COMPARISON OF ONDANSETRON VERSUS DEXAMETHASONE FOR PREVENTION OF NAUSEA AND VOMITING IN DIAGNOSTIC LAPAROSCOPIC GYNAECOLOGICAL PROCEDURES

Anaesthesiology

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ABSTRACT

BACKGROUND: Post-operative nausea and vomiting (PONV) affects 30-40% of patients after general anaesthesia.^[1]

AIMS: To compare the effect of Ondansetron and Dexamethasone for prevention of nausea and vomiting in diagnostic gynaecological laparoscopy.

METHODS: Ethical committee approval was taken. Consent was obtained. Patients were divided into 2 groups of 30 each. General anaesthesia was administered to all patients. Inj. Ondansetron 0.15 mg/kg i.v. was given to patients of group O. Injection Dexamethasone 0.2 mg/kg IV was given to patients of group D. Patients were monitored for nausea, vomiting, retching, pain score, side effects and requirement of rescue antiemetic.

RESULTS: Inj. Dexamethasone is better than Inj. Ondansetron for prevention of P.O.N.V. in diagnostic gynaecological laparoscopy.

KEYWORDS

Ondansetron, Dexamethasone, PONV.

INTRODUCTION

Post-operative nausea and vomiting (PONV) affects 30-40% of surgical patients after general anaesthesia^[1]. It causes dehydration, electrolyte imbalance, aspiration of gastric contents, oesophageal rupture, suture dehiscence and bleeding. Various patient specific factors like younger age, female gender, history of PONV/motion sickness, surgical procedures like laparoscopic, gynecological, middle ear surgery, ophthalmic surgery and anaesthesia factors like use of volatile anaesthetics, prolonged duration of anaesthesia, N₂O, opioids increase PONV.

AIM

To compare the effect of Ondansetron and Dexamethasone for prevention of nausea and vomiting in diagnostic gynaecological laparoscopy.

MATERIALS AND METHODS

Ethical committee approval was taken. Sixty patients were recruited into the study. Patients were counseled. Patients aged 20 to 50 yrs, ASA Grade I and II scheduled for diagnostic gynaecological laparoscopy were included in the study. Patients of pediatric and geriatric age group, ASA grade III and IV, patients with history of motion sickness/PONV, those who have received anesthesia in the last 24 hrs were excluded from the study. Consent was taken. Patients were premedicated with Inj. Glycopyrrolate 4 µg/kg and Inj. Fentanyl 2 µg/kg IV. Inj. Ondansetron 0.15 mg/kg i.v. was given to patients of group O. Injection Dexamethasone 0.2 mg/kg IV was given to patients of group D. Preoxygenation: with 100% O₂ for 3mins. Induction was achieved done Inj. Vecuronium Bromide 100 µg/kg and Inj. Thiopentone 4-6 mg/kg. Patient were intubated. Maintenance: 100% O₂ mixture with Isoflurane and Inj. Vecuronium bromide 25 µg/kg IV. Patients were mechanically ventilated. After surgery, neuromuscular blockade was reversed with Inj. Glycopyrrolate 8µg/kg and Inj. Neostigmine 50µg/kg. Patients were extubated and monitored for nausea, vomiting, retching, pain score, side effects, requirement of rescue antiemetic (Inj. Metoclopramide 0.15 mg/kg IV) and vital signs for 24hrs (0-2,2-6,6-12,12-18,18-24) post operatively.

ASSESSMENT

Nausea is a sensation of unease and discomfort with an involuntary urge to vomit. **Vomiting** was defined as expulsion of stomach contents.

Retching was defined as an involuntary attempt to vomit that did not produce stomach contents.

Nausea and vomiting were evaluated as follows:

PONV Score	Events
0	Complete response
1	Nausea
2	Nausea and vomiting

4-point verbal descriptive scale. Nausea assessment was made post operatively over a period of 24 hrs. (0-2,2-6,6-12,12-18,18-24).

