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The effectiveness of ondansetron and dexamethasone and their combination on the prevention of vomiting and nausea after surgical procedure of laparoscopic cholecystectomy: a randomized trial

Babak Hosseinzadeh Zoroufchi, Hamid Reza Hemmati and Abolfazl abdollahpour*

1Department of Anesthesiology, Kowsar Hospital, Semnan University of Medical Sciences, Semnan**, Iran**

***Correspondence:** Abolfazlabdollahpoor@semums.ac.ir **Received 15-10-2019, Revised: 08-11-2019, Accepted: 19-11-2019 e-Published: 29-11-2019**

Postoperative nausea and vomiting are unpleasant feelings emerging as the complications of anesthesia. They can exacerbate the pain of the surgery. Therefore, the main objective of this study was to compare the effectiveness of ondansetron and dexamethasone, and their combination on the prevention of vomiting and nausea after surgical procedure of laparoscopic cholecystectomy among patients in Iran. This was a randomized controlled trial conducted on a sample of patients who underwent laparoscopic cholecystectomy at a university hospital related to Semnan University of Medical Sciences, Semnan, Iran in 2016. Patients were randomly assigned into three equal groups (each 30 patients) as follows: Group D receiving: intravenous injection of dexamethasone 0.23 mg/kg; Group O receiving intravenous injection of ondansetron 0.06 mg/kg; and Group DO receiving the two drugs as described above. Six and 24 hours after the surgery, the patients in the recovery room were assessed for the incidence of vomiting and nausea and the requirement for additional drugs. Assess the incidence of nausea and vomiting in the patients who underwent laparoscopic cholecystectomy. In all, 10 patients (11.1%) had vomiting and 34 of them (37.8%) had nausea. The incidence rate of nausea among D, O, and DO groups was 46.7%, 40.0%, and 26.7%, and it was 13.3%, 13.3%, and 6.6% for vomiting, respectively. Following intervention, the incidence rate of vomiting and nausea in the DO group was lower than D and O groups, but there were no significant differences among groups. The combination of ondansetron and dexamethasone might lead to a better result in decrement of postoperative vomiting and nausea following laparoscopic cholecystectomy. Further studies are recommended to confirm the findings.

Keywords: Ondansetron, Dexamethasone, Nausea, Vomiting, Laparoscopic Cholecystectomy

INTRODUCTION

Postoperative nausea and vomiting are major complications of anesthesia that postpone the discharge of patients from hospital (Chaiyakunapruk et al., 2006). The incidence rate of postoperative vomiting and nausea among patients who undergoing general anesthesia, especially whose do not have any preventive interventions is at the range of 50-70%. (Wakasugi et al., 2015). As a result, patients might develop dehydration, electrolyte disturbances, hypoxia, increased blood pressure, stretch of the sutures, increased bleeding from skin flaps, distress, delayed oral consumption of

food, medicine and fluids. All these might delay discharge of patients, and readmission. Even, if the airway reflux is reduced due to the effects of anesthetics residuals, this complication can increase the risk of pulmonary aspiration (Entezariasl et al.,2010)

.Although metoclopramide is the most commonly used drug for controlling and preventing postoperative nausea and vomiting; extrapyramidal complications sometimes observed and thus there should be always a caution in prescribing it (Nanjundaswamy NH, Sridhara, 2018). Instead, due to lack of serious side effects Ondansetron is used in various studies (Selvam et al., 2018; Taniguchi et al., 2018; Yimer et al., 2018). Several reports have recommended about the usability of dexamethasone in controlling postoperative vomiting and nausea (Rathna et al., 2018; Nado et al.,2017; Chatterjee et al,2017; Alkaissi et al,2017). Studies have shown that dexamethasone was effective in reducing nausea and vomiting (Isazadehfar et al., 2016)

Different randomized controlled trials (RCTs) have been conducted so far to compare the effects of dexamethasone and ondansetron in preventing of postoperative nausea and vomiting, but the results of these studies do not indicate absolute superiority for these two drugs (Sánchez-Rodríguez et al.,2010; Bergese et al.,2012). Indeed, the main objective of the present study was to evaluate the application of dexamethasone, ondansetron and a mixture of them in prevention and controlling postoperative vomiting and nausea following surgical procedure of laparoscopic cholecystectomy.

MATERIALS AND METHODS

Trial design

This study was conducted as a randomized clinical trial and registered with the code of IRCT 2017200725732N13 in the Iranian registry of clinical trial.The method of the study was approved by the Ethics Committee of Semnan University of Medical Sciences.

