

# Randomized Trial Study on Ramosetron and Dexamethasone in the Prevention of Nausea and Vomiting after Laparoscopic Cholecystectomy under General Anesthesia

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**Abstract.** objective: this study aims to identify whether dexamethasone can be used in the prevention of nausea and vomiting after laparoscopic cholecystectomy (LC) under general anesthesia. Methods: 400 patients who were performed with LC under general anesthesia were chosen and divided randomly into two groups with 200 patients each, namely ramosetron group and dexamethasone group. Results: there's no significant difference in the effectiveness of complete inhibition of nausea and vomiting within 24 hours after the surgery in both groups ( $P > 0.050$ ). Meanwhile, there's no significant side effects in association with the anti-emetic drugs within 24 hours after the operation in both groups, either. Conclusion: Dexamethasone plays a similar effective role as Ramosetron in the prevention of nausea and vomiting after laparoscopic cholecystectomy under general anesthesia.

## 1 Instruction

Postoperative nausea and vomiting (PONV) is a common and major complication of patients after surgery. Literatures show that the incidence of PONV in some operations is 25%-30%. Therefore, the control of PONV remains to be a challenge<sup>[1, 2]</sup>. Even though PONV isn't a life-threatening postoperative complication, it's still a hazard that causes complications such as wound dehiscence, electrolyte disturbance and dysphoria<sup>[3,4]</sup>. Some prophylactic medications, such as antihistamines, 5-serotonin antagonist and steroid, are able to effectively reduce the incidence of PONV. These drugs, however, are limited in the widespread clinical application due to their prices and side effects. This study aims to discuss and explore whether Dexamethasone, a medicine with appropriate price and no adverse effect (or a low incidence of side effects), can achieve the same effect as ramosetron in the prevention of PONV.

### 1.1 Admission standard

400 patients who were about to be performed with laparoscopic cholecystectomy under general anesthesia were enrolled in this study. Before induction of anesthesia, 200 patients were treated with dexamethasone and the other 200 were treated with ramosetron. ASA grading: I-II grade, female patients aged 18-60. Obesities, pregnant women or women in lactation or menstrual period, smokers, alcoholics, drug addicts, patients that had used anti-nausea or anti-vomiting drugs within 24 hours before the surgery, patients with combined severe heart, liver, kidney, lung diseases, diabetes, patients

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with hypertension, migraine and central nervous system diseases, psychiatric patients, postoperative patients with preserved gastric tube as well as patients with PONV history were excluded. The risk score indicators were based on the simplified PONV risk scoring summarized in Apfel<sup>[5]</sup> for adult treated with inhaled general anesthesia, including women, nonsmokers, history of PONV and / or motion sickness as well as postoperative opioid use. The risk scores of patients fitting the profile of item 0,1,2,3,4 were respectively 0,1,2,3,4 with a respective incidence of PONV of 10%, 21%, 39%, 61% and 79%.

## **1.2 Anesthetic methods**

Before the induction of anesthesia, 10 mg dexamethasone of slow intravenous injection was given to the dexamethasone group, and 0.3 mg of ramosetron intravenous injection was slowly administered to the patients in the Ramosetron group. The injection time of induced anesthesia drugs were not less than 1min. All patients underwent general anesthesia with total intravenous anesthesia after tracheal intubation. Anesthesia was induced by intravenous injection of 0.1mg/kg midazolam, 0.5µg/kg sufentanil, 2mg/kg propofol, 0.05mg/kg cis-atracurium after rapid induction of tracheal intubation. During the operation, continuous infusion of propofol was used to maintain the target concentration of anesthesia at 4µg/ml. In addition, it's supplemented by intermittent intravenous injection of sufentanil. During the intraoperative and postoperative process, patients' ECG, cuff blood pressure and oxygen were monitored. After the surgery, it depended on patients' situation whether the mixture of 2mg neostigmine and 1mg atropine would be used to antagonize residual muscle relaxation. In terms of postoperative analgesia, they were given 0.5µg/ml sufentanil in 100ml dilution solution at the speed of 2ml/h.