No nausea	0
Mild nausea	1
Moderate nausea	2
Severe nausea	3

Visual Analogue Scale:

DATA ANALYSIS

Mean and standard deviations have been calculated for continuous variables like age, weight, duration of surgery and anaesthesia in the two drug groups. The values calculated have been compared and analyzed using Student 't' test. The number percentages have been calculated for patients having nausea, retching, vomiting, significant pain and use of rescue antiemetic. The number percentages hence obtained were assessed using —Chi square test. Software IBM SPSS 20.0 has been used for statistical analysis in our study. p-values have been calculated for evaluation of significant difference.

OBSERVATIONS AND RESULTS

Table 1: Demographic Data

	Group D (n=30)	Group O (n=30)	P value
Age	30.16 ± 4.44	28.6 ± 4.28	0.1712
ASA			
Grade - I	20	15	0.2913
Grade - II	10	15	
Duration of Surgery	67.36 ± 2.93	66.21 ± 2.26	0.0913
Duration of Anaesthesia	88.86 ± 1.88	87.83 ± 2.84	0.1030

Table 2: Nausea Wise Distribution

	Group D (n=30)	Group O (n=30)	P value
0-2 hrs.	9 (30.0%)	13 (43.3%)	0.421
2-6 hrs.	8 (26.6%)	10 (33.3%)	0.778
6-12 hrs.	2 (06.6%)	8 (26.6%)	0.083
12-18 hrs.	1 (03.3%)	7 (23.3%)	0.057
18 -24 hrs.	1 (03.3%)	7 (23.3%)	0.057

Table 3: Retching Wise Distribution

	Group D (n=30)	Group O (n=30)	P value
0-2 hrs.	6 (20.0%)	9 (30.0%)	0.551
2-6 hrs.	2 (06.6%)	8 (26.6%)	0.083
6-12 hrs.	0	6 (20.0%)	0.031
12-18 hrs.	0	2 (06.6%)	0.472
18 -24 hrs.	0	1 (03.3%)	1.000

Table 4: Vomitting Wise Distribution

	Group D (n=30)	Group O (n=30)	P value
0-2 hrs.	10 (33.3%)	13 (43.3%)	0.595
2-6 hrs.	7 (23.3%)	9 (30.0%)	0.770
6-12 hrs.	3 (10.0%)	8 (26.6%)	0.182
12-18 hrs.	0	6 (20.0%)	0.031
18 -24 hrs.	0	6 (20.0%)	0.031

Table 5: Four Point Score Wise Distribution

		Group D(n=30)	Group O (n=30)	P value
0-2 hrs.	None	26 (86.6%)	22 (73.3%)	0.332
	Mild	4 (13.3%)	6 (20.0%)	0.729
	Moderate	0	2 (06.6%)	0.472
	Severe	0	0	-
2-6 hrs.	None	23 (76.6%)	17 (56.6%)	0.171
	Mild	4 (13.3%)	10 (33.3%)	0.127
	Moderate	3 (10.0%)	2 (06.6%)	1.000
	Severe	0	1 (03.3%)	1.000
6-12 hrs.	None	25 (83.3%)	16 (53.3%)	0.026
	Mild	3 (10.0%)	11 (36.6%)	0.032
	Moderate	2 (06.6%)	2 (06.6%)	1.000
	Severe	0	1 (03.3%)	1.000
12-18 hrs.	None	27 (90.0%)	24 (80.0%)	0.469
	Mild	2 (06.6%)	4 (13.3%)	0.667
	Moderate	1 (03.3%)	2 (06.6%)	1.000
	Severe	0	0	-
18 -24 hrs.	None	28 (93.3%)	25 (83.3%)	0.421
	Mild	2 (06.6%)	4 (13.3%)	0.667
	Moderate	0	1 (03.3%)	1.000
	Severe	0	0	-

Table 6: Ponv Wise Distribution

		Group D (n=30)	Group O (n=30)	P value
0-2 hrs.	Nausea	07 (23.3%)	9 (30.0%)	0.770
	Vomiting	10 (33.3%)	8 (26.6%)	0.905
	PONV	17 (56.6%)	17 (56.6%)	0.794
2-6 hrs.	Nausea	6 (20.0%)	8 (26.6%)	0.760
	Vomiting	7 (23.3%)	6 (20.0%)	1.000
	PONV	13 (43.3%)	14 (46.6%)	1.000
6-12 hrs.	Nausea	2 (06.6%)	9 (30.0%)	0.045
	Vomiting	3 (10.0%)	1 (03.3%)	0.604
	PONV	5 (16.6%)	10 (33.3%)	0.233
12-18 hrs.	Nausea	1 (03.3%)	7 (23.3%)	0.057
	Vomiting	-	-	-
	PONV	1 (03.3%)	7 (23.3%)	0.057
18 -24 hrs.	Nausea	1 (03.3%)	7 (23.3%)	0.057
	Vomiting	-	-	-
	PONV	1 (03.3%)	7 (23.3%)	0.057

