Comparative Study on outcome between Ondansetron and Dexamethasone as Prophylaxis to Prevent Post Operative Nausea Vomiting (PONV)

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Abstract

Objective: In this study our main goal was to evaluate outcome between Ondansetron and Dexamethasone as preoperative prophylaxis in the management of PONV.

Method: The prospective observational study was done in total 80 patients underwent laparoscopic cholecystectomy at department of surgery at 250 Bed General Hospital, Kishoreganj, from January 2018 to June 2018.

Results: Patients were allocated randomly in two groups by a computer generated randomization scheme to receive the drugs by I/V route. Group A Ondansetron 4 mg in 0.9% NaCl or Normal Saline, total 5 ml. Group B Dexamethasone 8 mg in 0.9% NaCl, total 5 ml. The demographic profile which include age, weight and sex were comparable and no significant differences [p>0.05] were observed between the two groups. At time of interval 0-3 hours, nausea (32.5%), retching (27.5%), vomiting (35.0%) developed in group A but not developed in group B, however complete response was significantly higher in group B than group A (95.0% vs. 5.0%). At time of interval 3-6 hours, nausea (25.0%), retching (22.5%), vomiting (20.0%) was developed in group A but not developed in group B, however complete response was significantly higher in group B than group A (100.0% vs. 32.5%). Rescue treatment was found 2(5.0%) in group A and 2(5.0%) in group B. At time of interval 6-9 hours, nausea was developed 3(7.5%) in group A and 2(5.0%) in group B.However complete response was significantly higher in group B than group A (90.0% vs. 65.0%). Rescue treatment was found 3(7.5%) in group A and 2(5.0%) in group B. At time of interval 9-12 hours, nausea was (5.0%) in group A, not found in group B. Complete response was found 36(90.0%) in group A and 38(95.0%) in group B. At time of interval 12-24 hours, nausea and retching was not developed in both groups. However, vomiting, complete response and rescue treatment were not statistically significant (p>0.05) between two groups.

Conclusion: Dexamethasone has clinically better effect in the avoidance of PONV in the early postoperative period when compared to Ondansetron. Dexamethasone provides a cheaper alternative to Ondansetron with comparable effect in preventing PONV.

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Introduction

Post-operative nausea and vomiting (PONV) is a common problem and distressing symptom in surgical patient population. General anaesthesia with inhalational agents is associated with an average PONV incidence of 20-30 % in surgical patients.[1] PONV is difficult to treat and needs multiple drugs and combination of drugs. Granisetron and Ondansetron are among the commonly used 5HT3 antagonists and used in combination with Dexamethasone for prophylaxis against PONV.[1] It is of significance especially in the context of day care surgery. PONV is the reason for unanticipated hospital admission, resulting in stress and financial burden.[2] Nausea, vomiting and retching are among the most common post-operative complaints and can occur in general, regional and local anesthesia. There is a continued interest in methods to reduce the incidence and severity of PONV.[3] Various patients' related factors such as female sex, nonsmoking status, history of PONV, and motion sickness have been identified a srisk factors for PONV. Several anaesthesia related factors such as use of opioid and nitrous oxide and duration of general anaesthesia have been implicated as risk factors of PONV. Anumber of studies have compared Ondansetron with dexamethasone for PONV prophylaxis after laparoscopic surgeries.[4] Ondansetron is commonly used in prophylaxis and treatment of PONV.

Method

The study was conducted at the department of Surgery, 250 Bed General Hospital, Kishoreganj. The study was conducted over a period of six months from January 2018 to June2018. The study was a prospective observational study. Pre-anesthetic evaluation was done on the previous day and assessed for risk factors. Written informed consent was taken from all willing patients. 80 patients posted for elective laparoscopic cholecystectomy surgery were enrolled for the study. Patients in the age group of 20-60 years and ASA physical status class I and IIwere included for the study. Patients with known hypersensitivity or contra-indications to study drugs, history of nausea, vomiting or retching in 24 hours before anaesthesia, pregnant patients, patients who have received anti-emetic drugs or drugs with anti-emetic property during 24 hours before anesthesia, conditions requiring chronic opioids use, history of motion sickness and those suffering from gastrointestinal disorders, obesity, endocrine disorders, liver and renal diseases were excluded from the study.

