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Effectiveness of Ramosetron and Ondansetron for prevention of nausea and vomiting in elective lower segment

caesarean section patients under Spinal Anaesthesia.

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Conflicts of Interest: Nil

Abstract

Aim & Objective : The aim of this study was to evaluate and compare the efficacy and safety of inj. ondansetron 4 mg and inj. ramosetron 0.3 mg administered intravenously as an antiemetic in patients undergoing elective lower segment cesarean section under spinal anesthesia. The objective of this study was an assessment of the incidence of nausea and vomiting between ondansetron and ramosetron intraoperatively as well as postoperatively for 24 hours with respect to need for rescue antiemetic, patient satisfaction, adverse drug reaction.

Methods: In the randomized study, 100 parturients received inj. ondansetron 4 mg or inj. ramosetron 0.3 mg (n = 50 each) intravenously, immediately after clamping of the umbilical cord. Nausea, vomiting and adverse events were then observed for 24 h after administration of spinal anesthesia.

Results: Patients receiving ramosetron were more satisfied (34%) than patients receiving ondansetron (16%). Ramosetron is a better alternative to ondansetron for prophylaxis of emetic symptoms especially during postoperative period after cesarean section till 24 hrs.

Conclusion: Ramosetron and ondansetron were equipotent as per incidences of emetic symptoms during intraoperative period, early postoperative period (0-6 hours) and late post postoperative period (12-24 hours) were considered. Hence we suggest to use and incorporate ramosetron as a routine antiemetic for all women undergoing cesarean section as a departmental protocol.

Keywords: Nausea, retching and vomiting, Spinal anesthesia, Ondansetron, Ramosetron, Cesarean section.

Introduction:

Spinal anesthesia for cesarean section is a choice of anesthesia as it is economical, comparatively easy to perform and it avoids side effects of general anesthesia such as aspiration of gastric contents, management of airway, risk of failed endotracheal intubation and maternal as well as fetal depression.¹ There is evidence that general anesthesia is associated with an increased need for neonatal resuscitation. Although the use of general anaesthesia for caesarean section has declined while the use of regional technique has increased, for both planned and unplanned caesarean section.²

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Nausea and vomiting during regional anesthesia for caesarean section are common in patients receiving no pharmacological antiemetics.^{3,4} Many factors anaesthetic and non-anaesthetic, contribute to the incidence of nausea and vomiting during cesarean section. The anaesthetic risks are hypotension, use of intrathecal or intravenous opioids and an increase in vagal activity. The non-anaesthetic factor includes manipulation and exteriorization of uterus, vigorous movement of patients and use of uterotonic agents such as oxytocin. Emetic symptoms are distressing and fatal for the parturient and also may interfere with the surgical procedure.

Furthermore, post-delivery PONV can complicate postoperative care in several ways like aspiration of vomitus, electrolyte disturbance and dehydration, delay of nutrition, fluid intake, oral drug therapy and wound dehiscence due to frequent expulsive efforts, associated with delayed recovery and prolonged hospital stay.⁵

As there is no "magic bullet" that will prevent PONV in all patients, attempt should be made to identify and minimize contributing factors and some antiemetic techniques should be employed⁶. Multiple investigators have shown a useful effects of non-pharmacological methods in management of PONV. Non pharmacological method includes acupuncture wristbands, acustimulation (relief bands), acupuncture injections, electroacupuncture, Korean hand acupuncture and preoperative preloading.⁷

Commonly used older and traditional antiemetics for PONV include phenothiazines (promethazine), antihistaminics (diphenhydramine), butyrophenones (droperidol), benzamides (metoclopramide), anticholinergics (glycopyrolate, scopolamine) and dopamine receptor antagonists. These antiemetics have adverse effects such as dry mouth, dysphoria, sedation, hypotension, tachycardia, extra pyramidal reactions, dystonic effects and restlessness.⁸ Since the introduction (in the early 1990's) of 5 HT₃ receptor antagonists (Ondansetron, Granisetron, Ramosetron, Dolasetron, Palonosetron and Tropisetron) they have become the most widely used drugs for chemotherapy induced emesis. ³ They are considered one of the first line therapy for prevention of nausea and vomiting because of their efficacy and fewer side effects compared with other antiemetics.⁹

Ondansetron has been demonstrated to be an effective and well tolerated drug for the prevention and treatment of postoperative nausea and vomiting.¹⁰ Its use in surgical procedure accompanied by frequent postoperative nausea and vomiting seems reasonable.¹¹ Ramosetron also a selective 5-HT₃ receptor antagonist exibits significantly greater binding affinity for 5-HT₃ receptors with a slower dissociation rate from receptor binding, resulting in more potent and longer receptor antagonizing effects compared with older 5-HT₃ receptor antagonists.¹² 5-HT₃ receptor antagonists are associated with fewer side effects like headache, dizziness and myalgia.⁸ Use of these newer drugs have shown to improve patient satisfaction, decrease recovery time and hence discharge time.¹⁰

We undertook this study to find out a better drug for prevention of intraoperative as well as postoperative nausea and vomiting in terms of efficacy and safety of 4 mg ondansetron with 0.3 mg ramosetron given intravenously in patients undergoing elective LSCS under spinal anesthesia.

Parturiants and Methods:

The present study "Effectiveness of Ramosetron and Ondansetron for prevention of nausea and vomiting in elective lower segment caesarean section patients under Spinal Anaesthesia" was carried out in the Department of Anaesthesiology, AVBRH affliated to Jawaharlal Nehru Medical College, Sawangi (Meghe) from August 2015 – May 2017. After

approval from Hospital ethics committee, 100 patients posted for elective lower segment cesarean section under spinal anesthesia giving written informed consent and satisfying all inclusion criteria were included in the study. Parturiants were randomly allocated in two groups of 50 each according to the antiemetic drug received after delivery of baby and clamping of umbilical cord.

Group O (ondansetron) :- Patients receiving inj. ondansetron 2 ml (4mg) i.v.

Group R (ramosetron) :- Patients receiving inj. ramosetron 2 ml (0.3 mg) i.v.

INCLUSION CRITERIA

- ASA grade I and II patients.
- Women belonging to age 20 30 years.
- Patients giving written informed consent.
- Patients scheduled to undergo elective caesarean delivery under spinal anaesthesia.

