



ONDANSETRON VERSUS PALANOSETRON FOR PREVENTION OF POST-OPERATIVE NAUSEA AND VOMITTING IN ELECTIVE TOTAL ABDOMINAL HYSTERECTOMY UNDER SUB ARACHNOID BLOCK

Anaesthesiology

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KEYWORDS

INTRODUCTION

Total abdominal hysterectomy (TAH) is a commonly performed surgery worldwide, and neuraxial anesthesia (sub arachnoid block/spinal anesthesia) has shown to be an effective procedure for the smooth conduction of surgery.

However, Post operative nausea and vomiting (PONV) is a frequent complication after TAH due to various factors that can be patient related, surgical or due to anaesthetic agents. It is associated with clinical and economic consequences, including wound dehiscence, delayed nutrition, prolonged hospital stay, and reduced patient satisfaction.

Despite advances in prevention and treatment, the incidence of PONV remains high.

Some of the causative factors of PONV include :

- Tissue trauma and inflammation.
- Emetic neural circuitry producing fictive emesis from the caudal hindbrain.
- Stimulation of vagal afferent fibres innervating the stomach and intestine by paracrine factors.
- Activation of Bezold Jarish Reflex due to decreased venous return to the right heart, triggering receptors in the cardiac wall, leading to vasodilation, bradycardia and hypotension. Plenty of anti emetic drugs which are available these days including anticholinergic drugs, dopamine antagonist drugs, anti histaminic drugs, 5HT₃ receptor antagonists and steroids have been tried for prevention of post operative nausea and vomiting but no single drug is 100% effective & combination therapy has its own side effects.

Newer anti-emetics, which selectively antagonize 5HT₃ receptors, have proved effective and well tolerated in the treatment of post-operative vomiting and nausea.

Ondansetron was the first 5HT₃ receptor antagonist with relatively short half life of 3-5 hours and may be given several times a day depending on severity of symptoms.

Palonosetron is the first of second generation 5HT₃ receptor antagonist and claimed to be superior to first generation in respect of higher receptor affinity, it has prolonged mean elimination half life of about 40 hours. Methodology

After obtaining approval from the ethical committee, the present prospective, double blinded, randomized controlled study was carried out on patients of ASA grade I and II in the Department of Anaesthesiology, Amaltas Institute of Medical Sciences Dewas (M.P.) after obtaining well informed written consent from the patients.

Inclusion Criteria

1. Patient giving valid consent
2. Patients of ASA grade I & II
3. Patients of age group 30 to 60 years.

4. Patients of body weight between 40-80 kg selected after pre anaesthetic check-up.

Exclusion Criteria

1. Patient refusing to give consent
2. ASA grade III and onwards.
3. Patients under 30 year and above 60 year of age.
4. Known history of sensitivity to study drugs.
5. Prone to nausea vomiting and motion sickness.
6. Already received opioid analgesic or anti-emetics within 24 hours before anaesthesia.
7. Requiring continuous gastric suction for 24 hours in post-operative Period.
8. Contraindication to spinal anaesthesia, e.g. coagulation disorders, site infections etc. 60 patients of ASA grade I & II of scheduled for total abdominal hysterectomy under Spinal anaesthesia will be divided into 2 groups.

Grouping: Patients were randomly assigned to receive ondansetron 4 mg (group A) Palonosetron 0.075 mg (group B). Study medications were prepared, presented as identical 5 ml diluted with NS upto 5ml filled syringes and injected 10 minutes before spinal anaesthesia.

During the preoperative interview detailed information regarding the nausea intensity score and communication regarding need for rescue anti emetics in the postoperative period, was explained to the patients.

The patients were explained how to evaluate their own PONV intensity using a subjective scale on intensity score, scored from 0 to 3, where 0 = no nausea and 3 = severe nausea.

Patient were explained the difference between nausea, retching and vomiting.