Participants

The population under the study included volunteer male and female patients aged over 18 years old in the physical class of ASA I and II, who were admitted to Kowsar Hospital in 2016-2017. Accordingly, the patients who met the inclusion criteria and were willing to enter the study were enrolled into the study after obtaining informed consent. Considering the inclusion criteria for this study, only the patients who were ASA groups I and II and did not have high blood pressure were included in the study. We did not include patients who had gastro-esophageal reflux, severe obesity (with a BMI more than or equal to 30), problems in airway (intubation inability), pregnancy, lactation, liver or kidney disorders, history of drug addiction, alcoholism, musculoskeletal disorders, mental illness, diabetes mellitus, history of systemic diseases (cardiovascular or respiratory problems, and hypertension), high risk of nausea and vomiting (emergency patients with full stomach), malignancy, underlying diseases, and those taking any type of drugs. If any problems occurred during laparoscopic cholecystectomy, the patients were excluded from the study.

Procedure

Using block randomization method, the patients were randomly assigned into three groups. The three groups were the followings: D group included patients receiving dexamethasone 0.23 mg/kg; O group included patients receiving ondansetron 0.06 mg/kg; and D&O group included patients receiving Ondansetron0.06 mg/kg + dexamethasone 0.23 mg/kg after undergoing general anesthesia.

Intervention

After informing the patients about the procedure of the project and obtaining their consent, they were studied. The patients were first placed on an operation bed and the devices intended for electrocardiogram monitoring, pulse-oximetry, blood pressure measurement, and pericardial monitoring were connected. The aforementioned anti-nausea drugs were prepared in similar 2cc syringes and injected by an anesthetist immediately prior to the first surgical incision. All the patients received 2 mg intravenous midazolam, used as a precursor for all of the groups. Anesthesia induction in all the three groups was performed in a similar manner through the injection of fentanyl 1 µg/kg of body weight (one cc: 50 mg), midazolam 1 to 2 mg, and atracurium 0.5 mg/kg of body weight as a relaxant; they were administered together with 100% oxygen plus a MAC. After intubation for the continuation of anesthesia, the process was continued with a MAC of N2O 50% and four liters of oxygen per minute, administered every half hour. In order to maintain muscle relaxation during surgery, atracurium 0.25 mg/kg of body weight

was injected and the patients were mechanically ventilated during the surgery. At the end of the surgery, the administration of all anesthetics was discontinued and the administration of oxygen 100%, 6 liters per minute, was started for all the subjects in all the study groups. After the recovery of spontaneous respiration, muscle relaxation was recovered by injecting neostigmine 40 µg/kg of body weight and atropine 15 µg/kg of body weight. After the proper recovery of the respiratory system, the patients were extubated and transferred to the recovery room.

Outcome measures

In the recovery room, all the patients under the study were monitored by a medical student (the project administrator) for evaluating the incidence rate of vomiting and nausea, the number of vomiting, the need for antiemetic drugs, and to collect data on demographic characteristics, the factors affecting the incidence of nausea and vomiting (age, duration of the surgery), the need to receive opioid drugs, and the duration of the recovery. The mentioned data were collected and recorded in pre-designed checklists. In addition to the recovery room, the patients were also evaluated for the incidence of nausea and vomiting and related factors 6 and 24 hours after the surgery. Patients who had nausea and vomiting for over 5 minutes received metoclopramide and were excluded from the study. Both the patient and the assessor were unaware of the assigned group.

Randomization

Based on random allocation method, using block stratified randomization, three groups were divided into A (dexamethasone), B(ondansetron) and C (ondansetron+ dexamethasone) groups.

Sample size

In this study, we used at convenience sampling from eligible patients regarding the inclusion and exclusion criteria. Taking into consideration the findings of Yoksek et al.'s study in 2003 (Yuksek et al., 2003), a decrease of 40% in the incidence of nausea and vomiting (from 70% to 30%), α=5% and β=20%, and using the formula for comparing the two ratios, the calculated sample size included 30 patients in each of the three groups (a total of 90).

Statistical methods

The data were analyzed using SPSS V. 16 software. The data were presented as frequency, mean and standard deviation. Chi-square and one-way analysis of variance (ANOVA) and Pearson correlation tests were used to compare the data among the study groups. The significance level was set at 0.05.

RESULTS

Not any notable differences between the study samples were identified in terms of demographic characteristics and basic clinical symptoms (Table 1).

