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Original Research Paper

Anesthesiology

COMPARATIVE STUDY OF METOCLOPRAMIDE AND ONDANSETRON WITH PANTOPRAZOLE IN ELECTIVE CAESEREAN SECTION UNDER SPINAL ANAESTHESIA FOR ASPIRATION PNEUMONITIS PROPHYLAXIS.

Nimta Kishore* Assistant Professor, Dept Of Anaesthesiology, Autonomous State Medical College, Etah, Uttar Pradesh. *Corresponding Author

A.Varshneya Consultant,Deptt Of Orthopaedics,Centre For Trauma And Joint Replacement, Agra

A.Nagrath Professor And Ex.head Of Department,deptt.of Obs. And Gynae.,U.P. R.I.M.S & R,Saifai,Etawah

ABSTRACT

BACKGROUND- Caesarean delivery, one of the most commonly performed surgical procedure. The choice of anaesthesia is spinal blockade for elective caeserean-section,unless general anaesthesia is specifically indicated. Aspiration pneumonitis remains an important cause of morbidity and mortality in anaesthesia practise,particularly in obstetric patients,prophylaxis against it is paramount importance in pre-anaesthetic management.

AIMS AND OBJECTIVES- The aim of this study was to compare pH and volume of gastric contents after administration of combination of metoclopramide and pantoprazole versus ondansetron and pantoprazole during elective caesarean section under spinal anaesthesia for prophylaxis against aspiration pneumonitis.

METHODS: It is a prospective study where 100 parturient women, ASA 1 and 2 scheduled for elective caesarean section. They were divided into 2 groups: ondansetron(4mg) and pantoprazole(40mg),and metoclopramide(10mg), pantoprazole(40mg) administered intravenously 2hours before surgery. Gastric aspirate was taken in various positions before giving spinal anaesthesia and at the end of operation. Patients at risk were according to criteria of gastric volume more than 0.4ml/kg with pH <2.5.

RESULTS: Patients at risk were 7(14%) in metoclopramide group and 1(2%) in ondansetron group before giving spinal anaesthesia($p=0.027$) and 6(12%) in metoclopramide group and 0(0%) in ondansetron group at end of operation($p=0.012$) . Since p-value was less than 0.05 there was significant difference between two groups.

CONCLUSION: As there was significant difference between ondansetron and metoclopramide , it is recommended to use ondansetron and pantoprazole for prophylaxis against aspiration pneumonitis.

KEYWORDS : aspiration pneumonitis,spinal anaesthesia,caesarean section,pH,volume of gastric contents.

INTRODUCTION

Obstetrical patients are at an increased risk of aspiration of gastric contents due to delayed gastric emptying, leading to maternal morbidity and mortality; the risk is further increased in patients who require anaesthesia. It was first described by Curtis Mendelson in 1946, who differentiated airway obstruction by solid material and liquid aspiration which resulted in intense inflammatory reaction of the lung tissue manifesting as bronchospasm, pulmonary edema and hypoxia[1]. Maternal mortality has dramatically declined in the recent times because of the new fasting regimens, increasing use of regional anaesthesia for caserean section, and the universal adoption of Sellick's manoeuvre for aspiration prophylaxis[2] and universal use of various prophylactic agents against pulmonary acid aspiration syndrome. Aspiration pneumonitis resulting from the inhalation of gastric contents is still a cause of maternal morbidity and mortality, and it is important to use effective prophylaxis.

Aspiration of acidic gastric contents is an important complication in obstetric patients undergoing caesarean section under regional anaesthesia. Obstetric patients are more prone for acid aspiration because presence of high gastric content volume or low gastric pH can not be excluded (Roberts and Shirley, 1974)[3]. In pregnancy, airway oedema and heartburn increase cough sensitivity, whereas spinal anaesthesia with local anaesthetic decrease it. Decreased cough sensitivity increases the risk for aspiration pneumonitis, hence aspiration pneumonitis is increased after planned caesarean section under spinal anaesthesia with bupivacaine[4]

MATERIAL AND METHODS

The protocol was reviewed and approved by the medical ethics committee of the hospital.It was a randomised prospective single blind study where parturient women of atleast 36 weeks duration of ASA I and II(American Society of Anaesthesiology Grade I and II), aged between 19-40 years, without fetal distress, scheduled for elective and non urgent lower segment caesarean section under spinal anaesthesia formed the subjects of study. Informed written consent was obtained in all the patients in the presence of a witness.