EXCLUSION CRITERIA

- 1. ASA grade III or greater.
- 2. Age < 20 years and > 30 years.
- 3. History of hyperemesis gravidarum.
- 4. Body weight > 80 kilograms and height < 150 centimetres.
- 5. Any contraindication to spinal anaesthesia like hypotension, coagulation defects, spine abnormalities, local site infection.
- 6. Patients who had gastrointestinal disease, fetal prematurity (36 weeks) or those who had received antiemetic 24 hours prior to surgery.
- 7. Poorly controlled hypertension, angina and cardiopulmonary disease.
- 8. Allergic to the drugs.

Pre-anesthetic evaluation was done a day prior to surgery and all the parturiants were explained regarding the procedure of the study. A detailed general and systemic examination was done using history and routine investigation like Hb, CBC, ESR, LFT, KFT.

Antacid prophylaxis was given by Inj. Ranitidine 50 mg i.v 30 minutes before surgery.¹⁶ After shifting patient inside operation theatre, basic monitors were attached and vital parameters such as pulse rate (PR), blood pressure (BP), electrocardiogram (ECG), pulse oximetry (SpO₂), respiratory rate (RR) were recorded. Peripheral 18G i.v cannula was secured. Pre-hydration was done with i.v Ringer lactate 15 ml/kg body weight. Under all aseptic precautions lumbar puncture was performed with 25 gauge Quincke's needle in the L_3 - L_4 or L_4 - L_5 space in left lateral decubitus position using midline technique. After confirming free flow of CSF, 0.5 % hyperbaric bupivacaine 2 ml (10 mg) was injected and patients were immediately turned to supine position. A wedge of 15 degree was placed under the right hip. Supplemental oxygen (4 l/min) was administered via nasal prongs to all the parturient. After due confirmation of sub-arachnoid block by loss of sensation to pinprick at T₄-T₅ level, surgery was started. After delivery of baby and clamping of umbilical cord study drug either inj. ondansetron 4 mg i.v or inj. ramosetron 0.3 mg i.v was administered according to the group assigned and i.v oxytocin 10 units was administered in running infusion. Vital parameters at the interval of 5 mins from from

administration of SAB till delivery of baby and then at the interval of 10 mins till the end of surgery was recorded. Bradycardia was defined as pulse rate < 60/min and was treated with inj. atropine 0.6 mg, maternal hypotension after SAB was defined as fall in systolic blood pressure of >30% of baseline blood pressure or equal to 80 mm Hg and was treated by increasing the rate of i.v fluid administration and by injecting mephentermine 3 mg i.v in incremental doses. APGAR score was recorded at 1 minute and 5 minute, though we have given study drug after clamping of umbilical cord. Whether or not, uterus exteriorization was also noted. If patient complaint of episodes of nausea or vomiting intraoperatively before administration of the study drug, patient was then treated accordingly and excluded from the study. Inj. diclofenac 75 mg i.m. was given 2 hours after completion of surgery and further adviced as twice a day dose or on request from patient for postoperative analgesia. No opioids were given for analgesia during intraoperative or postoperative period at any point of time. Study variable was assessed according to Belville's score for nausea and vomiting, Belville's score 0 - No nausea, 1 - Nausea, 2 - Retching, 3 - Vomiting.¹⁵ Nausea was defined as subjectively unpleasant sensation associated with awareness of the urge to vomit. Retching was defined as labored spasmodic rhythmic contraction of respiratory muscles without the expulsion of gastric contents. Vomiting was defined as the forceful expulsion of gastric contents from mouth.^{13, 14} After administration of study drug intraoperative nausea or emetic episodes were recorded by direct questioning by an anesthesiologist or complaint by the patient during first 24 hours after anaesthesia: 0-3 hours and 3-6 hours in early postoperative period and then 6-12 hours and 12-24 hours in late postoperative period. Rescue anti-emetic i.v metoclopramide 10 mg was given when patient had > 2 emetic symptoms (i.e. nausea or retching or vomiting) during intraoperative period and postoperative period or at patients request. Complete response to study drug was defined as no emetic symptoms and no need for another rescue antiemetic. The degree of overall satisfaction with management of nausea and vomiting was assessed and asked to the patient at the end of observation period (24 hours) by Patient Satisfaction Score (Grade 0 = Poor, Grade 1 = Adequate, Grade 2 = Good, Grade $3 = \text{Excellent})^{3}$. In postoperative period vital parameters and adverse effects of study drugs like headache, constipation, dizziness and any other symptoms (flushing, hypotension, ECG changes, extra-pyramidal and allergic reactions) were recorded till 24 hours which was end point of the study.

Statistical analysis:

Statistical analysis was done by using descriptive and inferential statistics using Chi-square test and Student's unpaired t test, the software used in the analysis were SPSS 20.0 version and Graph pad Prism 6.0 version, p<0.05 is considered as level of significance.

Observations and Results:

Table 1: Distribution of Patients According to Age

Age (years)	Group O	Group R	value*	p-value
20-25	34(68%)	35(70%)		0.82 NS
26-30	16(32%)	15(30%)	0.04	
Total	50(100%)	50(100%)	0.01	0.02,115
Mean ± SD	24.90 ± 3.03	22.78 ± 2.60		

Table shows distribution of patients according to age in both groups. 69% of patients in our study were in range of 20-25 years, remaining 31% patients were in 26-30 years age group. Mean age of patients in group O was 24.90 ± 3.03 and in group R was 22.78 ± 2.60 years. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to age.





Table 2: Distribution of Patients According to Weight (Kg)

Weight (kilograms)	Group O	Group R	×2-value	p-value
50-55	9(18%)	6(12%)		
56-60	27(54%)	24(48%)		
61-65	11(22%)	13(26%)	2.54	0 46 NS
66-70	3(6%)	7(14%)	2.34	0.40,115
Total	50(100%)	50(100%)		
Mean ± SD	58.78±3.75	60.08±4.57		

Table shows distribution of patients according to weight in both groups. 15% of patients in our study were in range of 50-55 kg, 51% were in the range of 56-60 kg, 24% were in the range of 61-65 kg and remaining 10% patients were in 66-70 kg of weight. Mean weight of patients in group O was 58.78 ± 3.75 kg and in group R was 60.08 ± 4.57 kg. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to weight.