Overall 30 patients (33.3%) had nausea and nine patients (10.0%) had vomiting during the post-operative follow-up. Table 2 presents the incidence rate of vomiting and nausea in, D, O and D+O groups. As presented in the table, 24 hours after the surgery, none of the patients had vomiting or nausea. In spite of the fact that, the overall nausea occurrence rate (with or without vomiting) within the dexamethasone + ondansetron group was lower than that in the other two groups, there was not any notable difference among these 3 groups with regard to the total incidence rate of nausea (P=0.350) and vomiting (P=0.690). None of the patients needed anti-nausea and anti-vomiting drugs at the time of recovery and 6 and 24 hours after the surgery (Table 2).

Table 1: Demographic and basic clinical characteristics of patients

	D (n = 30)	**O (n = 30)**	**D+ O (n = 30)**	
	Mean (SD)	Mean (SD)	Mean (SD)	P
Age (year)	49.47± (9.29)	51.23± (14.24)	48.20± (13.94)	0.078
Body mass index	28.00 ±(2.23)	27.31 (2.22)	27.80 ±(4.19)	0.121
Duration of the surgical operation (min)	98.33 ±(40.67)	87.83± (24.52)	92.33± (25/55)	0.179
Systolic blood pressure	158/60 ±(20.97)	150/60± (19/02)	149/97± (19.35)	0.032
Diastolic blood pressure	96/63 ±(11/56)	97/80± (23/50)	98/70 ±(23/25)	0.219
Recovery time	19.50 ±(2.01)	20.17± (3.28)	20.67± (4.69)	0.103

D= Dexamethasone, O= Ondansetron, D+O= Dexamethasone+Ondansetron

Table 2: Incidence of postoperative nausea and vomiting

	D (n =30)	**O** (n =30)	**D+O** (n =30)	
	No. (%)	No. (%)	No. (%)	P
Nausea in recovery				0.770
Yes	1 (3.33)	2 (6.66)	1 (3.33)	
No	29(96.67)	28(93.33)	29(96.66)	
Nausea 6 hours after the operation				0.350
Yes	11 (36.66)	12 (40.00)	7 (23.3)	
No	19(63.34)	18(60.00)	23(76.67)	
Nausea 24 hours after the operation				1.00
Yes	0	0	0	
No	30(100)	30(100)	30(100)	
Vomiting in recovery				0.690
Yes	1 (3.33)	1 (3.33)	1 (3.33)	
No	29(96.67)	29(96.67)	29(96.67)	
Vomiting 6 hours after the operation				0.538
Yes	3 (10.00)	3 (10.00)	1 (3.33)	
No	27(90.00)	27(90.00)	29(96.67)	
Vomiting 24 hours after the operation				1.00
Yes	0	0	0	
No	30(100)	30(100)	30(100)	

D= Dexamethasone, O= Ondansetron, D+O= Dexamethasone+Ondansetron

DISCUSSION

Nausea and vomiting is a common complaint that is reported repeatedly after laparoscopic surgery (Bradshaw et al., 2002) and may even be more reported than postoperative pain. The occurrence of postoperative vomiting and nausea could even delay the process of patients discharge from hospital (Maitra et al.,2016)

Both ondansetron and dexamethasone were effective in decreasing the occurrence of postoperative vomiting nausea following surgical procedure of laparoscopic cholecystectomy. Anyway, the combination of ondansetron and dexamethasone might lead to a better result in decreasing postoperative vomiting and nausea following the surgical procedure of laparoscopic cholecystectomy.

Maitra et al., in 2016 conducted a meta-analysis study and compared ondansetron and dexamethasone to prevent postoperative nausea and vomiting in patients undergoing laparoscopic surgery. The results of this study, which reviewed seven clinical trials, showed that dexamethasone was significantly more effective than ondansetron in reducing postoperative nausea and vomiting six to four hours after the operation (Maitra et al.,2016)

Isazadehfar et al.,'s studyin 2016 showed a statistically notable difference among the two intervention groups and the control group; anyway, there was not any notable differences among these two intervention groups with regard to the prevalence of vomiting and nausea. The overall incidence rate of vomiting within the groups of ondansetron, dexamethasone and control was 26.7%, 23.3% and 56.7% respectively, and there was a significant difference between the control and intervention groups, but there was no significant difference between the ondansetron and dexamethasone groups. The outcomes of the present study demonstrated that both dexamethasone and ondansetron drugs could effectively decrease the incidence rate of postoperative vomiting and nausea following the surgical procedure of laparoscopic cholecystectomy, but there was no significant difference among the efficiency of

dexamethasone and ondansetron in terms of decreasing postoperative vomiting and nausea; which is in line with our study outcomes. However, in the present study, it was tried not to deprive any patient from taking anti-nausea and vomiting; therefore, in our study, instead of the control group, we had a drug combination (dexamethasone + ondansetron) group (Isazadehfar et al., 2016).

