Original Article

Comparison of Dexamethasone and Ondansetron for the prophylaxis of post operative Nausea and Vomiting in Laparoscopic Gynaecological procedures

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Abstract

Introduction: Post-operative nausea and vomiting (PONV) is one of the important complications after laparoscopic surgery resulting in patient dissatisfaction and consumption of healthcare resources. **Objectives:** We compared the efficacy of dexamethasone and ondansetron in preventing post operative nausea and vomiting in gynaecological laparoscopic surgeries. **Methods:** After approval from ethical committee and informed consent, the patients were randomly assigned to receive dexamethasone 8 mg or ondansetron 4 mg i.v. at induction. Postoperative PONV scores, pain scores, morphine consumption and Richmond Agitation sedation scores were compared one hourly for 6 hours and at 12 and 24 hours. **Results:** Both patient groups were similar in age, weight, height, duration of surgery and ASA distribution. No difference was observed in PONV scores at 1 hour (p=0.33), 2-3 hours (p=0.27), 4-6 hours (p=0.13) and 7-12 hours (test p=0.48); first episode of vomiting (4.87 sd ±2.29 vs. 4.29 sd ±1.32 hours, p=0.59); maximum pain scores at 1 hour (p=0.61), between 2-3 hours (p=0.32), 4-6 (p=0.47), 7-12 (p=0.57) and 13-24 hours (p=0.79); and post-operative Richmond Agitation Sedation scores (p =0.33; 0.48, and 0.50 at 1-3, 4-6, and 7-12 hours). Mean morphine consumption was similar in two groups at 1-3 hours (2.44 ± 2.18 vs. 3.0 ± 2.0 mg; p=0.24), 4-6 (3.73 ± 2.85 vs. 4.41 ± 2.72 mg; p=0.31), 7-12 (3.81 ± 2.91 vs. 4.75 ± 2.96 mg; p=0.18) and 13-24 hours intervals (3.94 ± 2.97 vs. 4.80 ± 2.97 mg; p=0.23). The time to first occurrence of nausea was significantly delayed in dexamethasone group, (3.85 ± 2.24 vs. 2.25 ± 1.38 hours; p=0.02). **Conclusion:** The efficacy of dexamethasone and ondansetron in preventing post-operative nausea and vomiting in gynaecological laparoscopic procedures is comparable; onset of nausea is significantly delayed in dexamethasone group. **Key Words:** Dexamethasone, Ondansetron, Postoperative Nausea And Vomiting, Ponv Prophylaxis, Gynaecological Laparoscopic Surgery.

INTRODUCTION

Postoperative nausea and vomiting (PONV) is a common and distressing side effect of anaesthesia that consumes valuable resources and time of healthcare professionals; various studies cite its incidence between 40 – 75%. Laparoscopic surgery has been recognized as one of the important risk factor for PONV [1]. Prophylactic administration of antiemetics may reduce overall PONV-related resource consumption and costs thus providing a higher patient satisfaction[2]. Various strategies are used to decrease the occurrence of PONV e.g., using single or multiple agents for prophylaxis, modifying anaesthetic technique or applying all of them in a multimodal approach to achieve maximum protection [3] Ondansetron, a highly selective serotonin-3 receptor antagonist is effective in the prophylaxis and treatment of PONV in adults.[4] Dexamethasone also reduces the incidence of PONV if given prophylactically [5]. The search in Pakistani journals revealed few studies probing the incidence of PONV[i] and comparing other drugs for its prevention[6] but none of the local studies and a few international studies compared dexamethasone and ondansetron for prophylaxis of PONV[7,8]. This study was undertaken in view of the important consequences of PONV with main emphasis on the patient satisfaction. We compared

dexamethasone and ondansetron regarding their efficacy in preventing post operative nausea and vomiting in gynaecological laparoscopic procedures when given at the time of induction. Post-operative analgesia, morphine consumption and Richmond Agitation Sedation scores were also compared as secondary outcomes.

OBJECTIVE

The study was designed to compare the efficacy of dexamethasone and ondansetron in preventing PONV among the patients undergoing Gynaecological laparoscopic pelvic surgery aged 20-50 years.

MATERIAL & METHODS

Study design: Quasi-experimental, randomized, double blind, comparative study

Setting: Department of Anaesthesia Hameed Latif Hospital, Lahore.