Graph 2: Distribution of Patients According to Weight (Kg)



Table 3: Distribution of Patients According to Height (cms)

Height (centimeters)	Group O	Group R	value ×2-value	p-value
150-155	23(46%)	24(48%)		
156-160	27(54%)	26(52%)	0.04	0.84 NS
Total	50(100%)	50(100%)	0.04	0.04,115
Mean ± SD	153.28±3.20	156.54±2.34		

Table shows distribution of patients according to height in both groups. 47% of patients in our study were in range of 150-155 cms and remaining 53% patients were in range of 156-160 cms of height group. Mean height of patients in group O was 153.28 ± 3.20 cms and in group R it was 156.54 ± 2.34 cms. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to height.

Graph 3: Distribution of Patients According to Height (cms)



ASA Grading	Group O	Group R	value ۲	p-value
Grade I	27(54%)	27(54%)		
Grade II	23(46%)	23(46%)	0.00	1.00, NS
Total	50(100%)	50(100%)		

 Table 4: Distribution of Patients According to ASA Grading

Table shows distribution of patients according to ASA grading in both groups. 54% of patients in our study were in grade I and remaining 46% patients were in grade II of ASA grading. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to ASA grading.

Graph 4: Distribution of Patients According to ASA Grading



Table 5: Distribution of Patients According to Gravida

Gravida	Group O	Group R	value*	p-value
Primigravida	23(46%)	22(44%)		
Multigravida	27(54%)	28(56%)	0.04	0.84, NS
Total	50(100%)	50(100%)		

Table shows distribution of patients according to gravida in both groups. 45% of patients in our study were primigravida and remaining 55% patients were multigravida. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to gravida.

Graph 5: Distribution of Patients According to Gravida



Table 6: Distribution of Patients According to Duration of Surgery

Durationofsurgery(minutes)	Group O	Group R	x2-value	p-value
30-35	7(14%)	3(6%)		
36-40	20(40%)	22(44%)		
41-45	22(44%)	24(48%)	0.36	0.54 NS
46-50	1(2%)	1(2%)	0.50	0.04,110
Total	50(100%)	50(100%)		
Mean ± SD	42.08±3.83	40.40±3.30		

Table shows distribution of patients according to duration of surgery in both groups. 10% of patients in our study were in range of 30-35 mins, 42% patients were in range of 36-40 mins, 46% patients were in range of 41-45 mins and remaining 2% patients were in range of 46-50 mins of duration of surgery. Mean duration of surgery of patients in group O was 42.08 ± 3.83 min and in group R it was 40.40 ± 3.30 min. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to duration of surgery.



Graph 6: Distribution of Patients According to Duration of Surgery

 Table 7: Distribution of Patients According to Uterus Exteriorization

Durationofuterusexteriorized (mins)	Group O	Group R	x2-value	p-value
No of patients	9(18%)	10(20%)	0.13	0.71,NS
Duration (mins)	11.55±1.33	12.40±1.54	0.15	

Table provides information regarding distribution of patients according to uterus exteriorized. 18% patients in group O and 20% patients in group R required uterus exteriorization. Mean duration of uterus exteriorized in group O was 11.55 ± 1.33 min and in group R was 12.40 ± 1.54 min. The difference was not statistically significant (p>0.05). The patients were comparable with respect to duration of uterus exteriorized.

Graph 7: Distribution of Patients According to Uterus Exteriorization



	Group O		Group R		t voluo	n voluo
	Mean	SD	Mean	SD	t-value	p-value
Pre-op	66.2	1.86	63.01	1.92	0.316	0.752,NS,p>0.05
After induction	68.09	2.75	65.02	2.72	0.219	0.827,NS,p>0.05
After study drug administration	81.84	6.74	80.46	6.78	0.281	0.779,NS,p>0.05
10 mins	79.2	5.82	77.46	5.28	0.665	0.507,NS,p>0.05
20 mins	80.84	5.92	81.4	5.77	0.478	0.633,NS,p>0.05
30 mins	80.02	5.27	78.84	5.92	0.731	0.467,NS,p>0.05
0-3 hours	70.64	4.19	68.7	4.97	0.065	0.948,NS,p>0.05
3-6 hours	70.7	4.97	69.5	4.19	0.065	0.948,NS,p>0.05
6 – 12 hours	61.57	2.67	60.23	2.14	0.206	0.837,NS,p>0.05
12 – 24 hours	63.23	2.07	62.83	3.20	0.111	0.912,NS,p>0.05

 Table 8 : Mean Pulse Rate (PR) at Different Time Points in Two Groups

The basal mean pulse rate in group O was 66.20 ± 1.86 and in group R was 63.01 ± 1.92 which was comparable and the difference was not statistically significant using student's unpaired t-test (p>0.05). The pulse rate was constant throughout the study period in all patients. There was no bradycardia episodes in our study.

Graph 8: Mean Pulse Rate (PR) at Different Time Points in Two Groups



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	Group O Group R			t-vəlue	n-value	
	Mean	SD	Mean	SD	t-value	p-value
Pre-op	123.26	5.09	120.18	5.00	0.079	0.937,NS
After induction	107.21	7.62	101.02	7.43	0.173	0.863,NS
After study drug administration	103.36	10.60	98.36	10.36	0.029	0.977,NS
At 10 mins	101.88	5.46	100.76	7.91	0.824	0.412,NS
At 20 mins	99.71	13.71	98.73	5.87	0.720	0.473,NS
At 30 mins	100.38	6.56	97.92	5.11	0.476	0.635,NS
At 0 – 3 hours	112.35	2.44	108.54	4.38	1.662	0.100,NS
At 3 – 6 hours	118.53	4.38	116.94	2.44	1.662	0.100,NS
At 6 – 12 hours	121.71	4.89	118.94	3.28	0.887	0.377,NS
At 12 – 24 hours	124.36	3.27	121.23	4.43	1.694	0.093,NS

Table 9 : Mean Systolic Blood Pressure (SBP) at Different Time Points in Two Groups

The basal mean systolic blood pressure in group O was 123.26 ± 5.09 and in group R was 120.18 ± 5.0 which was comparable and the difference was not statistically significant using student's unpaired t-test (p>0.05). After induction there was gradual fall in systolic blood pressure in both the groups till 10 mins which was expected after spinal anesthesia. No statistically significant difference was found among the groups. No patient required any aggressive treatment than inj. mephentermine (3 mg bolus in incremental doses) as our aim was to avoid excessive hypotension.