Rescue Anti-emetics: rescue anti emetic IV Dexamethasone 8 mg was administered on complaint of nausea, retching or vomiting when intensity score is more than or equal to 2.

Patients were admitted a day prior to surgery. Pre-anaesthetic check up was carried out with detailed history. General, physical examination and systemic examination, Airway assessment examination was done. Routine laboratory examination were done in all subjects in study groups.

Patients were kept nil orally for eight hours. On the day of surgery nil oral status was confirmed. No anti emetics or opioids were given 24 hours prior to the procedure. Patients were shifted to the operating room. In the operating theatre, intravenous (I/V) line was secured and drip was started with ringers lactate (RL). Pre-loading with Ringers Lactate was done with 10-15 ml/kg and baseline parameters were recorded.

Patients received I/V Ondansetron (4mg) diluted with NS upto 5ml given slowly intravenously over 10 seconds or I/V Palonosetron (0.075mg) diluted with NS upto 5ml given slowly intravenously over

10 seconds, 10 minutes prior to Sub Arachnoid Block.

Under All aseptic precautions, Sub arachnoid block was conducted in sitting position using 25 Gauge spinal needle in L3-L4 intervertebral space 3.0-3.2 ml of 0.5 % hyperbaric bupivacaine was instilled after free flow of cerebrospinal fluid to achieve a sub arachnoid block of T7-T8 level and procedure was started. Supplemental oxygen was administered via facemask at 4L/min. Maintenance fluids (10ml/kg in first hour and 5 ml/kg in subsequent hours) were given at room temperature.

Intra-operatively, before shifting and post operatively every patient was watched and monitored for nausea, retching and vomiting for 30 min, 60 min, 2 hour, 6 hour, 12 hour, and 24 hour of administering the drugs.

In case of hypotension (SBP < 90 mmhg), IV mephentermine 6 mg was administered. Decrease in heart rate to less than 50 beats/min was treated with 0.6mg atropine intravenously.

Any adverse effects during conduction of anaesthesia, intra-operatively and post operatively was recorded and treated accordingly. IM Diclofenac 75 mg was administered before shifting the patient to ward for analgesia and was prescribed in twice a day dose.

Obtained data was tabulated and evaluated on a subjective scale of nausea intensity scoring and was subjected to statistical analysis by using appropriate statistic software.

Parameters Studied

1. Magnitude of Post operative nausea and vomiting assessed by numerical rating scale.
2. PONV within 24 hours time interval.
3. Effect of each drug on hemodynamics.

Statistical Analysis Plan

The statistical analysis of this study was carried out by student t test where p value < 0.05 is statistically significant and p value > 0.05 is statistically insignificant and p value < 0.01 is statistically highly significant.

RESULTS & DISCUSSION

Table 1 Comparison Of Intraoperative Heart Rate

Time	Group B (Palonosetron)			Group A (Ondansetron)		
	Mean ±SD	p value	t value	Mean ±SD	p value	t value
Preop	85±6	-	-	85±6	-	-
0 min	90±5	0.00	-11.63	90±5	0.00	-6.00
5 mins	89±4	0.00	-5.24	88±4	0.003	-3.30
10 mins	88±6	0.001	-3.60	88±6	0.031	-2.27
15 mins	88±8	0.002	-3.47	91±8	0.00	-4.73
20 mins	90±6	0.00	-4.25	94±6	0.00	-6.16
25 mins	90±6	0.00	-5.30	95±6	0.00	-6.08
30 mins	89±7	0.00	-4.75	92±7	0.002	-3.48
40 mins	88±6	0.005	-3.01	91±6	0.001	-3.76
50 mins	89±5	0.005	-3.04	88±5	0.014	-2.63
60 mins	88±6	0.031	-2.30	88±6	0.086	-1.84
70 mins	87±4.2	0.00	-4.47	92±11	0.286	-1.23
80 mins				82±3		
90 mins						