Table 7: Rescue Antiemetic Wise Distribution

	Group D (n=30)	Group O (n=30)	P value
0-2 hrs.	8 (26.6%)	4 (13.3%)	0.332
2-6 hrs.	6 (20.0%)	4 (13.3%)	0.729
6-12 hrs.	6 (20.0%)	3 (10.0%)	0.469
12-18 hrs.	4 (13.3%)	1 (03.3%)	0.351
18 -24 hrs.	3 (10.0%)	0	0.236
VAS Score	Group D (n=30)	Group O (n=30)	P value
0 hrs.	1.06 ± 0.94	1.96 ± 0.92	0.004

Table 8: Vas Score Wise Distribution

1 hrs.	0.53 ± 0.62	1.26 ± 0.69	<0.0001
2 hrs.	0.50 ± 0.51	0.76 ± 0.56	0.062
4 hrs.	0.33 ± 0.54	0.33 ± 0.47	1.000
6 hrs.	0.16 ± 0.37	0.23 ± 0.43	0.501
24 hrs.	0.16 ± 0.37	0.23 ± 0.43	0.501

Table 9: Adverse Effect Wise Distribution

Adverse Effect	Group D (n=30)	Group O (n=30)	P value
Gastritis	4 (13.3%)	2 (06.6%)	0.6670
Flushing	0	2 (06.6%)	0.4720
Headache	0	4 (13.3%)	0.1205
Dizziness	0	3 (10.0%)	0.2361

DISCUSSION

PONV is occurs in 30-40% of patients^[11]. Patients undergoing laparoscopic surgery and gynecological surgeries have a higher incidence of P.O.N.V.

DEMOGRAPHY:

In our study we have chosen females of age group 20-50yrs and belonging to A.S.A 1 and 2. Out two groups were equal on baseline characteristics. The mean age in our two drug groups were Grp D(30.16+4.44) GRP O(28.6+4.24). The p value was 0.1712 which is non-significant. F. Moslemi et al.^[5] conducted a similar study with two drug groups with mean age 30.51+6.9 in Group D and 31.11+6.2 in group O. Their two groups were similar as were in our study.

Graph 1-Age Wise Distribution In Two Drug Groups **Graph 2- Duration Of Surgery And Anaesthesia In Two Drug Groups****HAEMODYNAMIC STABILITY :**

Not much difference was observed vitals in the two groups.

YEAR	AUTHOR	GROUP D		GROUP O		ANALYSIS
		MEAN SBP (mm Hg)	MEAN DBP (mm Hg)	MEAN SBP (mm Hg)	MEAN DBP (mm Hg)	
2016	F. MOSLEMI et al [15]	118.43 ± 16.02	70.83+12.2	117.63+12.7	70.83+12.2	NO STATISTICALLY SIGNIFICANT RELATIONSHIP
2017	OUR STUDY	112.87=14.55	79.02+7.4	113.83+10.54	77.27+8.8	NO STATISTICALLY SIGNIFICANT RELATIONSHIP

B. Gautam et al. 2008 "Antiemetic prophylaxis against PONV with Ondansetron-Dexamethasone combination compared to Ondansetron or Dexamethasone alone for patients undergoing laparoscopic cholecystectomy" reported no statistically significant difference in haemodynamic parameters.

F. Moslemi et al. [5] in 2016 studied effect of combined Ondansetron and Dexamethasone versus Dexamethasone and Ondansetron alone for prevention of PONV after outpatient gynaecological diagnostic laparoscopy no difference in haemodynamic parameters was observed.

Though better haemodynamic stability is expected in patients receiving Dexamethasone due to its anti-inflammatory activity which decreases peri-operative pain, in our study no statistically significant difference in peri-operative haemodynamic parameters was observed.