Duration of study: Two years and two months (Oct 2005 to Dec 2007)

Main outcome measures

1. PONV score measured on 0 to 10 scale and time to first episode of nausea and vomiting.
2. Post operative analgesia measured on 5 point scale and by total morphine consumption in mg.
3. Post operative agitation/sedation scored on Richmond Agitation-Sedation scale

Subjects: 70 patients of American Society of Anesthesiologists (ASA) I-II status undergoing gynaecological laparoscopic surgeries in two groups of 35 each

Study Settings

The study included a total of 70 patients divided randomly in two groups of 35 each and was conducted in Hameed Latif Hospital, Lahore, which is 250 bedded, tertiary care hospital

The study used convenient, non-probability sampling randomly allocated to two groups.

Sample Selection

Inclusion Criteria

The patients having following characteristics were included in the study.

1. Gender & Age: Female patients aged 20 - 50 years.
2. Patients of American Society of Anesthesiologists (ASA) Class I & II.
3. Procedure: Gynaecological Pelvic Laparoscopic surgery.

Exclusion Criteria

Following patients were excluded from the study:

1. Previous history of PONV or motion sickness.
2. Pre-Operative Emesis
3. Patients having fasting (NPO) interval of less than 5 hours for solids
4. Patients receiving anti-emetic medicines Preoperatively

Data Collection Technique

After approval from Hospital Ethical Committee and informed consent, patients fulfilling the inclusion criteria were included.

- All patients were premedicated with midazolam 2.5 mg I/V, 30 minutes before surgery in the preop room.

  The patient in Dexamethasone group received Inj. dexamethasone 8 mg I/V (Inj. DECADRON ®, MSD) whereas the patient in Ondansetron group received Inj. ondansetron 4 mg I/V (Inj. ONSET ®, Pharmedic) at induction.

  Patients in both of these groups received a standardized induction with general endotracheal anaesthesia with Thiopental 4 mg/kg I/V and Vecuronium 0.07 mg/kg I/V. Inj. Morphine 0.05 mg/kg I/V at induction was given for intra-op Analgesia. The patients were maintained on Isoflurane in 100% oxygen with a Fresh Gas Flow of 1 Litre/minute on soda lime closed circuit. Vecuronium 0.02 mg/kg was used for maintenance of relaxation every 30 min. Reversal of neuromuscular blockade was achieved with Neostigmine 2.5 mg + Atropine 1 mg I.V. at the end of surgery. For Post Operative analgesia Inj. Morphine 1.5 mg I/V S.O.S was used.
- To ensure double-blinding, both groups were followed in the post- operative period for 24 hours, by an anesthetist blinded to the type of drug used, who recorded outcome measures on a specially designed proforma (annex-2).

Outcome Measures

The following outcome measures were recorded in both groups:

The patients were asked to point on a 30 cm Visual Analog Scale marked with ‘0’ for No nausea at one

end and '10' for vomiting at other end with other numbers in between the two marks, on an hourly basis for 6 hours, then at 12 and 24 hours. This number was recorded as PONV score; primary outcome measure.

Figure 1

Replica of visual analogue scale used for PONV scoring

0	No Nausea
1	
2	Mild Nausea
3	
4	
5	Moderate Nausea
6	
7	
8	Severe Nausea
9	
10	Vomiting

Time of onset: of nausea/vomiting from induction was also noted in hours postoperatively.

Post-op analgesia was assessed on a 5 point scale as under

O	1	2	3	4
No pain Mild	Moderate	Severe	Very Severe	Pain

The requirement of analgesia was also noted by recording the milligrams of morphine consumed.

Post-operative agitation was assessed on Richmond Agitation-Sedation Scale

All the information was entered on a specially designed proforma.

DATA ANALYSIS PROCEDURE

Age, weight, height, duration of surgery, time to first occurrence of nausea/vomiting, time to first episode of vomiting, consumption of morphine in milligrams were recorded. Maximum PONV scores were taken at 1st hour, 2-3 hours, 4-6, 7-12 and 13-24 hours postoperatively. Pain scores and Richmond agitation sedation scores were also recorded. All the data was entered in latest SPSS version (version10) for analysis.

STATISTICAL TESTS

The student's t-test was used to analyse the following variables and a p-value of less than 0.05 was considered significant; age, weight, height, duration of surgery, time to first occurrence of nausea/vomiting, time to first episode of vomiting and consumption of morphine in milligrams.

The Chi square test or Fisher's exact test was used for the comparison of following variables and a p value of < 0.05 was considered significant; ASA distribution and PONV scores at different intervals.

