ROLE OF PROPHYLACTIC ONDANSETRON FOR PREVENTION OF SPINAL ANAESTHESIA INDUCED HYPOTENSION IN LOWER SEGMENT CAESAREAN SECTION

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ABSTRACT

Objective: To determine the efficacy of prophylactic administration of intravenous Ondansetron for prevention of spinal anaesthesia induced hypotension in lower segment caesarean section.

Study Design: Double blinded randomized controlled trial.

Place and Duration of Study: It was conducted in Anesthesiology department, CMH Rawalakot; from 3 Mar to 4 Jun 2014.

Material and Methods: One hundred patients were selected for this study, and randomly divided in two groups of 50 each, using random numbers table. Both groups were preloaded with Ringer's lactate at dose of 10ml/kg. Group A received 04 mg of IV ondansetron 5 min prior to spinal anaesthesia, whereas Group B received normal saline 05 minutes before administration of Spinal Anaesthesia.

Results: Average age of Group A was 28.62 ± 4.64 years, whereas that of Group B was 27.88 ± 3.98 (*p*-value= 0.394). Average weight of Group A was 70.30 ± 6.25 kg, whereas that of Group B was 70.74 ± 6.17 kg (*p*-value= 0.724). Hypotension was noted in 21 patients in group A (42%), whereas it was observed in 34 Patients in Group B (68%) (*p*-value= 0.009). Bradycardia was noted in 9 patients in Group A (18%) and 19 patients in Group B (*p*=0.026).

Conclusion: Intravenous administration of 04 mg of intravenous ondansetron, 05 minutes prior to subarachnoid block, is effective in decreasing frequency of hypotension.

Keywords: Intravenous ondansetron, LSCS, Spinal anaesthesia.

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INTRODUCTION

The use of regional anaesthesia in lower segment caesarian section (LSCS) has increased a lot in last few decades. Spinal anaesthesia is the most practiced amongst all regional anaesthesia techniques¹. may result different It in complications², particularly hypotension is commonly encountered in LSCS³. The frequency may be very high in those patients reporting for emergency LSCS (60-100%)⁴. This hypotension poses risk to both, mother and fetus⁵.

Pharmacological interventions are made to treat hypotension, and phenylephrine and ephedrine have been used particularly for this purpose⁶. However, main emphasis has been, on prevention of hypotension after administration of spinal anaesthesia.

Different methods have been tested to find effective prophylactic technique against hypotension, for example, crystalloid preloading or coloading, colloid coloading, use of different drugs like ephedrine or phenylephrine, and no single method was found effective alone.

Apart from hypotension, incidence of nausea and vomiting is also very high in patients undergoing LSCS. Without any prophylactic measure, it can vary between 50-80%⁷. And this can add to the sufferings patient is already going through. Ondansetron is a 5-HT 3 antagonist, and has been studied for its prophylactic role for nausea and vomiting in patients undergoing LSCS⁸.

Our aim was to study the efficacy of Ondansetron for prevention of spinal anaesthesia

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induced hypotension in local population when given in combination with crystalloid preload.

MATERIAL AND METHODS

This randomized double blinded controlled trial was conducted in main operation theatre, department of anesthesiology, CMH Rawalakot from 03 Mar to 04 Jun 14. Patients having American Society of Anesthesiology (ASA) status-I, and presenting for elective LSCS, were included in the study. Patients having contraindication to spinal anaesthesia, cardiovascular disease, pulmonary disease, renal disease, liver disease, morbidly obese, short statured or failed spinal block; were excluded When patients arrived in operation theatre, they were weighed and standard monitoring was applied before start of procedure. This was followed by intravenous cannulation with 18 G cannula. Group A was given 4 mg of intravenous ondansetron in 5 ml saline. Group B was given 5 ml saline. Medicines were prepared by staff nurse, and anesthetist was kept blinded from it. Ringer's lactate was then given over a period of 05 minutes. Heart rate and blood pressure were recorded. Then spinal anaesthesia was administered in sitting position, using a 25 G spinal needle in L3-4 space. 2 ml of 0.75% bupivacaine was used for subarachnoid blockage. They were immediately placed in supine position

Table-I. Average a	ige and weight of i		<i>J</i> .			
	Group	oup A G		roup B	<i>p</i> value	
Age (years)	28.62 ± 4	4.64 27.8		38 ± 3.98	0.394	
Weight (kg)	70.30 ± 0	6.25 70.		74 ± 6.17	0.724	
Table-II: Compari	son of hypotensio	n between	both Gro	ups.		
Hypotopsion	Group-A			Group-B		
Hypotension	No.	%)	No.	%	
Present	21	42.0		34	72.0	
Absent	29	58.0		16	28.0	
p value		0.009				
Table-III: Compar	ison of bradycard	ia between	both Gro	ups.		
Dradvoardia	Gro		Group-B			
Di aŭycal ula	No.	No. %	No.	%		
Present	9	18	0	19	38.0	
Absent	41	82	.0	31	62.0	
<i>p</i> -value	0.026					

Table-I: Average age and weight of both Groups.

from the study. Sample size was calculated using study of Sahoo T⁹. Keeping the power of test 90%, sample required was 52. And it was the number they had used for their study too. However, we increased the sample size for better result to 100. Patients were selected using convenience sampling. They were divided randomly into two Groups, A & B. Randomization was done using computer generated table of random numbers. The study was approved by ethical review committee of hospital. Written informed consent was obtained from the patients. with a wedge under right hip for left uterine displacement.

Sensory blockade was judged by pin prick technique, and a motor blockade was checked by inability to lift legs. Spinal anaesthesia was considered effective if T6 sensory blockade was achieved with inability to move legs.

