IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 22, Issue 3 Ser.13 (March. 2023), PP 12-15
www.iosrjournals.org

Effect of Ondansetron and Ondansteron in addition with dexamethasone in the treatment of post-operative nausea and vomiting.

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Keywords: *Ondansetron, Dexamethasone, Postoperative nausea and vomiting*

Date of Submission: 08-03-2023 Date of Acceptance: 21-03-2023

I. Introduction

The most common and distressing symptoms following surgery and anesthesia are pain, nausea, and vomiting. Pain causes suffering and draws first attention. Sometimes nausea and vomiting may be more distressing especially after minor and ambulatory surgery, delaying the hospital discharge (1). The incidence of postoperative nausea and vomiting is still very high despite few newer medication, in the range of 20-30%. The etiology and consequences of PONV are complex and multifactorial with patients' medical- and surgery-related factors. A thorough understanding of these factors, as well as the neuropharmacology of multiple emetic receptors and physiology relating to PONV is necessary to manage PONV (2).

Dexamethasone was first reported to be an effective antiemetic agent in patients undergoing cancer chemotherapy in 1981. Since then randomized, placebo controlled studies have shown that dexamethasone and other steroids are significantly better than other agents (metoclopramide, prochlorperazine, droperidol, domperidone) in preventing nausea and vomiting associated with chemotherapy (3).

Dexamethasone has been reported to be effective in reducing PONV in combination with Ondansetron (4). There are many causes of PONV, so antagonizing only one receptor type is not sufficient in many patients. It is logical to give drugs which have different mechanism of action. New evidence suggests that combination of antiemetics can act synergistically, even in pediatric cases (5).

Our study is to determine the safety and benefits of using combination of Dexamethasone and Ondansetron as a gold standard in elective common laparoscopic surgeries.

II. Aims and objectives:

The present study was undertaken to compare the efficacy of-

- A combination of Dexamethasone and Ondansetron

With

- Ondansetron alone

In prevention of post-operative nausea and vomiting (PONV) in elective laparoscopic surgeries-

1. Laparoscopic Cholecystectomy
2. Diagnostic laparoscopy
3. Laparoscopic Appendectomy

Methodology:

This study was conducted on 100 patients who came for elective laparoscopy. The patients were divided randomly into two groups, group O and group D, 50 in each group undergoing elective and Laparoscopic surgical procedures in Andhra Medical College, Visakhapatnam. An informed consent was taken from all patients.

Study design: Prospective, double blind, randomized, placebo controlled study.

Study Period: November 2011 to October 2013.

Group O: Ondansetron

Group D: Ondansetron + dexamethasone

Group O patients received 5ml of normal saline immediately after intubation.

Group D patients received 0.1mg/kg body weight of dexamethasone
(Maximum of 8mg) diluted into 5ml in a 5ml syringe. Immediately after intubation.
30 minutes before extubation both the group received 0.1 mg/kg body weight
Of Ondansetron

Inclusion criteria:
1. Patients of ASA Grade I and II undergoing laparoscopic surgery.
2. Patients between 20 and 55 years of age.
3. Patients weighing between 30 and 75 kg.
4. Elective laparoscopic surgeries
1. Diagnostic
2. Cholecystectomy
3. Appendectomy.

Exclusion criteria:
1. Patients belonging to ASA Grade III and IV.
2. Patients who had received opioids, nonsteroidal anti-inflammatory drugs, steroids, and antiemetic agents during the previous and post 24 h.
3. Patients with a history of motion sickness and previous PONV.
4. Co-morbidities: Diabetes Mellitus, Disturbed pituitary adrenal axis ex. Cushing's syndrome, Obesity with BMI > 20, etc.
5. Surgeries requiring retention of ryles tube.
6. Intra-operative Conversion into open surgery due to unforeseeable circumstances

III. Results:

The mean age of the group O is 42.62 ∓ 12.08 years and the mean age of the group D is 38.36 ∓ 13.70 years.
26% (13 patients) in group D and 29 patients (585) in group O had incidence of Nausea and vomiting.
Incidence of Nausea and vomiting:

Group	Yes	No	P Value
Group – D	13	37	0.0011
Group – O	29	21	

Group D had 30 females and 20 males; Group O had 22 males and 28 females.
Duration of surgery:

Group	Yes	P Value
Group – D	40.96	0.14
Group – O	47.30	

There was no statistically significant difference between Group-D and Group-O in the duration of surgery.