RESULTS

Both groups were similar regarding their age, weight, height, ASA grouping and duration of surgery. Mean age in dexamethasone group was 32.4 sd ±6.4 years while in ondansetron group it was 30.4 sd ±5.0 years (p= 0.15). Mean weight in dexamethasone group was 73.1 kg ± 15.1 and in the ondansetron group it was 67.2 kg ± 12.6 with a p = 0.08. Mean height in dexamethasone group was 156.7 cm and in ondansetron group it was 155.8, p value was insignificant (=0.4). Mean duration of surgery, measured from the time of induction to extubation, in dexamethasone group was 56 minutes while in ondansetron group it was 59 minutes with a p value of 0.17. Statistical comparison between ASA status distributions between the two groups with chi square showed a p value of 0.69. Comparing the maximum PONV score between the two groups within 1st hour postoperatively with Fishers exact test showed no significant difference (two tailed p=0.33). At 2-3 hour, maximum PONV scores were again comparable as shown by Fishers exact test (p=0.27). Maximum PONV scores of two groups between 4-6 hours postoperatively also showed no statistically significant difference (p = 0.13). Comparisons of maximum PONV scores from 7th to 12th hour with Fishers exact test gave p value (two tailed) =0.48, showing insignificant difference. Mean times of first occurrence of nausea/vomiting in dexamethasone and ondansetron group were 3.85 ± 2.24 hours and 2.25 ± 1.38 hours postop, respectively yielding a statistically significant difference, p=0.02. Mean times of first vomiting episodes in dexamethasone and ondansetron groups were 4.87 ± 2.29 and 4.29 ± 1.32 hours respectively. Comparing with t-test showed a p value of 0.59, i.e., statistically insignificant. The dexamethasone and ondansetron groups were compared regarding the maximum pain scores within 1st hour and between 2-3, 4-6, 7-12, 13-24 hours post operatively. The Chi square p-values were 0.61, 0.32, 0.47, 0.57, and 0.79, respectively showing no statistically significant difference between the two groups. Comparing the analgesia with mean of total morphine consumption

Table-1
Age distribution of the patients in two groups

Age groups (Years)	Count/%	Study drugs		Total
		Dexa-methason	Ondan-setron	
<20	Count	0	1	1
	%	.0%	2.9%	1.4%
20 to 29	Count	13	14	27
	%	37.1%	40.0%	38.6%
30 to 39	Count	20	18	38
	%	57.1%	51.4%	54.3%
40 to 49	Count	0	2	2
	%	.0%	5.7%	2.9%
50 to 59	Count	2	0	2
	%	5.7%	.0%	2.9%
Total	Count	35	35	70
	%	100.0%	100.0%	100.0%

Statistical analysis
Mean age for Dexamethasone group = 32.4 with ± 6.4 years
Mean age for Ondansetron = 30.4 ± 5.0 years
No statistical difference between mean age of two groups (t =1.4 and P= 0.15)

Table-2
Mean duration of surgery among two groups

Study groups	N	Mean duration of surgical procedure	Std. Deviation
Dexamethasone	35	56 min	10 min
Ondansetron	35	59 min	10 min

Statistical Analysis
t value =1.3 P value 0.17
No statistically significant difference in mean duration of surgery between two study groups

between the two groups at 1-3, 4-6, 7-12 and 13-24 hours intervals showed no statistically significant difference. The mean consumption of morphine in milligrams in dexamethasone and ondansetron groups were 2.44 ± 2.18 vs. 3.0 ± 2.0, 3.73 ± 2.85 vs. 4.41 ± 2.72, 3.81 ± 2.91 vs. 4.75 ± 2.96, 3.94 ± 2.97 vs. 4.80 ± 2.97 with a p-value of 0.24, 0.31, 0.18, 0.23, respectively.The post operative sedation/ agitation compared with Richmond Agitation Sedation scores showed chi square p-values of 0.33, 0.48, and 0.50, at 1-3, 4-6, and 7-12 hours respectively.

Table-3
Comparison postoperative nausea and vomiting (PONV) within 1 hour between two study groups

PONV Score within 1 hour	Count/ %	Study drugs		Total
		Dexa-methasone	Ondan-setron	
No Nausea (score=0)	Count	32	30	62
	%	91.4%	85.7%	88.6%
Mild to Severe Nausea (score=1-9)	Count	1	4	5
	%	2.9%	11.4%	7.1%
Vomiting (score=10)	Count	2	1	3
	%	5.7%	2.9%	4.3%
Total	Count	35	35	70
	%	100.0%	100.0%	100.0%

Statistical analysis
Fisher exact P value two tailed = 0.33 (> 0.05)
No statistically significant difference in maximum PONV scores within 1 hour between two groups
Note: 4 Cells have expected value less than 5 hence Chi-square is invalid

Table-4
Comparison postoperative nausea and vomiting (PONV) at 2-3 hours between two study groups