Graph 9: Mean Systolic Blood Pressure (SBP) at Different Time Points in Two Groups



Table 10 : Mean Respiratory Rate (RR) at Different Time Points in Two Groups.

Groups

	Group O		Group R		t-volue	n-value
	Mean	SD	Mean	SD	- t-value	p-value
Pre-op	14.37	1.50	13.32	1.53	0.066	0.948,NS
After induction	16.84	2.18	15.62	2.08	0.514	0.608,NS
After study drug administration	16.36	1.40	16.23	1.36	0.288	0.774,NS
At 10 mins	16.12	1.98	15.76	1.97	0.757	0.451,NS
At 20 mins	16.23	1.96	15.71	1.98	0.101	0.920,NS
At 30 mins	15.16	1.97	14.91	1.96	0.661	0.510,NS
At 0 – 3 hours	15.32	1.47	14.78	1.47	0.000	1.000,NS
At 3 – 6 hours	15.9	1.31	15.8	1.53	0.350	0.727,NS
At 6 – 12 hours	15.82	1.50	15.82	1.39	0.000	1.000,NS
At 12 – 24 hours	14.46	1.39	13.78	1.50	0.000	1.000,NS

The basal mean respiratory rate in group O was 14.37 ± 1.50 and in group R it was 13.32 ± 1.53 which was comparable and the difference was not statistically significant using student's unpaired t-test (p>0.05). The respiratory rate was constant throughout the study period in all patients. No patient went in respiratory depression in our study.





	Group O	Group R	value ² -value	p-value
No of patients	10(20%)	7(14%)	1 27	0.25.NS
Dose (mg)	10.10±2.46	8.92±3.46	1.27	0.20,110

Table shows distribution of patients according to mephentermine required. 14% patients in group R and 20% patients in group O required inj. mephentermine. Mean dose of inj. mephentermine required in group O was 10.10 ± 2.46 mg and in group R it was 8.92 ± 3.46 mg. The difference was not statistically significant (p>0.05). The groups were comparable with respect to number of patients and total dose of mephentermine required during cesarean section.

Graph 11: Distribution of Patients According to Mephentermine Administration



Table 12 : APGAR Score

Apgar score	Group O	Group R	t-value	p-value
1 min	8.50±0.50	8.52±0.50	0.19	0.84,NS
5 min	9.50±0.50	9.52±0.50	0.19	0.84,NS

Table shows Apgar score. At 1 min the mean was 8.50 ± 0.50 in group O. and 8.52 ± 0.50 in group R. At the end of 5 min the mean was 9.50 ± 0.50 in group O and 9.52 ± 0.50 in group R. This shows neonatal Apgar scores did not differ amongst the study groups.



Graph 12: Distribution of Patients According to APGAR Score in Two Groups

Table 13: Distribution of Patients According to Belville Score in Intraoperative Period

Time (after	Gre	oup ()	Rescue	Group R		2	Rescue		
administration of study drug)	1	2	3	antiemetic	1	2	3	antiemetic	t-value	p-value
10 mins	1	0	0	0	1	0	0	0		
20 mins	0	2	0	0	0	1	0	0	0.97	0.33 NS
30 mins	0	1	0	0	0	0	0	0	0.97	0.00,110
Mean ± SD	0.14	0.14 ± 0.49			0.06 ± 0.31					

Table shows distribution of patients according to Belville score in intra-operative period. After administration of study drug, at 10 mins 1 patient each in both groups had Belville score of 1. After 20 mins 1 patient in group R had Belville score of 2 while in group O, 2 patients had Belville score of 2 at 20 mins and at 30 mins only 1 patient in group O had Belville score of 2. The average score was 0.14 ± 0.49 in group O and 0.06 ± 0.31 in group R. The emetic episodes according to Belville score was not statistically significant when compared in both groups. (p>0.05) Similarly, no patients in either group required any rescue antiemetic drug during intraoperative period. Hence we observed that both the drugs were comparable and equipotent in controlling emetic symptoms in intraoperative period.



Graph 13: Distribution of Patients According to Belville Score in Intraoperative Period.

Table 14: Distribution of Patients According to Belville Score in Early Postoperative Period

Duration	Gro	oup O)	Rescue	Group R			Rescue	t-value	n-value
Duration	1	2	3	antiemetic	1	2	3	antiemetic	t-value	p-value
0-3 hours	2	3	3	3	1	2	0	0		
3 – 6 hours	1	2	3	2	1	1	0	1	2.73	0.007,S
Mean ± SD	0.62 ± 1.08			0.16 ± 0.50						

Table shows distribution of patients according to Belville score in early postoperative period. After administration of study drug, at 0-3 hours 1 patient in group R and 2 patients in group O had Belville score of 1 while 2 patients in group R and 3 patients in group O had Belville score of 2 and 3 patients in group O had Belville score of 3 as compared to none in group R. At 3-6 hours 1 patient in both the groups had Belville score of 1 while 1 patient in group R had Belville score of 2 as compared to 2 patients in group O. 3 patients in group O had Belville score of 3 as compared to none in group R. At 3-6 hours 1 patient in group O. 3 patients in group O had Belville score of 3 as compared to none in group R. The average score was 0.62 ± 1.08 in group O and 0.16 ± 0.50 in group R. Ramosetron was found to be more potent in controlling emetic symptoms then ondansetron during early postoperative period. (p<0.05) Also, when rescue antiemetic requirement was compared in both the groups, it was found, in group O more number of patients required rescue antiemetic compared to group R (χ 2-value for rescue antiemetic=5.67,p=0.017,S).



Graph14 (A): Distribution of Patients According to Belville Score in Early Postoperative Period.