The patients were made to fast for 8 hours prior to surgery. All were given ~~Tab~~ Ranitidine 150mg orallyon the previous night and on the morning of surgery and Diazepam 5mg orally at 6.00 AM on the day of surgery. Patients were allocated randomly to one of the 2 groups (group A 40 patients and group B 40 patients)by a computer generated randomization scheme to receive the following drugs by I/V route. Group A Ondansetron 4 mg in 0.9% NaCl or Normal saline, total 5 ml (2ml ondansetron + 3ml normal saline). Group B – Dexamethasone 8 mg in 0.9% NaCl or Normal saline, total 5 ml (1.6 ml Dexamethasone +3.4 ml normal saline). It was prepared by personnel not involved in the study in identical 5 ml syringes to ensure blinding to the anesthetist. Medications were administered intravenously before induction of anaesthesia. All patients were given general anaesthesia with endotracheal intubation. Fentanyl was given I/V prior to induction to provide background analgesia. Induction was with Thiopental sodium. Intubation was facilitated by Succinyl choline Maintenance of anaesthesia was with N_2O and intermediate acting muscle relaxant Vecuronium bromide. Analgesia was supplemented with injection Diclofenac sodium IM. At the end of procedure, the

secretions and blood in oropharynx were suctioned under vision.Residual neuromuscular blockade was antagonized with Neostigmine methyl sulphate and Atropine sulphate and extubation was done when patient was awake. After shifting to recovery room, patients were observed for 24 hours and vital signs, nausea and vomiting and pain assessment were done. All episodes of nausea and vomiting during the interval of 0-3 hours(immediate PONV), 3-6 hours (early PONV), 6-9 hours (intermediate PONV), 9-12 hours (late PONV) and 12-24 hours (delayed PONV) were evaluated by a numeric scoring system of PONV.

0 = no nausea or vomiting

1 = nausea but no vomiting

2 = vomiting once in 30 minutes or more

Results

Mean age, BMI, duration of anaesthesia, duration of surgery were not statistically significant ($p>0.05$) between two groups (Table-I). Male were predominant in both groups, 23(57.5%) in group A and 21(52.5%) in group B. The male female difference was not statistically significant ($p>0.05$) between two groups (Table-II). At time of interval 0-3 hours, nausea (32.5%), retching (27.5%), vomiting (35.0%) was developed in group A but not developed in group B, however complete response was significantly higher in group B than group A (95.0% vs. 5.0%).

Table I: Demographic and intra-operative parameters (n=80)

Parameters	Group A (n=40)		Group B (n=40)		P value
	Mean	±SD	Mean	±SD	
Age (years)	31.37	±9.18	32.42	±11.51	0.653^{ns}
BMI (kg/m^2)	22.46	±2.98	23.25	±3.39	0.271^{ns}
Duration of anaesthesia (min)	105.36	±21.25	106.12	±24.27	0.881^{ns}
Duration of surgery	89.17	±13.25	87.25	±22.10	0.638^{ns}

Group A- Ondansetron; Group B- Dexamethasone

ns=not significant; P value from unpaired t-test *P value by chi square test

Table II: Sex distribution (n=80)

Sex	Group A	Percentage	Group B	Percentage	P value
Male	23	57.5	21	52.5	
Female	17	42.5	19	47.5	$*0.653^{ns}$

ns=not significant; *P value by chi square test

Rescue treatment was found 2(5.0%) in group A and 2(5.0%) in group B. At time of interval 3-6 hours, nausea (25.0%), retching (22.5%), vomiting (20.0%) was developed in group A but not developed in group B, however complete response was significantly higher in group B than group A (100.0% vs. 32.5%).