COMPARISON OF INTRAOPERATIVE HEART RATE

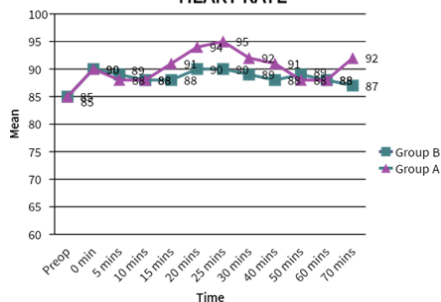


Table 1: showing comparison of the mean heart rates with the preoperative basal heart rates at different time intervals. In group B, mean HR values significantly differ from preoperative baseline at all

the time intervals (p<0.05). In group A, mean HR values significantly differ from preoperative baseline at most of the time intervals except at 60, 70 and 80 mins intervals (p>0.05). These findings are similar to studied conducted by Naseem A et al, Syed M et al, Mostafa A et al etc.

Table 2 Comparison Of Systolic Blood Pressure

Time	Group B			Group A		
	Mean ± SD	p value	t value	Mean ± SD	p value	t value
Preop	126±6	-	-	126±6	-	-
0 min	123±6	0.00	6.89	121±6	0.00	4.79
5 mins	119±5	0.00	12.81	115±5	0.00	11.06
10 mins	118±5	0.00	14.14	112±5	0.00	12.22
15 mins	116±5	0.00	13.78	110±4	0.00	12.72
20 mins	115±5	0.00	14.11	107±5	0.00	13.49
25 mins	115±5	0.00	14.62	105±5	0.00	16.00
30 mins	115±4	0.00	14.06	104±4	0.00	14.92
40 mins	115±4	0.00	13.11	106±4	0.00	15.82
50 mins	115±4	0.00	13.51	108±4	0.00	13.37
60 mins	114±3	0.00	10.73	108±3	0.00	8.97
70 mins	113±3	0.00	7.72	107±3	0.001	9.59
80 mins				109±4		
90 mins						

COMPARISON OF SYSTOLIC BLOOD PRESSURE

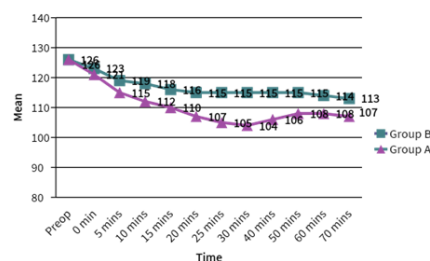


Table 2 : showing comparison of the SBP with the preoperative basal SBP at different time intervals. In both groups, there is significant fall in SBP from the pre-op basal value (p < 0.05) at all time intervals. These findings are similar to studied conducted by Meenoti et al, Malivan et al, Naseem A et al, Syed M et al, Mostafa A et al etc.

Table 3 Comparison Of Diastolic Blood Pressure

Time	Group B			Group A		
	Mean±SD	p value	t value	Mean±SD	p value	t value
Preop	80±6	-	-	79±6	-	-
0 min	76±5	0.00	10.80	76±5	0.00	4.79
5 mins	73±6	0.00	13.55	72±6	0.00	8.95
10 mins	72±5	0.00	14.22	69±5	0.00	10.04
15 mins	70±5	0.00	15.74	67±5	0.00	11.29
20 mins	69±6	0.00	14.22	65±6	0.00	11.50
25 mins	68±7	0.00	13.99	62±7	0.00	12.72
30 mins	68±5	0.00	13.35	62±5	0.00	12.93
40 mins	67±7	0.00	14.29	62±7	0.00	10.93
50 mins	67±7	0.00	13.92	64±7	0.00	10.40
60 mins	67±7	0.00	13.44	65±7	0.00	7.14
70 mins	70±9	0.00	11.73	61±9	0.024	3.55
80 mins				59±4		
90 mins						

Intragroup Comparison of Intra-operative Diastolic blood pressure among the three groups