Graph3- Perioperative Heart Rate Fluctuations In Two Drug Groups.

Graph 4- Perioperative Fluctuations In Diastolic Blood Pressure

INCIDENCE OF NAUSEA:

In 2001, R Thomas and N. Jones in their study found that incidence of early post operative nausea was 28.3% in patients receiving

YEAR	AUTHOR	Grp DEXAMETHASONE	Grp. ONDANSETRON	INFERENCE
2001	R. THOMAS, N. JONEZ et al. ^[15]	45.72%	33.3%	EARLY POSTOP- ONDANSETRON IS BETTER. LATE POSTOP- BOTH ARE COMPARABLE.
2015	X.X.WANG et al. ^[21]	33.33%	36.7%	EARLY POSTOP- ONDANSETRON IS BETTER. LATE POSTOP- DEXAMETHASONE IS BETTER
2016	F. MOSLEMI et al. ^[5]	40%	22.8%	ONDANSETRON WAS FOUND TO BE BETTER IN PREVENTION OF PONV
2017	OUR STUDY	30%	43.3%	EARLY POSTOP- ONDANSETRON IS BETTER. LATE POSTOP- DEXAMETHASONE IS BETTER

INCIDENCE OF RETCHING-

R. Thomas and N. Jones^[15] in their study in 2001 reported that Ondansetron was better in controlling retching episodes than Dexamethasone in the early post-operative period. The incidence of retching episodes in the two drug groups was found to be similar in late post-operative period.

In our study we observed that retching episodes were seen in 20% of patients receiving Dexamethasone and 30% of patients receiving Ondansetron in early post-operative period. Retching episodes were observed in none of the patients in group D and 3% of patients in group O (p-value-0.03) this result was statistically significant.

Dexamethasone and 22% in patients receiving Ondansetron and hence the results were statistically significant and ondansetron was considered better. In late postoperative period 15% of patients receiving Dexamethasone complained of nausea and 13.5% of patients receiving Ondansetron complained of nausea. The difference was significant for late post-operative nausea.

X.X.Wang et al. in 2015 concluded that in the early post-operative stage (0-6 hrs) Ondansetron was better at controlling PONV (p-value-0.03), while in late postoperative stage Dexamethasone was better in controlling PONV (p-value-0.03)

F.Moslemi et al. in 2016 concluded that Ondansetron was better for prevention of postoperative nausea. In their study 8 out of 35 patients receiving Ondansetron experienced nausea and 11 out of 35 patients receiving Dexamethasone experienced nausea.

In our study a significant declining trend was observed in incidence of nausea with the passage of postoperative time. It can hence be concluded that Dexamethasone is better than Ondansetron for prevention of postoperative nausea when given as a part of pre-medication during induction of anaesthesia.

Graph 5- Number Of Patients Experiencing Nausea At Different Post Operative Intervals.

Graph 6- Four Point Verbal Descriptive Scale Wise Distribution Of Patients Having Nausea At Different Postoperative Intervals.

Graph 7- Number Of Patients Having Retching Episodes At Different Post Operative Intervals.

In our study we observed that retching episodes were seen in 20% of patients receiving Dexamethasone and 30% of patients receiving Ondansetron in early post-operative period. Retching episodes

were observed in none of the patients in group D and 3% of patients in group O (p-value-0.03) this result was statistically significant.

YEAR	AUTHOR	GROUP D		GROUP O		INFERENCE
2001	R. THOMAS N. JONEZ et al. [15]	EARLY	LATE	EARLY	LATE	ONDANSETRON IS BETTER IN CONTROLLING POST OP RETCHING
		8%	0%	1.6%	0%	
2017	OUR STUDY	20%	0%	30%	3%	DEXAMETHASONE IS BETTER IN CONTROLLING POST OP RETCHING

INCIDENCE OF VOMITING:

Significant difference was observed in the number of patients experiencing nausea in two drug groups which was further pronounced with the passage of post-operative time in our study. It can be concluded that Dexamethasone is better than

Ondansetron for prevention of postoperative vomiting. A great significant difference was observed in late postoperative period beyond 12hrs implying that Dexamethasone is far better than Ondansetron for the prophylaxis of late PONV^[11].

Graph 8- Number Of Patients Having Vomiting At Different Post Operative Intervals.