PONV Score in 2-3 hour	Count/%	Study drugs		Total
		Dexa-methasone	Ondan-setron	
No Nausea (score=0)	Count	30	25	55
	%	85.7%	71.4%	78.6%
Mild to Severe Nausea (score=1-9)	Count	5	9	14
	%	14.3%	25.7%	20.0%
Vomiting (score=10)	Count	0	1	1
	%	.0%	2.9%	1.4%
Total	Count	35	35	70
	%	100.0%	100.0%	100.0%

Statistical analysis
Fisher exact P value two tailed = 0.27 (> 0.05)
No statistically significant difference in maximum PONV scores in 2-3 hours between two groups
Note: 2 Cells have expected value less than 5 hence Chi-square is invalid

Table-5

Comparison of postoperative nausea and vomiting (PONV) within 4-6 hour between two study groups

PONV Score in 4-6 hour	Count/%	Study drugs		Total
		Dexa-methasone	Ondan-setron	
No Nausea (score=0)	Count	19	27	46
	%	54.3%	77.1%	65.7%
Mild to Severe Nausea (score=1-9)	Count	9	5	14
	%	25.7%	14.3%	20.0%
Vomiting (score=10)	Count	7	3	10
	%	20.0%	8.6%	14.3%
Total	Count	35	35	70
	%	100.0%	100.0%	100.0%

Statistical analysis
Chi-square =4.13 P value = 0.13 (> 0.05)
No statistically significant difference in maximum PONV scores at 4-6 hours between two groups

Table-6

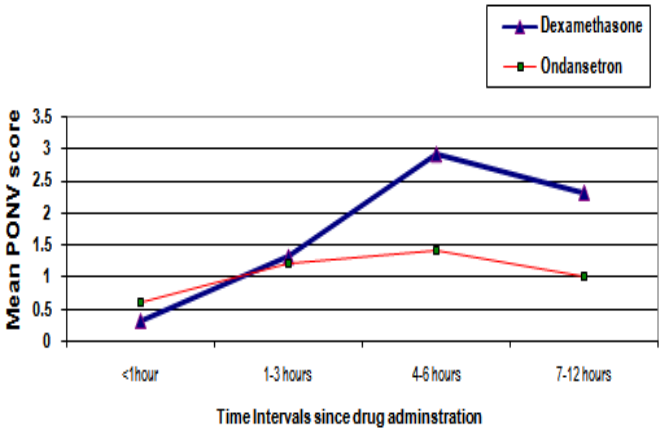
Comparison postoperative nausea and vomiting (PONV) within 7-12 hour between two study groups

PONV Score in 7-12 hour	Count/%	Study drugs		Total
		Dexa-methasone	Ondan-setron	
No Nausea (score=0)	Count	26	30	56
	%	74.3%	85.7%	80.0%
Mild to Severe Nausea (score=1-9)	Count	5	3	8
	%	14.3%	8.6%	11.4%
Vomiting (score=10)	Count	4	2	6
	%	11.4%	5.7%	8.6%
Total	Count	35	35	70
	%	100.0%	100.0%	100.0%

Statistical analysis
Fisher exact P value two tailed = 0.48 (> 0.05)
No statistically significant difference in maximum PONV scores in 7-12 hours between two groups
Note: 4 Cells have expected value less than 5 hence Chi-square is invalid

Figure-2

Comparision of mean postopreative nausea vomiting (PONV) score series of time intervals post operatively



Time Intervals	P value for independent t- test
1st (<1hour)	0.56
1-3 hours	0.60
4-6 hours	0.21
7-12 hours	0.21
13-24 hours	-

Table-7

Comparison of time to first nausea episode in two group

Study groups	N	Mean time in hours	Std. Deviation
Dexamethasone	10	3.85	2.24
Ondansetron	19	2.25	1.38

Statistical Analysis
t value =2.37 P value 0.02 (<0.05)
There is statistically significant difference in mean time to first occurrence of nausea in two study groups

DISCUSSION

Our study compared the efficacy of dexamethasone with ondansetron for prophylaxis of postoperative nausea and vomiting in gynaecological laparoscopic surgeries when given at the time of induction. The time to occurrence of first episodes of nausea and vomiting was also compared. Post operative analgesia; assessed on a 5-point pain scale, and requirement of analgesics; measured in mg of morphine consumed, were also compared between the two groups as

secondary outcome measure. The degree of irritability as measured on the Richmond Agitation-Sedation Scale was also compared between the two groups. Both of the groups were comparable in their age, weight, height, duration of surgery and ASA status. Dexamethasone and ondansetron were comparable in preventing PONV in respective groups of our study when maximum PONV scores were compared during 1st hour, 1-3, 4-6 and 7-12 hours giving p-values of 0.33, 0.27, 0.13 and 0.48 respectively. The PONV scores during 13-24 hours could not be compared due to early discharges of some of the patients, which remain a limitation of the study.