Graph 14 (B) : Distribution of Patients According to Rescue Antiemetics Required in Early Postoperative Period



Fable 15: Distribution of Patients Accordin	ng to Belvi	lle Score in	Late Posto	perative Period
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Duration	Gr	oup	0	Rescue	Group R			Rescue	t-value	n-value
Duration	1	2	3	antiemetic	1	2	3	antiemetic	t-value	p-value
6 – 12 hours	3	3	4	6	2	1	1	1	2.71	0.007 S
12 – 24 hours	4	3	3	4	1	2	2	1	2., 1	0.007, 5

Mean \pm SD	0.90 ± 1.12	0.36 ± 0.85	

Table shows distribution of patients according to Belville score in late postoperative period. After administration of study drug, at 6-12 hours 2 patient in group R and 3 patients in group O had Belville score of 1 while 1 patient in group R and 3 patients in group O had Belville score of 2 and 1 patient in group R and 4 patients in group O had Belville score of 3. At 12-24 hours 1 patient in group R and 4 patients in group O had Belville score of 1 while 2 patients in group R had Belville score of 2 as compared to 3 patients in group O. 2 patients in group R had Belville score of 3 as compared to 3 patients in group O and 0.36 ± 0.85 in group R. Ramosetron was found to be more potent in controlling emetic symptoms then ondansetron during late postoperative period. (p<0.05) Also, when rescue antiemetic requirement was compared in both the groups, it was found, in group O more number of patients required rescue antiemetic compared to group R (χ 2-value for rescue antiemetic=6.06,p=0.013,S)

Graph15 (A): Distribution of Patients According to Belville Score in Late Postoperative Period





Graph 15 (B) : Distribution of Patients According to Rescue Antiemetics Required in Late Postoperative Period

Table 16: Distribution of Patients According to Patient Satisfaction Score in Both Groups

Saama	Group O	Group O Group R		n voluo
Score	N (%) N (%)		χ <i>z</i> -value	p-value
Excellent (3)	8 (16)	17 (34)		
Good (2)	23 (46)	26 (52)	8 97	0.029.5
Adequate (1)	13 (26)	5 (10)		0.029,5
Poor (0)	6 (12)	2 (4)		

Table shows distribution of patients according to satisfaction score which was taken at the end of study period. 16% patients in group O and 34% patients in group R had satisfaction score of 3. In group O, 46% patients and in group R, 52% patients had satisfaction score of 2. In group O, 26% patients and in group R, 10% patients had satisfaction score of 1. Only 4% of the patients in group R had poor satisfaction score as compared to 12% patients in group O. The difference was statistically significant (p<0.05). When the graphs were compared regarding satisfaction score, it was found that overall satisfaction was more in group R.



Graph16: Distribution of Patients According to Patient Satisfaction Score in Both Groups

Table 17: Distribution of Patients According to Adverse Effects in Both Groups

Adverse effects	Group O	Group R	χ2-value	p-value
Headache	5(10%)	2(4%)		
Constipation	1(2%)	1(2%)	0.64	0.72 NS
Dizziness	2(4%)	1(2%)	0.04	0.72,115
Others	0(0%)	0(0%)		

Table shows distribution of patients according to adverse effects. 10% patients in group O and 4% patients in group R and had headache. 2% patients in both groups R and group O had constipation. 4% patients in group O and 2% patients in group R had dizziness. No other adverse effects were seen in both the groups. The difference was not statistically significant (p>0.05). The patients were comparable in respect to adverse effects.



Graph 17: Distribution of Patients According to Adverse Effects in Both Groups

Discussion

Spinal anesthesia is a choice of anesthesia for cesarean section as it is economical, easy to perform and it avoids side effects of general anesthesia such as aspiration of gastric contents, management of airway, risk of failed endotracheal intubation and maternal and fetal depression.¹ It also allows the parturient to be awake to witness the delivery of her baby thus enabling her to participate and enjoy the birthing experience. There is evidence that general anesthesia is associated with an increased need for neonatal resuscitation. There has been a move towards more caesarean sections being performed under regional anaesthesia compared to general anaesthesia and the most common method of anaesthesia for elective and emergency caesarean sections.²

Pregnancy is associated with increased chances of aspiration than non-pregnant state, increased gastric volume, delayed gastric emptying and a reduction in lower oesophageal sphincter tone are the underlying causes. ¹⁷ Nausea and vomiting during regional anaesthesia for caesarean section are relatively quite high i.e. more than 66% without prophylactic antiemetic. ¹⁸ Nausea and vomiting like pain is a subjective response of the individual which can vary according to inherent tolerance and also the surroundings in the perioperative period. The etiology of emetic symptoms following regional anaesthesia for caesarean section is complex and depends on a variety of factors including maternal demographics, operative procedure, the occurrence of postoperative pain, use of perioperative opioids, anaesthetic techniques, peritoneal traction and exteriorisation of uterus.^{18, 19, 20} Apart from these, number of factors including age, gender, smoking habit, history of motion sickness, previous postoperative emesis, and pain are all considered to affect the occurrence of emetic symptoms.²¹

Traditional antiemetics like benzamides (metoclopramide) associated with impaired taste, smell, hot flushes and high incidences of dystonic reactions. Other commonly used antiemetics had numerous disadvantages which included phenothiazines (promethazine) which produces significant sedation and lethargy in patients, delayed recovery from

general anesthesia and also associated with high incidence of extrapyramidal side effects, ranging from restlessness to oculogyric crisis, antihistaminics (diphenhydramine) associated with sedative effects, anticholinergics (glycopyrolate, scopolamine) produce undesirable side effects like dry mouth, visual disturbance, sedation, memory dysfunction, dysphoria, confusion, disorientation and hallucinations, butyrophenones (droperidol) associated with significant drowsiness and has extrapyramidal effects and can cause restlessness and anxiety.²²

Now a days, selective serotonin $5HT_3$ receptor antagonists are considered first line of treatment in the prevention of emetic symptoms, due to its proven efficacy and favourable side effects profile. Its introduction into clinical practice was in the early 1990's and have been recognized as important advances in the control of nausea and vomiting associated with cancer treatment. ²² The major advantages is that they generally do not produce the extrapyramidal reactions associated with dopamine antagonists.²²