Wakasugi et al. (2015) only used dexamethasone and placebo in their study. Their study results demonstrated that utilizing of 8 mg of dexamethasone, as compared with the placebo, had no significant effect on postoperative nausea and vomiting, and had no clinical advantage (Wakasugi et al., 2016)

At their study, Mortazavi et al., in [2014] compared the effect of administering metoclopramide and ondansetron in combination with dexamethasone on controlling and prevention the incidence of vomiting and nausea following laparoscopic cholecystectomy. The results of this study showed that nausea was observed in 19 patients (38%) in the first group (metoclopramide and dexamethasone) and 14 patients (28%) in the second group (ondansetron and dexamethasone); in addition, vomiting was observed in 15 patients (30%) in the first group and 8 patients (16%) in the second group; based on the results, there was not any statistical significant difference among these two groups. Finally, the present study authors concluded that ondansetron and dexamethasone, as compared with metoclopramide and dexamethasone, were more effective in decreasing postoperative vomiting and nausea following surgical procedure of laparoscopic cholecystectomy; anyway, in accordance with the present study, the available difference was not considerable(Mortazavi et al., 2014)

At their study, Eidi et al., in [2012] compared the effectiveness of dexamethasone and ondansetron in reduction and prevention of occurrence of postoperative vomiting and nausea following tympanoplasty, the researchers found that the reduction of nausea and vomiting in the ondansetron and dexamethasone group was more significant than that in the control group; in addition, dexamethasone was found to be more effective than ondansetron (Eidi et al.,2012).The inconsistency between the results of our study and the results of the mentioned study might be probably attributed to possible effect of the type of surgery on the occurrence rate of postoperative vomiting and nausea.

In a study by Tavasoli et al., in 2011, entitled “Comparison of Ondansetron and the Combination of Dexametasone-Metocholopromide on Post-Operative Nausea and Vomiting”, it was found that ondansetron was 91% more effective than dexamethasone-metoclopramide in reducing the occurrence rate of postoperative vomiting nausea (Tavasoli et al., 2011)

Alghanem et al., in 2010 investigated the incidence rate of postoperative vomiting and nausea following laparoscopic cholecystectomy and assessed the effects of dexamethasone, ondansetron, and normal saline. Ondansetron, dexamethasone, normal saline reduced the occurrence rate of postoperative vomiting and nausea by 32%, 30%, and 33%, respectively. The results of this study showed no significant difference among the studied groups. On the other hand, the results of this study for those two groups are in line with the fidings of the present study (Alghanem et al., 2010)

In 2008, Erhan et al. conducted a study in the United States that was aimed at comparing the effects of the administration of ondansetron, dexamethasone, and granisetron on the prevention of vomiting and nausea following the surgical procedure of laparoscopic cholecystectomy. The results of this study demonstrated that postoperative the prevalence rate of nausea and vomiting was 75%, 35%, 30% and 25%, respectively, in the control group, ondansetron, granisetron, and dexamethasone groups. Although the prevalence rate of postoperative nausea and vomiting in the intervention groups was notably lower in comparison with the control group, in line with the results of our study, there was not any notable difference among the intervention groups. The authors of the mentioned study recommended the use of ondansetron, dexamethasone, and granisetron to prevent the onset of nausea and vomiting after laparoscopic cholecystectomy (Erhan et al., 2008)

In another study, Wattwil et al., in 2003 examined the effect of ondansetron and dexamethasone on the prevention of vomiting nausea following breast surgery and reported the similar effects of the two drugs in decreasing the occurrence rate of postoperative vomiting and nausea. Based on their results, intravenous administration of 4 mg of ondansetron and 4 mg of dexamethasone were equally beneficial in preventing vomiting and nausea, and they differed only in terms of the cost of these two types of

drugs. As the authors suggested, when monotherapy is recommended to be used for prevention of postoperative vomiting and nausea, the use of dexamethasone is preferred (Wattwil et al., 2003). At the present study, there were not any notable differences among these two studied drugs with regard to their effects on the prevention of postoperative vomiting and nausea. Thus, the choice of these two drugs could be based on secondary factors such as the cost of their preparation. For instance, Subramaniam et al., in 2001, concluded that dexamethasone was a more cost-effective alternative to ondansetron for preventing the occurrence of postoperative vomiting and nausea following pediatric strabismus surgery (Subramaniam et al., 2001)