Biswas BN et al compared ondansetron (4mg), dexamethasone (8mg), and ondansetron plus dexamethasone vs. placebo (n=40 in each group) in their laparoscopic tubal ligation patients. They found a complete response (defined as no postoperative nausea and vomiting) of 60% and 63% respectively in ondansetron and dexamethasone groups (no significant difference). The incidence of PONV in the ondansetron plus dexamethasone group when compared with ondansetron or dexamethasone alone was also statistically insignificant (p=0.091 and 0.143 respectively).[10] Yuksek MS et al while comparing ondansetron (4mg) with dexamethasone (8 mg) in gynaecological laparoscopic surgeries found ondansetron to be better than dexamethasone (incidence of PONV 35% vs. 55% respectively) with significant difference only in the first 3 hrs postoperatively when used for PONV prophylaxis at induction. They used propofol for induction and epidural morphine + fentanyl for analgesia which is different from our study.

Apfel CC et al in their very large study enrolling 5199 high risk surgical patients, found a comparable reduction in PONV by ondansetron and dexamethasone prophylaxis of about 26%, though the study population is a mixed one.[11] Ondansetron 4 mg has been compared by Grimsehl K and colleagues with marzine 50 mg as equipotent for PONV prophylaxis given at induction in gynaecological laparoscopic surgeries. They found no difference in both groups regarding incidence of PONV (54% vs 56%).[12]

The differences in study populations appear to be a likely explanation for the differences in prophylactic efficacy of ondansetron and dexamethasone in these studies. Genetic differences among patients due to genetic polymorphism in cytochrome P450 (CYP2D6) isoform[13] or presence of three copies of CYP2D6 gene [14] leading to different rates of ondansetron metabolism have also been linked to difference in prophylactic efficacy of ondansetron in different patient populations. From clinical point of view, the combination prophylaxis with ondansetron plus dexamethasone has been found to be better than dexamethasone alone.[15]

Time to first episode of nausea/vomiting in our study was delayed in dexamethasone group having 3.85 ± 2.24 hours and 2.25 ± 1.38 hrs in ondansetron group which was statistically significant (p=0.02). Paech MJ while comparing the different dose combinations of dexamethasone and ondansetron observed a similar effect with an increased incidence of nausea in patient groups receiving lower dose of dexamethasone (2 mg).[16] Our study did not show a statistically significant difference between the dexamethasone and ondansetron groups when times to the occurrence of first vomiting were compared (4.87±2.29 hrs vs. 4.29±1.32, p=0.59).

The comparison of pain scores between the two groups in our study showed no significant difference, p-values at 1st hour and between 2-3, 4-6, and 7-12 hours post operatively were 0.61, 0.32, 0.47, and 0.57, respectively. Morphine consumption was decreased in the dexamethasone group as compared to the ondansetron group. It was 2.44 ± 2.18 (mean±sd) vs. 3.0 ± 2.0 within 1st hour, 3.73 ± 2.85 vs. 4.41 ± 2.72 at 3 hours, 3.81 ± 2.91 vs. 4.75 ± 2.96 at 6 hours, 3.94 ± 2.97 vs. 4.80 ± 2.97 at 12 hours, but the difference was not statistically significant (p-value of 0.24, 0.31, 0.18, and 0.23, respectively). Yuksek MS et al compared dexamethasone and ondansetron in gynecological laparoscopic patients and found no significant differences in the pain scores or the use of morphine between their groups.

This decrease in analgesic requirements with dexamethasone, although not significant in our study, has also been described by other researchers e.g., Fujii Y et al found statistically significant reduction in PONV (p=0.001) and analgesic (indomethacin) requirement (p=0.029) after dexamethasone (8 mg) prophylaxis in their study among gynecological laparoscopic surgery patients.[17]

In our study groups Richmond Agitation-Sedation Scores at 1-3, 4-6, 7-12 hours revealed no statistically significant differences with p-values of 0.33, 0.48, and 0.50, respectively. Yuksek MS et al found similar sedation scores between their study groups when comparing dexamethasone with ondansetron in gynaecological laparoscopic studies.

CONCLUSION

The efficacy of dexamethasone and ondansetron in preventing post-operative nausea and vomiting in gynaecological laparoscopic procedures is comparable; onset of nausea is significantly delayed in dexamethasone group.

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