Ondansetron, a selectively inhibits 5-HT₃ receptors while is devoid of dopamine, histamine, cholinergic or adrenergic receptor activity. After oral or intravenous dosing, mean terminal elimination halflife is about 3.5 hours. The metabolites are conjugated rapidly to form glucoronides and sulphates, which are excreted in urine. Renal clearance of unchanged ondansetron accounts a small proportion of the administered dose (typically <5%). Ramosetron also a 5-HT₃ receptor antagonist, exibits greater binding affinity for 5-HT₃ receptors with a slower dissociation rate, resulting in more potent and longer receptor antagonizing effects compared with older 5-HT₃ receptor antagonists. Intravenous doses of 0.1 to 0.8 mg showed that the plasma concentration of unchanged drug declined biphasically with half-life approximately 5 hours. ^{23.} We chose 4 mg ondansetron as our study dose because it has been shown that it is as effective as higher doses in preventing and treating postoperative nausea and vomiting.²⁴ Fujii et al ^{24,25,26} mentioned that ramosetron is effective in preventing PONV after major gynecological surgery, and ramosetron 0.3 mg is an effective dose for preventing PONV. In addition to that, the manufacturer's recommended dose is 0.3 mg i.v. once a day. Hence ramosetron 0.3 mg dose was chosen for the study. Before initiation of this study, ethical committee approval and written informed consent was taken. 100 patients of ASA I and II physical status, aged between 20-30 years, scheduled to undergo elective cesarean section under spinal anesthesia and satisfying all the inclusion criteria were enrolled in the study and were randomly allocated into two groups of 50 each. Group O patients received inj. ondansetron 2 ml (4mg) i.v. and Group R patients received inj. ramosetron 2 ml (0.3 mg) i.v. after clamping of umbilical cord.²⁷

In our study, we collected and compared data in two groups in terms of age, weight, height, ASA grading, gravida, duration of surgery, uterus exteriorization, mephentermine administration, pulse rate, systolic blood pressure, respiratory rate, Apgar score, assessment of emetic symptoms by Belvillle score in intraoperative and postoperative period, patient satisfaction score and adverse effects.Data was collected and statistical analysis was done by using descriptive and inferential statistics using Chi-square test and Student's unpaired t test, the software used in the analysis were SPSS 20.0 version and Graph pad Prism 6.0 version, p<0.05 is considered as level of significance.

Demographic data

Table 1, graph 1 shows distribution of patients according to age in both groups. 69% of patients in our study were in range of 20-25 years, remaining 31% patients were in 26-30 years age group. Mean age of patients in group O was 24.90

 \pm 3.03 and in group R was 22.78 \pm 2.60 years. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to age in both groups.

Table 2, graph 2 shows distribution of patients according to weight in both groups. 15% of patients in our study were in range of 50-55 kg, 51% were in the range of 56-60 kg, 24% were in the range of 61-65 kg and remaining 10% patients were in 66-70 kg of weight. Mean weight of patients in group O was 58.78 ± 3.75 kg and in group R was 60.08 ± 4.57 kg. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to weight.

Table 3, graph 3 shows distribution of patients according to height in both groups. 47% of patients in our study were in range of 150-155 cms and remaining 53% patients were in range of 156-160 cms of height group. Mean height of patients in group O was 153.28 ± 3.20 cms and in group R it was 155.54 ± 2.34 cms. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to height.

Table 4, graph 4 shows distribution of patients according to ASA grading in both groups. 54% of patients in our study were in grade I and remaining 46% patients were in grade II of ASA grading. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to ASA grading. All these parameters were collectively taken and similar results were seen by Garcia-Miguel et al ²⁴ in 2000, Vasantha et al ²⁸ in 2014, Chauhan et al ²⁹ in 2014 and Jain et al ³⁰ in 2015 for cesarean section patients when age, weight, height and ASA grade was considered.

Table 5, graph 5 shows distribution of patients according to gravida in all groups. 45% of patients in our study were primigravida and remaining 55% patients were multigravida. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to gravida. We considered gravida because patients with previous cesarean section may require more visceral and peritoneal handling leading to visceral pain and finally resulting in nausea and vomiting.^{18,19,20,31}

Duration of surgery

Table 6, graph 6 shows distribution of patients according to duration of surgery in all groups. 10% of patients in our study were in range of 30-35 mins, 42% patients were in range of 36-40 mins, 46% patients were in range of 41-45 mins and remaining 2% patients were in range of 46-50 mins of duration of surgery. Mean duration of surgery of patients in group O was 42.08 ± 3.83 min and in group R it was 40.40 ± 3.30 min. The difference was not statistically significant (p>0.05) among the groups. The patients were comparable with respect to duration of surgery. Similar duration of surgery was observed by Garcia-Miguel et al in 2000²⁴, Chauhan et al in 2014²⁹, Thakur et al ²¹ in 2015 and Chattopadhyay et al ³¹ in 2015 when duration of surgery was considered.

Uterus exteriorization

Uterus exteriorization will lead to visceral traction, pain and emetic symptoms, so we considered this parameter to compare amongst the groups. ^{21,29} Table 7, graph 7 provides information regarding distribution of patients according to uterus exteriorized. 20% patients in group R and 18% patients in group O required uterus exteriorization. Mean duration of uterus exteriorized in group O was 11.55 ± 1.33 min and in group R it was 12.40 ± 1.54 min. The difference was not statistically significant (p>0.05). The patients were comparable with respect to duration of uterus exteriorized. Similar

results were given by Dasgupta et al ¹⁸ in 2012 and Chattopadhyay et al ³¹ in 2015 when uterus exteriorization was the considered parameter.

Haemodynamic variables

Table 8, graph 8 shows basal mean pulse rate in group O was 63.20 ± 1.86 and in group R was 63.01 ± 1.92 which was comparable and the difference was not statistically significant using student's unpaired t-test (p>0.05). The pulse rate was constant throughout the study period in all patients. No patient went in bradycardia in our study.

Table 9, graph 9 shows basal mean systolic blood pressure in group O was 123.26 ± 5.09 and in group R was 120.18 ± 5.0 which was comparable and the difference was not statistically significant using student's unpaired t-test (p>0.05). After induction there was gradual fall in systolic blood pressure in both the groups till 10 mins which was expected after spinal anesthesia. No statistically significant difference was found among the groups. Did not required any aggressive treatment than inj. mephentermine (3 mg bolus in repeated doses) as our aim was to avoid excessive hypotension.

Table 10, graph 10 shows basal mean respiratory rate in group O was 14.37 ± 1.50 and in group R was 13.32 ± 1.53 which was comparable and the difference was not statistically significant using student's unpaired t-test (p>0.05). The respiratory rate was constant throughout the study period in all patients. No patient went in respiratory depression in our study. All the vital parameters considered were not significant during the study period. Similar haemodynamic comparision was cited by Thakur et al ²¹ in 2015 and Jain et al ³⁰ in 2015.

