].

Although many elder less expensive drugs than ondansetron like dropredіol and metoclopramide are available to prevent or treat PONV, most or them cause significant side-effects including sedation, extrapy - ramidal symptoms, dry mouth, dysp - horia and delayed discharge. The present study reported no significant side - effects reported with the use of either ondansetron or dexamethasone, no changes in the awakening time, vital signs and laboratory parameters. Animal study showed that extrapyra - midal reaction did not occurred even when the dose of either ondansetron or dexamethasone was increased to 5 times the therapeutic dose.

Conclusion

Dexamethasone and ondansetron were quite effective and have limited side-effects profile when given as single prophylactic antiemetic doses in patients undergoing middle ear surgery. The advantages of dexamethasone over ondansetrone were its prolonged antiemetic effect, its analgesic effect and the lower cost. Most physicians believe that a single dose of steroids does not have any significant effect on wound healing and wound infection [9].

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دراسة مقارنةإكلينكية على المرضى وأخرى تجريبية على الحيوان لمقارنة إستخدام جرعة وقائية واحدة لكل من عقاربالديكساميثاسون والأوندانسيترون لمنع غثيان وقئ مابعد جراحات الأذن الوسطى

خالد طه عطيه ندا

قسم التخدير بطب عين شمس

أُجريت الدراسة على عدد 150 مريضاً معدين لإجراء جراحات الأذن الوسطى من الصنف الأول والثانى على حسب تصنيف الجمعية الأمريكيةلأطباء التخدير (تصنيف وتقييم مرضى الجراحة من حيث درجة الخطورة) وقد قسم المرضى بطريقة عشوائية غير معلومة إلى ثلاث مجموعات متساوية :- 1. مجموعة الديكساميثاسون (50 مريضاً) والتى تلقت عند بدء التخدير جرعة واحدة من عقار الديكساميثاسون 10 مج بالحقن الوريدى، 2. مجموعة الأوندانسيترون(50 مريضاً)، والتى تلقت عند بدء التخدير جرعة واحدة من عقار الأوندانسيترون 4 مج بالحقن الوريدى، 3. المجموعة الضابطة(50 مريضاً)، والتى تلقت عند بدء التخدير محلول ملح 5 مل بالحقن الوريدى.

وقد بينت الدراسة أنه فى الفترة اللاحقة مباشرة للجراحة(0-6 ساعات) كانت نسبة حدوث الغثيان ومحاولة التقئ والتقئ عالية(بدلالة إحصائية) فى مجموعة المحلول الملحى عن كل من مجموعتى الديكساميثاسون والأوندانسيترون، ولم تكن هناك آى فروق ذو دلالة إحصائية بين مجموعتى الديكساميثاسون والأوندانسيترون. وأوضحت الدراسة أيضا أنه فى الفترة المتأخرة لما بعد الجراحة (6- 24 ساعة)، كانت نسبة حدوث الغثيان والقئ عالية فى مجموعة المحلول الملحى عن كل من مجموعتى الديكساميثاسون والأوندانسيترون، ولكن كانت نسبة حدوث الغثيان والقئ أقل ما يمكن فى مجموعة الديكساميثاسون،أى أنه وجدت فروق ذو دلالة إحصائية بين مجموعتى الديكساميثاسون والأوندانسيترون. هدا وقد لوحظ أيضا بشكل واضح أن عدد المرضى الدين إحتاجوا إلى جرعات إضافية من مسكنات الألم فى ال8 ساعات الأولى التالية للجراحة كان أقل ما يمكن فى مجموعة الديكساميثاسون،وذلك مقارنة بمجموعتى الأوندانسيترون والمجموعة الضابطة.

هذا وقد أظهرت الدراسة التجريبية على الفئران أنه لم تحدث أى أعراض تخشبية أو تصلبية على فئران التجارب بالرغم من إعطائها جرعات متزايدة من عقارى الديكساميثاسون والأوندانسيترون بلغت خمسة أضعاف الجرعة العلاجية ، وذلك بعد إستثارتها بالصوت والضوء والتيار الكهربائى.

وختاماً نستنتج أن إعطاء جرعة واحدة عند بدء التخدير من أى من عقارى الديكساميثاسون والأوندانسيترون للوقاية من غثيان وقئ ما بعد جراحات الأذن الوسطى مفيد للغاية وينتج عنه قليل من الآثار الجانبية،هذا ويتميز عقار الديكساميثاسون عن عقار الأوندانسيترون فى تأثيرة طويل المدى كعقار مضاد للقئ ، فضلا عن أثرة المسكن للألم ، وقلة تكلفتة.