Rescue treatment was found 2(5.0%) in group A and 2(5.0%) in group B. At time of interval 6-9 hours, nausea was developed (7.5%) in group A and 2(5.0%) in group B. However complete response was significantly higher in group B than group A (90.0% vs. 65.0%). Rescue treatment was found 3(7.5%) in group

A and 2(5.0%) in group B. At time of interval 9-12 hours, nausea was 2(5.0%) in group A, not found in group B. Complete response was found 36(90.0%) in group A and 38(95.0%) in group B. Rescue treatment was found 2(5.0%) in group A and 2(5.0%) in group B. The difference was not statistically significant (p>0.05) between two groups. At time of interval 12-24 hours, nausea and retching was not developed in both groups. However, vomiting, complete response and rescue treatment were not statistically significant (p>0.05) between two groups (Table-III). 3(7.5%) had headache in group A and 2(5.0%) in group B. Dizziness was found 3(7.5%) and hypotension 2(5.0%) in group A but not found in group B. The difference was not statistically significant (p>0.05) between two groups (Table-IV).

Table III: Incidence of nausea, retching and vomiting with time of interval (n=80**)**

Time of interval	Group A (n=40)		Group B (n=40)		P value
	n	%	n	%	
Time of interval					
0-3 hours					
Nausea	13	32.5	0	0.0	0.001[s]
Retching	11	27.5	0	0.0	0.001[s]
Vomiting	14	35.0	2	5.0	0.001[s]
Complete response	2	5.0	38	95.0	0.001[s]
Rescue treatment	2	5.0	2	5.0	0.608[ns]
Time of interval					
3-6 hours					
Nausea	10	25.0	0	0.0	0.002[s]
Retching	9	22.5	0	0.0	0.004[s]
Vomiting	8	20.0	0	0.0	0.009[s]
Complete response	13	32.5	40	100	0.001[s]
Rescue treatment	2	5.0	2	5.0	0.608[ns]
Time of interval					
6-9 hours					
Nausea	3	7.5	2	5.0	1.000[ns]
Retching	5	12.5	0	0.0	0.064[ns]
Vomiting	6	15.0	2	5.0	0.266[ns]
Complete response	26	65.0	36	90.0	0.016[s]
Rescue treatment	3	7.5	2	5.0	1.000[ns]
Time of interval					
9-12 hours					
Nausea	2	5.0	0	0.0	0.473[ns]
Retching	0	0.0	0	0.0	-
Vomiting	2	5.0	2	5.0	0.608[ns]
Complete response	36	90.0	38	95.0	0.671[ns]
Rescue treatment	2	5.0	2	5.0	1.000[ns]
Time of interval					
12-24 hours					
Nausea	0	0.0	0	0.0	-
Retching	0	0.0	0	0.0	-
Vomiting	5	12.5	2	5.0	0.428[ns]
Complete response	35	87.5	38	95.0	0.428[ns]
Rescue treatment	4	10.0	2	5.0	0.671[ns]

s=significant; ns=not significant; P value by chi square test

Table IV: Incidence of adverse complaints in different groups (n=80)

Side effects	Group A (n=40)		Group B (n=40)		P value
	n	%	n	%	
Headache	3	7.5	2	5.0	1.000^{ns}
Dizziness	3	7.5	0	0.0	0.239^{ns}
Hypotension	2	5.0	0	0.0	0.473^{ns}

ns=not significant; P value ~~for~~ unpaired t-test *P value by chi square test

Discussion

Difference of the mean age, BMI, duration of anaesthesia, duration of surgery were not statistically significant (p>0.05) between two groups. Male were predominant in both groups, 23(57.5%) in group A and 21(52.5%) in group B. The male female difference was not statistically significant (p>0.05) between two groups. Sandhya and Sugandha[2] study reported the demographic profile which include age, weight and sex were comparable and no significant differences (p>0.05) were observed between the two groups. Nanjundaswamy and Sridhara[1] observed that the groups were comparable with respect to age and body mass index, consumption of analgesics, duration of surgery and anaesthesia were comparable. Gupta and Jain[3] found the mean age was not statistically significant (p>0.05) between two groups.

In this study showed at time of interval 0-3 hours, nausea (32.5%), retching (27.5%), vomiting (35.0%) was developed in group A but not developed in group B, however complete response was significantly higher in group B than group A (95.0% vs. 5.0%). Rescue treatment was found 2(5.0%) in group A and 2(5.0%) in group B. At time of interval 3-6 hours, nausea (25.0%), retching (22.5%), vomiting (20.0%) was developed in group A but not developed in group B, however complete response was significantly higher in group B than group A (100.0% vs. 32.5%). Rescue treatment was found 2(5.0%) in group A and 2(5.0%) in group B. At time of interval 6-9 hours, nausea was developed 3(7.5%) in group A and 2(5.0%) in groupB. However complete response was significantly higher in group B than group A (90.0% vs. 65.0%). Rescue treatment was found 3(7.5%) in group A and 2(5.0%) in group B.