Since various medical conditions and drugs can contribute or predispose to intra-operative nausea and vomiting, these variables were minimised by extending the exclusion criteria to as many of these conditions as possible. Patients presenting with symptoms of acid related gastrointestinal diseases, history of severe acid peptic disease, gastro oesophageal reflux disease, non ulcer dyspepsia, previous gastric surgery, complicated pregnancies like twins, hydramnios, eclampsia and known drug allergies or ingestion within past 2 to 3 days of medications known to affect gastric motility and secretions. Maternal history suggestive of chronic uteroplacental insufficiency, tobacco chewers, active smokers(smoking had to be stopped for one year) were excluded.

Because the secretion of ondansetron into colostrum/milk is still undetermined, women who planned to breast-feed were excluded. The exclusion criteria also included significant maternal medical problems such as cardiac, gastrointestinal, hepatic, renal or known psychiatric disease(like depression, chronic anxiety), pregnancy-induced hypertension, history of motion sickness, weight more than 100 kgs or history of nausea and or vomiting within 24 hrs before the induction of anaesthesia. Patients with diabetes mellitus, chronic cough/ chronic respiratory disease, allergic rhinitis, respiratory tract/ upper airway infection during last month, ASA grade III, IV or V, known hypersensitivity to 5-HT_3 antagonist and history of hyperemesis gravidarum were also excluded. Since opioids may initiate nausea and vomiting no such drugs were added to bupivacaine. The patients would be excluded if an opioid or a anaesthetic was required to control intra-operative pain. Patients receiving any of the following drugs within 24 h before

the study were also excluded: opioids, tricyclic antidepressants, droperidol, phenothiazine, metoclopramide, antacids, H_2-antagonists, scopolamine, cannabinoids, antihistamines, corticosteroids, benzodiazepines, ACE inhibitors or angiotensin II receptor inhibitors. Patients with pharyngo-laryngeal diseases and with neurological disorders were also excluded. Both primi and multi gravida patients were included in study.

After placing the patient on operation table in supine position with little left lateral position, pulse rate, non invasive blood pressure, oxygen saturation by pulse oximetry were recorded before anaesthesia and then every 3 minutes for 60 minutes after anaesthesia. Before induction of spinal anaesthesia a lubricated 16 French gauge nasogastric tube will be passed through the nose into the stomach and the correct position will be confirmed either by the aspiration of the gastric contents or if none was obtained, by auscultation of 2ml of insufflated air, The gastric contents will be aspirated with gastric tube (by syringe) in several positions and patient supine, tilted to the right, left, head down and head up position. Gastric contents will be visually inspected for particles, the volume of gastric content measured by syringe and gastric pH will be estimated by using pH paper,(pH 1-10)

Neonatal data were recorded(Apgar score at 1 and 5 minutes,birth weight and requirement of intensive neonatal care unit admission).

Each patient will receive 20ml per kilogram of lactated Ringer solution[5] before administration of spinal anaesthesia to prevent hypotension. One litre of lactated Ringer's solution was administered within 20 min of the spinal block and another litre was continued during surgery. More fluid was administered when required depending on the cardiovascular stability and clinical estimation of blood loss. To prevent hypotension, ephedrine was infused continuously (50 mg in 250 ml saline)[6].Hypotension was defined as a decrease of the mean arterial blood pressure by 20%. When it occurred, it was treated promptly by additional fluids and intravenous increments (5-10 mg) of ephedrine.

All patients will receive oxygen via a plastic face mask at a flow rate of 3 litres/minute, a pulse oximeter was placed and ECG was connected, since induction of spinal anaesthesia. The patients were positioned in the right / left lateral decubitus or sitting position and a 23 gauge Quinke spinal needle was introduced through the midline approach at the L_3-L_4 interspace. Patients received 2.5 ml 0.5% hyperbaric bupivacaine subarachnoid injection and were turned to the supine position with left uterine displacement to avoid aorto-caval compression which was avoided by placing a single folded blanket beneath the right buttock. The level of analgesia was assessed by pin-prick, was measured every 5 minutes for 20 minutes and all patients had analgesia upto T6 level. Surgery was started when a sensory block upto T_6 dermatome was obtained.