At their study, Yoksek et al., in 2003 which compared the preventive effects of dexamethasone ondansetron on vomiting and nausea following a gynecological laparoscopy, the researchers did not found any remarkable differences among these two group of drugs with regard to the happening of postoperative vomiting and nausea, which is in line with the outcomes of the present study (Yoksek et al., 2003)

In a study that compared the prevalence of nausea and vomiting in terms of gender, it was found that female gender was one of the risk factors for postoperative nausea and vomiting[12]. In our study, the prevalence of nausea and vomiting in females was more than that in males. In addition, some other studies have reported the higher prevalence of postoperative nausea and vomiting in young people and lower prevalence in older people (Islam and Jain, 2004). In our study, the difference in the incidence of nausea and vomiting in different age groups was not statistically significant, since 52.6% of the patients in the young age group, 32.1% of middle age people, and 16.7% of the elderly had postoperative nausea and vomiting. Therefore, it can be said that the overall incidence of nausea and vomiting was higher in the younger age group and lower in the older age group.

In addition to the strengths, this study had also some limitations. First, it was a single-center study, which inevitably imposed the selection bias. On the other hand, due to the limitations of the measurement tools, it was not possible to examine other factors associated with the incidence of postoperative nausea and vomiting after laparoscopic cholecystectomy. In the present study, isoflurane was prescribed to maintain anesthesia, and one of the side effects of this drug is nausea and vomiting. Therefore, it was an intervening factor for obtaining the overall prevalence of nausea and vomiting in the present study. However, due to the similarity of the type of anesthesia in all the three groups, the mediating effect of this drug on the occurrence rate of postoperative vomiting and nausea in the three groups was automatically eliminated. On the other hand, people with underlying disease were excluded; hence, the results of this study cannot be generalized to patients with severe underlying disease. In addition, it was not possible in this study to investigate the economic issues, such as the cost of the preparation of ondansetron and dexamethasone in order to assess the cost-effectiveness of these drugs.

Overall, the results of this study showed that both ondansetron and dexamethasone were advantageous in decreasing the occurrence rate of postoperative vomiting and nausea following surgical procedure of laparoscopic cholecystectomy. The efficacy of simultaneous use of both ondansetron and dexamethasone in decreasing vomiting and nausea following surgical procedure of laparoscopic cholecystectomy is more than the efficacy of each drug when administered separately. In Hemmati et al., study in Semnan in 2014, the results also showed that receiving a single dose of dexamethasone ten minutes before the removal of the tracheal tube does not have any effects on the prevention of postoperative vomiting and nausea following the surgical procedure of laparoscopic cholecystectomy (Hemmati et al.,2014), this finding is in line with the results of our study. Therefore, it is recommended to use both ondansetron and dexamethasone for decreasing the risk of vomiting and nausea following surgical procedure of laparoscopic cholecystectomy and to improve the efficacy and outcome. However, in order to generalize the results of this study to other surgical procedures, it is necessary to conduct further studies.

CONCLUSION

The results of this study, similar to the results of most other similar studies, show a relatively high incidence of postoperative nausea and vomiting after laparoscopic cholecystectomy. Therefore, given the high risk of complications and health hazards in the patients, the likely decrease in the efficacy of treatment, and the decreased satisfaction of individuals with the outcome of the surgery, it is necessary to identify the best available drug for the prevention of postoperative nausea and vomiting. Furthermore,

the high figures reported by other studies indicate a high incidence of this problem in different societies. As a result, the obtained results highlight the need for monitoring postoperative nauseas and vomiting at various treatment centers, especially using more accurate monitoring systems at different times, and investigating the efficacy of various drugs, especially ondansetron and dexamethasone, for controlling this problem.

CONFLICT OF INTEREST

The authors declared that present study was performed in absence of any conflict of interest.

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AUTHOR CONTRIBUTIONS

BHZ and HM as supervisor of this study played the major roles within the present study. All data were collected by NS and AM and RB was the main researchers who presented the first draft. RB and BHZ as study advisors played a major role at the study design and through reviewing the paper critically presented the final draft. MM and HM as advisors of this study, played an essential role in the writing process. MM as the statistical advisor played fundamental role in data analysis. Finally, all authors of this study reviewed and approved the final manuscript.

Ethics approval and consent to participate

The ethics Committee of the Semnan university medical of sciences approved the present study. All patients who participated within the present study signed the informed consent form.

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