At time of interval 9-12 hours, nausea was 2(5.0%) in group A, not found in group B. Complete response was found 36(90.0%) in group A and 38(95.0%) in group B. Rescue treatment was found 2(5.0%) in group A and 2(5.0%) in group B. The difference was not statistically significant (p>0.05) between two groups. At time of interval 12-24 hours, nausea and retching was not developed in both groups. However, vomiting, complete response and rescue treatment were not statistically significant (p>0.05) between two groups. Sandhya and Sugandha[2] reported on studying PONV during the early postoperative period i.e. 1st 6 hours, there was no significant difference between the two drugs. 83.3% had no vomiting in the Dexamethasone group as compared to 93.3% in the Ondansetron group (p>0.05). Similarly two groups were comparable when assessed for complete response in the delayed postoperative period(6-24 hrs).86.7% had no vomiting in Ondansetron group as compared to 93.3% in Dexamethasone group. (p=0.39). 13.3% of patients in Ondansetron group required rescue antiemetics. Nanjundaswamy and Sridhara Complete response for 0-12 hour

was 100%, 100%and 61.9%% in group 1, group 2 and group 3 respectively. There were no adverse effects noted in any of the groups in first 6 hours. The incidence of PONV are tabulated at intervals of 6 hours and complete response was noted in all two groups.

There was no statistical difference observed between group 1 and 2 in first 12 hours but significant difference was observed between group 1, group 2 and control groups.[1] Over 24 hours period, the complete response was 84% in Group 1 and Group 2. There was no statistically significant difference observed at 24 hours. Therefore, the incidence of PONV was 16% in Groups 1 and 2. Sanjowal et al.[5] reported complete response of 92% with Ondansetron and Dexamethasone combination. Ahsan et al.[6] study with O +D combination in cholecystectomy had incidence of 12%. In our study the incidence is 16%. Results of our study concur with the results of metaanalysis proving that antiemesis with combination of 5HT3 and Dexamethasone is effective than single drug therapy.[7,8] Dexamethasone administered as single antiemetic drug too has a significant reduction in PONV. In our study too, Dexamethasone group had incidence of PONV of 68% and complete response was 32%. Significant difference was observed between groups A with group. During 12-24 hours of the postoperative period, none of the patients had nausea and retching. Thomas and Jones et al.[9] conducted a prospective randomized comparative study of Dexamethasone, Ondansetron, and Ondansetron + Dexamethasone as prophylactic antiemetic therapy in patients undergoing day case gynecological surgery. They found that failure of prophylaxis during first 3 hours after surgery was recorded in 22%, 28.3%, and 8.6%. The overall incidences for the 24 hours post surgery were 42.4%, 48.3%, and 34.5%, respectively.

In this study observed that 3(7.5%) had headache in group A and 2(5.0%) in group B. Dizziness was found 3(7.5%) and hypotension 2(5.0%) in group A but not found in group B. The difference was not statistically significant ($p>0.05$) between two groups. Sandhya and Sugandha[2] comparing the side effects, 10% of patients of Ondansetron group and 3.3% of patients in Dexamethasone group had headache. Transient perineal itching probably due to the vehicle was experienced in 36.7% of patients in Dexamethasone group. Other side effects were not significant. In Nanjundaswamy and Sridhara[1] study, there was no incidence of adverse effects like headache, dizziness, drowsiness and sedation, however, Thomas et al.[9] reported adverse effects like fatigue, dizziness and flushing and Gan et al.[10] reported drug related adverse effects as 3% in O+D group. Gupta and Jain[3] reported in Group O (Ondansetron), 8% (2) patients complained of headache, 8% (2) had dizziness and 4% (1) patient had hypotension. In Group D, only 4% (1) patient complained of headache.

Conclusion

Dexamethasone has clinically better effect in the avoidance of PONV in the early postoperative period when compared to Ondansetron. Dexamethasone provides a cheaper alternative to Ondansetron with comparable effect in preventing PONV.

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