In all the patients the uterus was exteriorised during surgery. After delievery of baby and umbilical cord clamping 5-10 units of syntocinon was given intravenously to each of the patients of both groups. Duration of operation was noted. Postoperative analgesia was maintained by NSAID (ketorolac) with H_2receptor blocker(ranitidine).

Blood pressure measurements were recorded every 3 minutes by auscultaroy method until delivery of baby, then every 3 minutes till the patient was transferred to the recovery room. The eyes of the patient were covered with cotton pads to minimize anxiety evoked by the atmosphere of the operating theatre. Hypotension was defined as a decrease in systolic arterial blood pressure of 20% from baseline, or a systolic blood pressure below 100mmHg.

Each patient was observed for the intraoperative occurrence of nausea and vomiting. Retching and or vomiting were taken as positive responses for vomiting .At every 5 minutes interval during the surgery, the patient was questioned about nausea, observed for the presence of vomiting using a 3 point scale: asymptomatic, nausea only, vomiting. Chest tightness, hypotension, bradycardia, oxygen desaturation, post dural puncture headache were also recorded during the study.

For the purpose of investigation, the patients will be considered to be at risk of aspiration pneumonitis if combination of gastric volume more than 0.4 ml/kg and gastric pH less than 2.5.

Patients were randomly allocated into one of two treatment groups-

Group I : Patients who received Metoclopramide (10 mg) and Pantoprazole (40mg) intravenously 2 hours before induction of spinal anaesthesia.

Group II: Patients who received Ondansetron (4 mg) and Pantoprazole (40 mg) intravenously 2 hours before induction of spinal anaesthesia.

Postoperative analgesia was maintained by NSAID (ketorolac) with H_2receptor blocker(ranitidine).

DISCUSSION

Spinal blockade is considered the procedure of choice for elective caesarean section in countries such as India,where it can be used in up to 85% of Caesarean section at some maternal centres. The spread of anaesthetic drug in cerebrospinal fluid(CSF) is less predictable in parturients, because of increased spinal canal pressure[7] ;CSF acid-base balance[8] and protein content[9]. Side effects like intraoperative nausea and vomiting predisposing to aspiration pneumonitis and hypotension are more common[10].

Parturients at risk of aspiration pneumonitis during abdominal surgery under regional anaesthesia have a multifactorial origin and factors such as anxiety;arterial hypotension;hypoperfusion of brainstem;abrupt visceral movements[11] have an effect on them. Additionally increased intra-abdominal pressure and hormonal changes predispose full-term parturients to risk of aspiration pneumonitis. Also, Indian women are preoccupied with anxiety,fear and apprehension about operative intervention which are known to inhibit gastric emptying. Further the emotional overtones associated with the sex of new arrival may be a contributing factor[12], hypotension as a result of haemorrhage may cause nausea and vomiting as well as altered consciousness which predispose to pulmonary aspiration of gastric contents.

According to study by Lussos et al[13] emetic symptoms after delivery are related to the surgical manipulation of uterus,abdominal viscera, and peritoneum;even in the presence of adequate sensorimotor blockade. In our study most of these factors were well-controlled ,so that any difference in at risk patients during spinal anaesthesia for caesarean section can be attributed to study drugs.

In our study of 100 full-term parturients,50 patients in each group, a total of at risk patients were 7(14%) in metoclopramide treated group and 1(2%) in ondansetron treated group before giving spinal anaesthesia and 6(12%) in metoclopramide treated group and 0(0%) in ondansetron treated group at end of operation. In this study ,we have observed that patients who received ondansetron(4mg) and pantoprazole(40mg) intravenously 2hrs before induction of spinal anaesthesia for caesarean delivery had significantly decreased risk of aspiration pneumonitis as compared with combination of metoclopramide(10mg) and pantoprazole (40mg) without any maternal and neonatal effects.