Incidence of Nausea:

Group	Yes	No	P Value
Group – D	12	38	0.0038
Group – O	27	23	

There is statistically significant difference in Group-D patients compared to Group-O for NAUSEA (0-4hrs); $p<0.05$.
Incidence of Vomiting:

Group	Yes	No	P Value
Group – D	9	41	0.016
Group – O	21	29	

There is statistically significant difference for Vomiting (0-4 hrs) between Group-D & Group-O ($p<0.05$)

Requirement of anti-emetic medication in the first 24 hours of post-operative period:

Group	Yes	No	P Value
Group – D	13	37	0.0011

Group – O	29	21	

There is a significant difference in the requirement of another dose of antiemetic between Group D & O

IV. Discussion:

PONV is one of the main complaints in patients undergoing surgery under general anesthesia. The incidence of PONV in patients undergoing laparoscopy ranges from 40% to 75%. It is one of the most important factors that determine the length of hospital stay after ambulatory anesthesia. In fact, its contribution to patient dissatisfaction is such that over 70% of patients considered avoidance of PONV to be very important. Numerous factors can affect PONV, such as age, gender, obesity, motion sickness, history of PONV, duration of the procedure, anesthetic technique, use of opioids, and pain (6).

The patients who received Ondansetron alone (group O) had a higher incidence of PONV (48%) than those who received a combination of dexamethasone and Ondansetron (22%).

On further analysis of incidence of late PONV we found that the difference in PONV between two groups was significant only in the first 4hrs post operatively. This was similar to a study by Leksoswski who also found a decrease in incidence of PONV in the first 4hrs with combination of Ondansetron and dexamethasone.

However other studies have shown better control of late PONV rather than early PONV which is unlike results from this study. Many studies have shown that dexamethasone alone or in combination with other antiemetics used prophylactically prevents PONV.

Although $5HT_3$ antagonists are potent antiemetics, no single drug has been successful in effectively controlling PONV. This has led to a number of studies investigating the efficacy of the combination of various antiemetics with an assumption that using a combination of antiemetics acting on different receptors can further reduce the incidence of PONV.

The mechanism of action of corticosteroids is unknown; however, there have been some suggestions, such as central and peripheral inhibition of production of 5HT, central inhibition of synthesis of prostaglandins, or changes in permeability of the blood–brain barrier to serum proteins. It was shown that dexamethasone was most effective when administered at the time of induction of anesthesia. As for ondansetron, it was suggested that it might be relevant to administer the drug towards the end of the surgery as the half-life of ondansetron is approximately 3.5-4 hours in adults. The onset of action of Ondansetron is 30 mins. We assumed that the timing of antiemetic is 30 mins before extubation. In our study, the complete response occurred in 42% of the cases in ondansetron group and 74% in ondansetron and dexamethasone group. This is comparable to the study conducted by Panda *et al.*

In our study, the incidence of complete response is comparable to other studies in patients undergoing laparoscopic tubal ligation. This may be explained due to variation in the type and duration of laparoscopic procedures in our study as compared to a single type of laparoscopic procedures in those studies.

In our study, 13 cases in Group D had complaints of PONV of which 13 cases (26%) needed another dose of antiemetic. This can be compared with 29 cases (58%) in Group O who had complaints of PONV and all of them needed another dose of antiemetic. The need for another dose of antiemetic is more in Group O than in Group D, which is comparable to a study conducted by Elhakim *et al* .

RAJEEVA et al[55] compared 4 mg Ondansetron IV alone, Group 1 (n = 26) and combination of 4 mg Ondansetron and 8 mg dexamethasone iv, Group 2 (n = 25) and found that the postoperative nausea score was lower in Group 2 than Group 1, 0 hr ($P < 0.01$), 2 hr ($P < 0.05$) and 24 hr($P< 0.01$). They also showed better control of delayed vomiting [$P<0.001$] than early vomiting in the group with combination therapy than those with mono therapy using Ondansetron.

The incidence of PONV and pain was less in Group D than in Group O. This probably reflects the strong anti-inflammatory action of dexamethasone, which has been shown to decrease postoperative pain. This is comparable to the study conducted by Elhakim *et al* .

In our study we have compared the efficacy of Ondansetron alone with the combination of Ondansetron and dexamethasone in adult patients undergoing elective laparoscopic surgery under general anaesthesia. In the present study, there were no adverse effects that we could specifically attribute to the single dose of dexamethasone we had administered. Thus, prophylactic antiemetics therapy with dexamethasone is considered to be relatively free to side effects.

V. Conclusion:

Our prospective, randomized controlled study compared the efficacy of adding dexamethasone for the prevention of post-operative nausea and vomiting in 100(50 in each group) patients having laparoscopic procedures.

There was a clear reduction in the incidence of nausea and vomiting in the group that received dexamethasone, in the first 4 hours of post-operative period.

There was no significant adverse effects we could attribute to the administration of single dose of dexamethasone.

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