Blood pressure was checked every 03 minutes for 15 minutes. This was followed by every five minutes for next 15 minutes. If Systolic blood pressure was decreased >20% from baseline reading during this time frame, it was labeled as "hypotension present". Heart rate was monitored continuously in this time frame, and rate less than 50 per minute, was defined as "bradycardia present".

Data Analysis Procedure

Data were analyzed using SPSS version 20. Age and weight of patients, were compared using Independent samples t-test. Bradycardia and hypotension were noted down as "present" or "absent" frequency of bradycardia and hypotension between the two groups was compared using Chi Square test. *p*-value <0.05 was taken as significant.

RESULTS

Total 100 patients were included in study, divided in two groups of 50 each. Average age and weight of Group A was 28.62 ± 4.64 years and 70.30 ± 6.25 kg. Average age and weight of Group B was 27.88 ± 3.98 years and 70.74 ± 6.17 kg (table-I). Hypotension was present in 21 patients in group A (42%), where as it was present in 34 patients in Group B (68%) (table-II).

associated with it², hypotension being commonly encountered³.

This can have fatal effects on mother and fetus¹¹. Different techniques for prevention have been studied. Some studies compared crystalloid preloading to colloid preloading¹². Others tested preloading to coloading¹³. Yet, others compared use of pharmacological drugs with fluid loading¹⁴. Different doses routes or of administration of drugs were also tested for the sake of prophylaxis 5,15. Physical methods like lower leg compression have been tested too. But these methods vary in their effectiveness¹⁶, however, none of them is effective alone to prevent hypotension^{11,16}. And that is why combinations were tested to find preventive strategy against spinal anaesthesia induced hypotension¹⁷.

We decided to study a combination of 04 mg intravenous ondansetron and crystalloid preloading at dose of 10 ml/kg for prevention of spinal anaesthesia induced hypotension.

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Hospital Outcome parameters	Group A (n=50)	Group B (n=50)				
Mortality (as per study definition)	NIL	NIL				
Morbidity for 4 observed Parameters						
Hypertensive encephalopathy	0	0				
ACS	6	7				
MI (Lab proven)	0	0				
Negative pulmonary edema (NPPE)	1	2				

Table IV: Mortality/ Morbidity pattern among the study groups.

Statistically higher frequency of hypotension is present in Group B (p=0.009). Bradycardia was present 9 in patients of Group A (18%) and 19 patients in Group B (38%) (table-III). Statistically lower frequency was encountered in Group A (p=0.026). Mortality and morbidity pattern given in table-IV.

DISCUSSION

Regional anaesthesia has improved safety profile for LSCS in recent years. Pregnancy is associated with diffetarent physiological changes which increases the chances of difficult intubation¹⁰. Thus, its use has increased a lot. However, it has its own set of complications Ondansetron is a 5-HT3 antagonist, and has been studied in LSCS for its effects against post operative nausea and vomiting⁸. It has also been associated with decrease in incidence of post dural puncture headache in patients undergoing LSCS under spinal anaesthesia¹⁸. Also, it decreases the incidence of shivering associated with spinal anaesthesia^{19, 20}.

Other researchers have also worked on intravenous administration of ondansetron for prophylaxis against spinal anaesthesia induced hypotension. Sahoo et al⁹ studied ondansetron effect in patients undergoing LSCS. Similar to this study, they had given 4mg of ondansetron; however, they included 52 patients in their study, and preloaded them with crystalloid at dose of 20 ml/kg over a period of 30 minutes. They concluded that prophylaxis with I.V 04 mg ondansetron is effective against spinal anaesthesia induced hypotension.

Wang et al²¹ compared different doses of ondansetron for the sake of prophylaxis. They compared placebo with 02, 04, 06 and 08 mg of ondansetron in 150 patients undergoing LSCS (30 in each group). Also, they gave Ringer's lactate at a very low rate, just enough to keep the vein patent. They increased the dose of crystalloid infusion after administration of spinal anaesthesia to a maximum dose of 10 ml/kg. They found that 04 mg of ondansetron was the optimal dose.

Similar to this study, Trabelsi et al²² had used dose of 4 mg ondansetron and 10 ml/kg of crystalloid. But they used saline instead of Ringer's lactate and chose a sample of 80 patients undergoing LSCS. They found that the incidence of hypotension and bradycardia were less in those who were given prophylactic ondansetron.

Apart from studies on patients undergoing LSCS, Researchers have worked on other surgeries too. Like Marashi et al²³ studied prophylactic effect of intravenous ondansetron in patients undergoing elective orthopedic, urology and gynecologic surgery. They chose 210 patients, and divided them in three equal groups. They preloaded their patients with 5 ml/kg of ringer's lactate and gave saline as placebo, 06 mg of ondansetron and 12 mg of ondansetron. Frequency of bradycardia and hypotension were less in group which were given ondansetron as compared to placebo. However, there was no statistically significant difference between 06 and 12 mg groups.

Owczuk et al²³ included 71 patients in their study, and gave 08 mg of ondansetron to one group, and saline as placebo to other Group. They gave maximum of 200 ml of normal saline during the study period. They found that systolic blood pressure was higher in ondansetron group as compared to placebo. There was no change in heart rate between two groups.

Apart from this, Owczuk et al²⁴ also studied use of 08 mg of intravenous ondansetron in geriatric population and concluded that it is effective in prophylaxis against decrease in mean arterial pressure and diastolic blood pressure.

CONCLUSION

This present study demonstrates that combination of 04 mg of intravenous ondansetron and 10 ml/kg of crystalloid preload is effective in reducing the frequency of bradycardia and hypotension.

Though other effects of ondansetron, like decreasing frequency of post operative nausea and vomiting, Post dural puncture headache and shivering associated with spinal Anaesthesia, were not included in this study; however, these effects add more advantages to its use in spinal anaesthesia.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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