Pulmonary aspiration of gastric contents is one of the most feared complication of anaesthesia and is one of the major

causes of maternal morbidity and mortality[14] . Therefore, prophylaxis of aspiration pneumonitis should be considered a routine procedure in obstetric anaesthesia patients presenting for Caeserean section. The first and foremost measure to prevent aspiration pneumonitis is to choose regional instead of general anaesthesia for caesarean section whenever possible[15]. Regional anaesthesia has become more popular and widely practised aanesthesia technique to prevent aspiration pneumonitis and other maternal complications of G.A.[16,17]. The damage produced by aspiration of gastric contents depends upon the volume and Ph of the fluid that enters the lungs. The 'at risk' criteria of our study has a similarity to the concept of a critical pH and volume of aspirate which was introduced in 1974 by Roberts & Shirley[18] from data obtained in rhesus monkeys,the results of which were extrapolated to humans to identify patients at risk of pulmonary aspiration.

Metoclopramide,a benzamide,is a traditional antiemetic used widely in clinical practise. Similar studies done previously by Chestnut et al[5] and Lussos[13] demonstrated anti-emetic effect of metoclopramide which in turn reduced the risk of aspiration pneumonitis. Mechanism of action of metoclopramide is both central(CTZ and area postrema vomiting centres) and peripheral(GIT) anti-emetic action, by blocking dopaminergic receptors, and increasing esophageal sphincter tone and promoting gastric motility[19]

Ondansetron serotonin receptor antagonist is highly effective for prevention of aspiration pneumonitis. It's mechanism of action involve both central and peripheral mechanisms. Centrally they bind competitively and selectively to serotonin receptors in the CTZ of the central nerves system. In addition to this central effect, they also block receptors in the gastrointestinal tract, which prevents the action of serotonin and inhibits emetic syndrome[20]

Abdominal surgery and the physical disruption and manipulation of abdominal viscera that it induces may cause the release of humoral substances including 5-HT, which may stimulate 5-HT3 receptors on the afferent vagus nerves, triggering the emetic reflex especially in awake patients[21].

Our study demonstrated the efficacy of ondansetron in prevention of aspiration pneumonitis(as study drugs reduced intraoperative nausea and vomiting which predisposed to pulmonary aspiration of gastric contents) similar to study by Abouleish et al[22]. In our study ; we administered 4mg ondansetron because it has been shown that it is as effective as higher doses in preventing nausea, vomiting and in turn aspiration pneumonitis and 4mg dose of ondansetron does not induce any side effects.

In our study,we administered 4mg of ondansetron and 10mg of metoclopramide and no side effects were observed,because we used a smaller dose compared to previous reports in which there were some associated side effects[23]. In contrast to study by Pearman et al[24] that suggested 8mg of ondansetron to be more effective;our study found that 4mg of ondansetron was well-tolerated with no side effects.

Our study had striking resemblance to methodology in studies by Zahedi H[25] and Garcia[26] with regard to doses of study drugs. But unlike previous reports[13] , our study found significant difference in prophylactic effect of ondansetron and metoclopramide in prevention of aspiration pneumonitis. In our study,incidence of intraoperative nausea and vomiting was comparable to study by Pan et al[27,28].

In our study, pantoprazole, a new potent and fast acting proton pump inhibitor, was administered in both the groups. 40mg intravenously, 2 hours before inducing spinal anaesthesia. Study done by Memis D. et al[29] have concluded that I/V pantaprozole is effective in reducing gastric pH and volume.

Table 1 There were 50 patients in each group. The two groups were similar with regard to maternal charachterestics. Data is expessed as mean +- standard deviation.

MATERNAL VARIABLES	METOCLOPRAMIDE GROUP	ONDANSETRON GROUP	P VALUE
Age(years)	25.10+-3.950	25.62+-3.319	0.48
Height(cm)	148.94+-2.738	148.83+-2.496	0.989
Weight(kgs)	47.64+-3.729	47.63+-3.842	0.828
Parity	0.70+-0.839	0.62+-0.697	0.522
Socioeconomic status	3.42+-0.928	3.28+-0.701	0.412
ASA Grading Obstetric variable	1.38+-0.490	1.34+-0.479	0.699
APGAR score at 1st min	7.04+-0.402	7.16+-0.370	0.159
APGAR score at 5min	9.92+-0.340	9.94+-0.340	0.743

Table 2

OPERATIVE VARIABLES	METACLOPRAMIDE GROUP	ONDANSETRON GROUP	P VALUE
Hb(gm%)	10.00+-1.161	10.09+-0.977	0.715
RBS(mg/dl)	92.39+-9.586	90.37+-14.230	0.390
Gastric sampling time before anaesthesia	13.52+-2.206	13.70+-2.252	0.706
Gastric sampling time after anaesthesia	50.02+-9.139	49.50+-9.850	0.802
pH before anaesthesia	4.78+-1.590	5.27+-1.096	0.115
pH after anaesthesia	4.63+-1.611	5.01+-1.130	0.227
Residual gastric volume(ml) before anaesthesia	37.71+-17.141	18.88+-7.679	0.000
Residual Gastric volume(ml) after anaesthesia	18.91+-11.501	9.08+-3.652	0.000

Incidence and variables related with spinal anaesthesia for C-section.