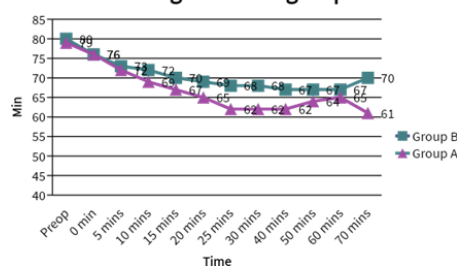


Table 3 : showing comparison of the DBP with the preoperative basal

DBP at different time intervals. In both the groups, there is significant fall in DBP from the pre-op basal value ($p < 0.05$) at all time intervals. These findings are similar to studied conducted by Meenoti et al, Malivan et al, Naseem A et al, Syed M et al, Mostafa A et al etc.

Table 4 : Comparison Of Nausea Score

Score	Group B	Group A	p value
0	30	27	0.07
	100%	90%	
1	0	3	
	0.0%	10%	
2	0	0	0.0%
	0.0%	0.0%	

Intergroup comparison of intraoperative nausea score among the three groups

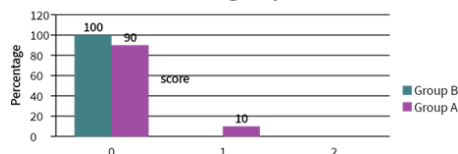


Table 4 : showing nausea score among the two groups, there is statistically insignificant association between nausea scores. In group B none of the patient experienced nausea while in group A 3 patients experienced nausea showing that palonosetron is more effective in prevention of nausea but not significantly. These findings are similar to studied conducted by Usha K et al, Rohit Balyan et al, Guilherme Oliveira Campos et al, Meenoti et al, Malivan et al, Naseem A et al, Syed M et al, Mostafa A et al etc.

Table 5 : Comparison Of Vomitting

	Group B	Group A	p value
Absent	30	26	0.003
	100%	86%	
Present	0	4	
	0%	13%	

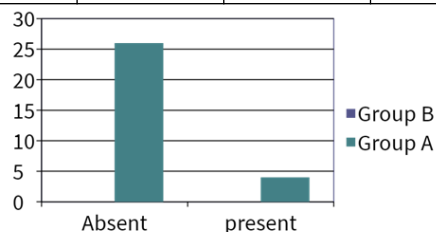


Table 5 : showing incidence of vomiting among the two groups which is statistically significant with palonosetron and ondansetron having significant difference in controlling vomiting. There is no episodes of vomiting in group B while 4 patients experienced vomiting in group A which is statistically significant. These findings are similar to studied conducted by Usha K et al, Rohit Balyan et al, Guilherme Oliveira Campos et al, Meenoti et al, Malivan et al, etc.

CONCLUSION

On The Basis Of The Present Study Following Conclusions Are Drawn:-

- Both palonosetron and ondansetron have similar effect on hemodynamics, when given 10 minutes before spinal anesthesia in patients undergoing total abdominal hysterectomy.
- Both palonosetron and ondansetron are effective in reducing the incidence of nausea and vomiting with palonosetron being more effective.
- No side effects were noted with either of the drug during the study.

Summary

- The present study was undertaken to evaluate the efficacy of intravenous ondansetron and palonosetron in prevention of post operative nausea and vomiting in patients undergoing total abdominal hysterectomy under spinal anesthesia.
- 60 patients of ASA grade I and II, aged between 30-60 years, scheduled for total abdominal hysterectomy under spinal anesthesia, were randomly divided into 2 groups. In Group A, Inj. ondansetron 4 mg (diluted upto 5 ml with NS) I/V ; In Group B, Inj.

Palonosetron 0.075 mg (diluted upto 5 ml with NS) I/V were injected, 10 minutes prior to spinal anesthesia.

- The difference in heart rates among 2 groups were insignificant.
- Similarly, total number of patients free from nausea were higher in palonosetron group compared to ondansetron group.
- None of the patient in either palonosetron group had vomiting, while 4 in ondansetron group had vomiting.

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