Our results are in consensus with the observations of F.Moslemi^[5]. In our study we conclude that Dexamethasone is better than Ondansetron for prevention of post operative vomiting. Since the difference in the incidence of post operative vomiting in two groups is more pronounced 12hrs postoperatively, it can hence be concluded that Dexamethasone has longer duration of antiemetic action than ondansetron when administered as a part of premedication during induction of anaesthesia. Though Dexamethasone has proved to

reduce incidence of PONV in our study and a cost-effective alternative to Ondansetron as per study of Subramanyam et al^[18], its shortcomings in terms of long duration of onset of action and more use of rescue antiemetic medication when it is used as sole antiemetic can't be overlooked. Hence use of Dexamethasone should be encouraged in a combination therapy as an adjuvant anti-emetic rather than as a sole antiemetic premedication for prophylaxis of PONV.

YEAR	AUTHOR	Grp. DEXAMETHASONE	GRP. ONDANSETRON	INFERENCE
2001	N. JONEZ et al. [15]	EARLY 10% LATE 0%	EARLY 0% LATE 6.66%	ONDANSETRON BETTER IN EALY PONV. DEXAMETHASONE BETTER FOR LATE PONV.
2008	GAUTAM et al. [11]	EARLY 12.8% LATE 2.1%	EARLY 4.2% LATE 6.3%	DEXAMETHASONE IS LESS EFFEVTIVE FOR EARLY PONV
2015	F.MOSLEMI et al. [5]	EARLY 31.4% LATE 0%	EARLY 43.5% LATE 3.33%	ONDANSETRON BETTER IN EALY PONV. DEXAMETHASONE BETTER FOR LATE PONV.
2017	OUR STUDY	EARLY 33.3% LATE 0%	EARLY 43.5% LATE 20%	DEXAMETHASONE WAS FOUND TO BE BETTER IN PREVENTION OF POST OPERATIVE VOMITING

TOTAL PONV SCORE

R. Thomas and N. Jonez [15] in 2001 in their study concluded that ondansetron is better for prevention of early PONV and Dexamethasone for prevention of late PONV.

Gautam B. et al in 2008 in their metaanalysis concluded that Dexamethasone has little effect in prevention of early PONV.

F Moslemi et al.[5] in their study concluded that Ondansetron and Dexamethasone combination therapy has a better prophylactic role in PONV than either of two drugs used alone. Though the overall

incidence and severity of PONV was similar when two drugs was used alone and remarkably better when two drugs were used in combination.

In our study we have seen that PONV scores are lesser in patients receiving Dexamethasone as antiemetic prophylaxis than those receiving Ondansetron. The statistical significance of difference is more pronounced after 6 hours postoperatively thereby implying that Dexamethasone is better than Ondasetron in decreasing incidence and severity of PONV more so in the late postoperative period.

Graph 9- Comparison Of Ponv In Two Drug Groups

USE OF RESCUE ANTIEMETIC-

Study of Gautam et al in 2008[1], F. Moslemi in 2015[5] and the meta-analysis of R.C.T's by Sauvik Maitra in 2016[17] the failure of Dexamethasone in controlling PONV in early post operative period warranting the use of rescue antiemetic was observed to be quite high.

In our study, we observed that the requirement of rescue antiemetic and

hence the failure of prophylaxis is more in the Dexamethasone group as compared to the Ondansetron group even though Dexamethasone has proved to be better in reducing the incidence of nausea and vomiting. Hence, the results of our study were in consensus with reference studies as far as usage of rescue-antiemetic medication is concerned.

Graph 10- Number Of Patients Receiving Rescue Antiemetic At Different Postoperative Intervals.

In our study we have used a single drug for the prevention of post-operative nausea and vomiting unlike our reference studies where a combination of drugs has been used for prophylaxis of

P.O.N.V. this could have been a major reason for higher usage of rescue anti-emetic medication in our study.