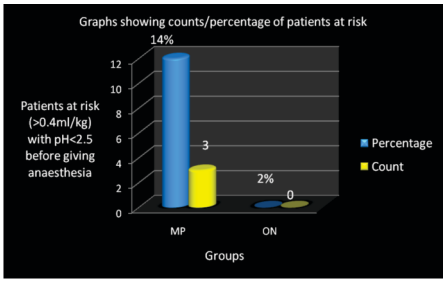
Table 3

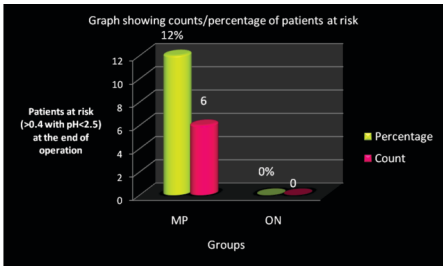
Incidence of intraoperative Nausea and vomiting	Metoclopramide group	Ondansetron group
Nausea(%)	39	19
Vomiting(%)	36	19

Incidence of adverse affects

Table 4

Incidence of adverse effects	Metoclopramide group % count	Ondansetron group %count
PDPH	1 (1)	1 (1)
O2 saturation	1 (1)	0 (0)
Bradycardia	2 (2)	3 (3)
Chest tightness	34 (34)	40 (40)
Hypotension	15 (15)	15 (15)





CONCLUSION

Our study suggests that intravenous administration of ondansetron 4mg 2hrs before the induction of spinal anaesthesia is more effective than metoclopramide 10mg in prevention of aspiration pneumonitis during spinal anaesthesia for caesarean section. The dosage of both study drugs appears safe for mother and the newborn. We recommend the preoperative use of 4mg intravenous ondansetron and 40mg intravenous pantoprazole in pregnant patients presenting for caesarean delivery receiving spinal anaesthesia.

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30. Demographic,obstetric ,and surgical variables were recorded. Statistical methods included analysis of variance for quantitative variables. Chi-square for qualitative variables, and student's t-test for paired data. The level of significance was established at $P<0.05$.
31. There were a total of 100 patients, out which 50 were in ondansetron group and 50 in metoclopramide group. All patients had an adequate level of surgical anaesthesia upto T6 level. The two study groups were matched with regard to maternal and obstetrics variables(Table 1); and operative management.(Table 2).
32. Patients were considered at risk according to criteria of gastric volume more than 0.4ml/kg with pH <2.5. A total of at risk patients were 7(14%) in metoclopramide treated group and 1(2%) in ondansetron treated group before giving spinal anaesthesia ($p=0.027$) and 6(12%) in metoclopramide treated group and 0(0%) in ondansetron treated group at the end of operation($p=0.012$). Since $p<0.05$ thus these data are statistically significant. No side effects of ondansetron or metoclopramide were observed in any of the study patients.
33. Patient's at risk according to criteria of pH <2.5 (only) before giving spinal anaesthesia were 7(14%) in metoclopramide treated group and 1(2%) in ondansetron treated group($p=0.027$). At the end of operation at risk patients were 8(16%) in metoclopramide and 2(4%) in ondansetron treated group. ($p=0.046$) .Since $p<0.05$ thus these data are statistically significant
34. Patient's at risk according to criteria of residual gastric volume of 0.4ml/kg (only) before giving spinal anaesthesia were 37(74%) in metoclopramide treated group and 15(30%) in ondansetron treated group($p=0.000$). At the end of operation at risk patients were 20(40%) in metoclopramide and 0(0%) in ondansetron treated group. ($p=0.000$) .Since p value is very less than 0.05 thus these data are statistically significant.