Mephentermine required

Table 11, graph 11 shows distribution of patients according to mephentermine required. 10% patients in group O and 14% patients in group R required inj. mephentermine. Mean dose of inj. mephentermine required in group O was 10.10 ± 2.46 mg and in group R was 8.92 ± 3.46 mg. The difference was not statistically significant (p>0.05). The groups were comparable with respect to number of patients and total dose of mephentermine required during cesarean section. Hypotension may trigger the vomiting center to induce emesis due to hypoxia. ³¹ In our study pre-loading, left uterine displacement and administration of incremental doses of mephentermine were the strategies for prevention of hypotension. Similar strategies for prevention of hypotension was used by Chauhan el al ²⁹ in 2014 and Thakur el al ³² in 2015.

APGAR Score

Table 12, graph 12 shows Apgar score. At 1 min the mean was 8.50 ± 0.50 in group O and 8.52 ± 0.50 in group R. At the end of 5 min the mean was 9.50 ± 0.50 in group O and 9.52 ± 0.50 in group R. This shows neonatal Apgar scores did not differ amongst the study groups. Though we administered the study drug after clamping of the umbilical cord, we considered this parameter to assess the neonatal outcome as postoperative emotional status of the mother may lead to anxiety and it do play an important role in incidences of emetic symptoms.³³

Emetic symptoms

Table 13, graph 13 shows Table shows distribution of patients according to Belville score in intra-operative period. After administration of study drug, at 10 mins 1 patient each in both groups had Belville score of 1. After 20 mins 1 patient in group R had Belville score of 2 while in group O, 2 patients had Belville score of 2 at 20 mins and at 30 mins only 1 patient in group O had Belville score of 2. In our study during intraoperative period, complete response was maximum in

group R (96%) and similarly in group O (92%). The average score was 0.14 ± 0.49 in group O and 0.06 ± 0.31 in group R. The emetic episodes according to Belville score was not statistically significant when compared in both groups. (p>0.05) Similarly, no patients in either group required any rescue antiemetic drug during intraoperative period. Hence we observed that both the drugs were comparable and equipotent in controlling emetic symptoms in intraoperative period. Similar studies of excellent control of emetic symptoms by both drugs during intraoperative period were found i.e. incidence of nausea was found to be 8.2% and vomiting 0% by Garcia-Miguel et al ²⁴ in 2000, nausea 6% and vomiting 0% by Thakur et al ²¹ in 2015 in ondansetron group. Similarly, incidence of nausea was found 8% by Chauhan et al ²³ in 2014 and nausea 4% and vomiting 0% by Thakur el ²¹ in 2015 in ramosetron group during intraoperative period. They also found complete response in maximum patients during intraoperative period and none of the patients required rescue antiemetic.

Table 14, graph 14 (A and B) shows distribution of patients according to Belville score in early postoperative period. After administration of study drug, at 0-3 hours 1 patient in group R and 2 patients in group O had Belville score of 1 while 2 patients in group R and 3 patients in group O had Belville score of 2 and 3 patients in group O had Belville score of 3 as compared to none in group R. At 3-6 hours 1 patient in both the groups had Belville score of 1 while 1 patient in group R had Belville score of 2 as compared to 2 patients in group O. 3 patients in group O had Belville score of 3 as compared to none in group R. In our study during early postoperative period, complete response was 72% in group O and 90% in group R. The average score was 0.62 ± 1.08 in group O and 0.16 ± 0.50 in group R. Ramosetron was found to be more potent in controlling emetic symptoms then ondansetron during early postoperative period. (p<0.05) Also, when rescue antiemetic requirement was compared in both the groups, it was found, in group O more number of patients required rescue antiemetic compared to group R (γ 2-value for rescue antiemetic=5.67,p=0.017,S). Similar results were observed in ondansetron group, where Kumar et al ²⁸ in 2014 found incidences of nausea to be 36% during 1st hour, 6% at 2nd hour and 2% at 6th hour, retching 6% and vomiting 14% at 1st hour, 6% at 2nd hour and 2% at 6th hour, whereas Chauhan et al²³ in 2014 found incidence of nausea to be 8% during 0-3 hours and 4% at 3-6 hours. Also Thakur et al³² in 2015 found incidence of nausea to be 14% and incidence of vomiting to be 6% during early postoperative period. In study done by Agarkar et al ³⁴ in 2015, they found incidence of Nausea 38.8%, retching 15.5% and vomiting 12.6% whereas incidence of nausea was 16.7% and vomiting was 13.3% in the study done by Makker et al ³⁵ in 2017. Similarly in ramosetron group, study done by Ghosh et al²⁷ in 2012 incidence of nausea and vomiting was 6.6%, whereas in study done by Chauhan et al²³ in 2014, incidence of nausea was found to be 4% in 0-3 hours and 0% in 3-6 hours. In study done by Agarkar et al ³⁴ in 2015, incidence of nausea was 35%, retching 8.7% and vomiting was 14.6% whereas Chattopadhyay et al ³¹ in 2015 found 9% nausea and 12.9% vomiting. Naik et al ²¹ in 2015 and Thakur et al ³² in 2015 in their study found incidence of nausea to be 6% and vomiting 0% in early postoperative period. When the incidence of emetic symptoms were compared between the groups, ramosetron was found to be more potent in controlling emetic symptoms then ondansetron during early postoperative period. Also when rescue antiemetic was compared in both the groups, it was found, in group O more number of patients required rescue antiemetic compared to group R.