## **1.3 Observation on curative effect in the prevention of PONV**

The time of extubation was recorded and the incidence of PONV within 24 hours after extubation was recorded as well. Vomiting without gastric content, namely, retching, or vomiting with the gastric content were not strictly distinguished and were both regarded as vomiting. Patient with severe retching or vomiting might be given remedial drug intervention upon their request and the consent of the clinician.

## **1.4 Statistical analysis**

SPSS 13.0 software was adopted to conduct data analysis. t test was used in the comparison of measurement data and the comparison of enumeration data were subjected to  $\chi^2$  test.  $P < 0.050$  indicated significant differences.

## **2 Results**

The basic data of the test group are as shown in table 1. There were no significant differences in age, height, weight, BMI, ASA grade, operation time (min) and bleeding volume (ml) between the two groups. The effective rates of complete inhibition of nausea and vomiting in the dexamethasone group and ramosetron group within 24 hours after the surgery were respectively 78.00% (156/200) and 84.50% (169/200). In addition, their postoperative nausea rates were respectively 22% (44/200) and 15.50% (31/200) while postoperative vomiting rates were respectively 10.50% (21/200) and 7.50% (15/200), suggesting no significant difference between the two groups ( $P > 0.050$ ). Moreover, no significant adverse effects associated with anti-emetics were observed within 24 hours postoperatively.

**Table 1.** The basic data of the test group

	Dexamethasone	Ramosetron	P
Average age/years	38(9)	39(10)	>0.20
Average weight /kg	56(11)	58(9)	>0.10
BMI/,kg/m2	24(9)	23(9)	>0.50
ASA □ /n(%)	91(58)	95(57)	>0.20
ASA □ /n(%)	65(42)	74(43)	>0.05
The operationg time ,min	172(5)	169(8)	>0.10
The bleeding,ml	6(2)	6(1)	>0.50

### 3 Discussion

Vomiting is a complex reaction mediated by the vomiting center. Nucleus tractus solitaries, dorsal nucleus and reticular structure of peripheral ambiguous nucleus in the brainstem constitute the vomiting center which is able to accept the impulses from many areas, including chemical triggering zone, gastrointestinal autonomic nervous system and vestibular organs. PONV is a common and major complication for postoperative patients. It will delay the recovery time after anesthesia in the recovery room, prolong the hospitalization time and increase the cost of treatment. PONV is a result of a variety of factors and often occurs after regular anesthesia.

A large number of prospective data show that the incidence of PONV is associated with risk factors related to patients or anesthesia, instead of the operation itself<sup>[6]</sup>, which explains the impact of formulations of anesthetic drug on PONV. Sinclair and other scholars<sup>[7]</sup> found that every time the operation time was prolonged for 30min, the incidence of PONV would increase by 60%. However, the approaches of laparoscopic cholecystectomy surgeries were almost the same with similar operation time. In addition, based on the high similarity of samples, drug dosage for induction of anesthesia and anesthesia maintenance, methods and frequency were rather similar. Therefore, the sample selection criteria resulted in a greater similarity of anesthetic formula given to each patient. In this study, patients were given 10mg dexamethasone or 0.3mg ramosetron before the operation.

The effective rate of inhibition of nausea and vomiting within 24h after the surgery of dexamethasone group and ramosetron group were respectively 78.00% (156 /200) and 84.50% (169/200). The incidence of postoperative nausea were respectively 22.00% (44/200) and 15.50% (31/200) while the incidence of postoperative vomiting were respectively 10.50% (21/200) and 7.50% (15/200), indicating no significant difference between the two groups ( $P > 0.050$ ). Moreover, no significant adverse effects in associated with anti- nausea and anti- vomiting medicines were observed during 24 hours postoperatively. And yet similar effects were observed in the prophylaxis of PONV in laparoscopic cholecystectomy under general anesthesia.

However, questions such as whether a smaller dose of dexamethasone will have the same antiemetic effects in the control of PONV and whether the combination use of dexamethasone and ramosetron will play a more effective role in the control of PONV still require further study.

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