YEAR	AUTHOR	Grp. DEXAMETHASONE	Grp. ONDANSETRON	INFERENCE
2008	GAUTAM et al. ^[1]	31.9%	29.2%	MORE TREATMENT FAILURE IN DEXAMETHASONE GROUP
2015	F.MOSLEMI et al. ^[5]	26.5%	17.5%	MORE TREATMENT FAILURE IN DEXAMETHASONE GROUP
2016	SOUVIK MAITRA et al. ^[17]	42%	42%	USAGE OF RESCUE ANTIEMETIC WERE EQUAL IN TWO GROUPS
2017	Our study	26%	13.3%	MORE RESCUE ANTI-EMETIC USED IN DEXAMETHASONE GROUP

INCIDENCE OF PAIN:

In 2001, R. Thomas and N. Jones et al.^[15] observed a significantly decrease in severity of postoperative pain when Dexamethasone was used as a part of antiemetic premedication as compared to Ondansetron. The incidence of pain was though found to be higher in patients receiving Dexamethasone.

pain scores as well as number of patients experiencing significant pain were less when Dexamethasone was used as antiemetic premedication instead of Ondansetron.

Gautam B.^[1] in 2008 in their study found that mean VAS score at 6hrs was 2.7 and 24 hrs was 1.9. Mean VAS score in group O was 3.2 at 6hrs and 2.2 at 24 hrs postoperatively.

F. Moslemi et al.^[5] in 2015 in their study observed decrease in mean

Graph 11- Mean Vas Score Observed

In our study pain was calculated using faces type of VAS scale. We observed that mean pain scores were significantly less in the Dexamethasone group (0.16) compared to the Ondansetron group (0.23) specifically in the immediate post operative period and the first two post operative hours probably due to the anti inflammatory action of Dexamethasone. The result was concluded to be statistically

significant with p-values significant throughout, specially in the immediate post operative period (0-2 hrs.)

We observed that the severity of pain and the number of patients experiencing clinically significant pain were less in Group D as compared to Group O.

YEAR	AUTHOR	GRP. DEXAMETHASONE	GRP. ONDANSETRON	INFERENCE
2001	N.JONEZ et al. ^[15]	40%	35%	INCIDENCE OF SIGNICANT PAIN WAS HIGHER IN DEXAMETHASONE GROUP
2015	F.MOSLEMI et al. ^[5]	45.7%	37.1%	INCIDENCE OF SIGNICANT PAIN WAS HIGHER IN DEXAMETHASONE GROUP
2017	OUR STUDY	16.6%	23.33%	MEAN PAIN SCORES WERE LESS IN DEXAMETHSONE GROUP

Not much coherence has been observed in the results in the incidence of pain in our study and the reference studies. Assesment of pain is a subjective matter and it largely depends on the pain scale used and psychosomatic factors. Also, the standardized anaesthetic techniques were different in various studies.

Fauzia Bano et al.^[6] in 2008 studied the effect of Ondansetron and Dexamethasone for prevention of PONV. They found that side effects like flushing and irritation were more with Ondansetron and absent with Dexamethasone.

R.thomas and N.Jones^[15] also concluded that side effects like headache flushing and irritation are present with use of Ondansetron and absent with use of Dexamethasone.

SIDE EFFECT PROFILE:

Moreover mere addition of Dexamethasone as an adjuvant antiemetic significantly reduced side effects of other drugs in combination antiemetic drug therapy^[5,6,15].

Graph 12- Adverse Effects Seen In Two Drug Groups.

In our study we observed that Dexamethasone has a better side effect profile as compared to Ondansetron when used for prevention of post operative nausea and vomiting, gastritis being the only side effect that's higher with the use of Dexamethasone.

CONCLUSIONS:

- 1) Inj. Dexamethasone is better than Inj. Ondansetron for prevention of postoperative nausea and vomiting in diagnostic laparoscopic gynaecological procedures more so in the prevention of late PONV.
- 2) Inj. Dexamethasone has a longer duration of antiemetic action as compared to Inj. Ondansetron.
- 3) Dexamethasone has a added advantage of decreasing post operative pain due to its anti-inflammatory action.
- 4) Even though Dexamethasone has better action compared to Ondansetron in prophylaxis of PONV, the use of rescue antiemetic was more in patients receiving Inj. Dexamethasone as antiemetic prophylaxis.
- 5) Dexamethasone has a more favourable side effect profile as compared to Ondansetron.
- 6) Dexamethasone by decreasing the hospital stay has proved to be cost-effective as compared to Ondansetron.

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