Table 15, graph 15 (A and B) shows distribution of patients according to Belville score in late postoperative period. After administration of study drug, at 6-12 hours 2 patient in group R and 3 patients in group O had Belville score of 1 while 1

patient in group R and 3 patients in group O had Belville score of 2 and 1 patient in group R and 4 patients in group O had Belville score of 3. At 12-24 hours 1 patient in group R and 4 patients in group O had Belville score of 1 while 2 patients in group R had Belville score of 2 as compared to 3 patients in group O. 2 patients in group R had Belville score of 3 as compared to 3 patients in group O. In our study during late postoperative period, complete response was 60% in group O and 82% in group R The average score was 0.90 ± 1.12 in group O and 0.36 ± 0.85 in group R. Ramosetron was found to be more potent in controlling emetic symptoms then ondansetron during late postoperative period. (p<0.05) Also, when rescue antiemetic requirement was compared in both the groups, it was found, in group O more number of patients required rescue antiemetic compared to group R (χ 2-value for rescue antiemetic=6.06, p=0.013,S) In late post postoperative period, ondansetron was not effective due to its shorter halflife i.e 3.5 hrs when comapared with halflife of ramosetron i.e. approximately 5 hrs. The Belville score was statistically significant (p < 0.05) when compared in both groups. The patients were not comparable with respect to Belville score in late postoperative period. In studies of ondansetron which was conducted by Thakur et al³² in 2015, they found incidence of nausea to be 12% and vomiting 10% whereas in study by Makker et al ³⁵ in 2017 result of nausea was 26.67% and vomiting was 20% during late postoperative period. While for ramosetron, study done by Ghosh et al ²⁷ in 2012 showed nausea 6.6% and vomiting 5%. Agarkar et al ³⁴ in 2015 found nausea 1% and vomiting 0% and Thakur et al ³² in 2015 found nausea 10% and vomiting 0%. According to the values in our study we found ramosetron to be more potent in controlling emetic symptoms than ondansetron during late postoperative period. When rescue antiemetic was compared in both the groups, it was found, in group O more number of patients required rescue antiemetic compared to group R.

5-HT₃ receptors are widely distributed within the neurons of the GI tract as well as spinal cord and in the brain and the activation of 5-HT₃ receptors, results in intestinal secretions, peristaltic activity and emesis. ³⁶ The released serotonin binds to 5-HT₃ receptors present in the afferent vagal nerve ending in the gastrointestinal mucosa and this neuro-stimulation induces emesis via vomiting center.³⁷ Ondansetron and ramosetron hydrochloride are considered to exert their antiemetic action by blocking the 5-HT₃ receptors. Ramosetron is superior to ondansetron due to significant long halflife. (5 hours compare to 3 hours) It also has a high binding affinity to 5 HT₃ receptors than ondansetron. ^{22,29}

Our study suggests that efficacy of ramosetron for prevention of nausea and vomiting is superior to ondansetron and also in reducing the requirement of rescue antiemetic. In group O 10% and 20% patients required rescue antiemetic in early and late postoperative period. While 2% and 4% patients in group R required rescue antiemetic in early and late postoperative period. In study of Fujii et al ³⁸, none of the patient required rescue antiemetic in group R while Kim et al ³⁹ found 15% patient required rescue antiemetic with ramosetron because of higher incidence of PONV as their study was on laparoscopic surgery. Higher incidence of requirement of rescue antiemetic i.e 43% with ondansetron was found by Bordner et al ⁴⁰ in patients undergoing laparoscopic surgery.Repeating the prophylactic or a similar class antiemetic in case of PONV within 6 hours is considered futile. Current guidelines recommend the use of agent belonging to different class when prophylaxis fails. Hence we decided to use metoclopramide 10 mg as a rescue antiemetic in our study. ²³

Satisfaction score

Table 16 shows distribution of patients according to satisfaction score. 16% patients in group O and 34% patients in group R had satisfaction score of 3. In group O, 46% patients and in group R, 52% patients had satisfaction score of 2. In

group O, 26% patients and in group R, 10% patients had satisfaction score of 1. Only 4% of the patients in group R had poor satisfaction score as compared to 12% patients in group O. The difference was statistically significant (p<0.05). Patients in group R were more satisfied than patients in group O. Similar results were cited by Thakur et al ³² in 2015. Table 17 shows distribution of patients according to adverse effects. The most frequently reported adverse effects of 5-HT₃ receptor antagonists are headache, dizziness and constipation. 4% patients in group R and 10% patients in group O had headache. 2% patients in both groups R and group O had constipation. 2% patients in group R and 4% patients in group O had dizziness. No other adverse effects were seen in both the groups. The difference was not statistically significant (p>0.05). The patients were comparable in respect to adverse effects. Similar results were observed by Thakur et al ³² in 2015, Kim et al ³⁹ in 2009 and Lee et al ⁴¹ in 2011. Only 12% patients of group O and 4% patients of group R were not satisfied because they had experienced headache/ dizziness/constipation and/or vomiting in postoperative period.

Ramosetron was found to be more effective than ondansetron for prophylaxis of emetic symptoms especially during postoperative period after caesarean section till 24 hours.

Conclusion

Ramosetron and ondansetron were equipotent as per incidences of emetic symptoms during intraoperative period were considered. During early postoperative period (0-6 hours) ondansetron reduces nausea and vomiting, but when compared with ramosetron, ramosetron was found to be a better alternative. In late post postoperative period (12-24 hours), ramosetron was found to be better than ondansetron as ondansetron was not at all effective due to its short halflife of 3.5 hours. The requirement of rescue antiemetic was more in ondansetron especially in late postoperative period. Adverse effects such as headache, dizziness and constipation were similar in both the study drugs and they were devoid of many side effects associated with traditional antiemetics. Patients receiving ramosetron were more satisfied (34%) than patients receiving ondansetron (16%). Ramosetron is a better alternative to ondansetron for prophylaxis of emetic symptoms especially during postoperative period after cesarean section till 24 hrs.

Abbreviations :

PONV	—	Post operative nausea and vomiting
LSCS	_	Lower segment caesarean section
5HT	_	5 Hydroxytryptamine
CRTZ/CTZ	_	Chemoreceptor Trigger Zone
mg	_	milligram
VS	_	versus
kg	_	kilogram
i.v	_	intravenous
min	—	minutes
ASA	_	American Society of Anesthesiologist
JNMC	-	Jawaharlal Nehru Medical College
AVBRH	—	Acharya Vinoba Bhave Rural Hospital

ECG	—	Electrocardiogram
eg	_	example
yrs	_	years
D_2	_	Dopamine
N_2O	_	Nitrous Oxide
O_2	_	Oxygen
Inj	_	Injection
PR	_	Pulse Rate
SBP	_	Systolic Blood Pressure
RR	_	Respiratory Rate
SpO_2	_	oxygen saturation
cms	_	Centimeter
ml	-	millilitre
hrs	_	hours
SAB	_	Subarachanoid block

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