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EFFICACY OF I.V. GRANISETRON IN PREVENTION OF SHIVERING DURING CAESAREAN SECTION UNDER SPINAL ANAESTHESIA: A RANDOMIZED CONTROLLED STUDY.

Anaesthesiology

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ABSTRACT

INTRODUCTION: Shivering, the "big little problem" has an incidence of 19-60% following spinal anaesthesia. Shivering is not only distressing to the patients but can lead to physiological changes such as increased tissue oxygen consumption and carbon dioxide production resulting in hyperapnoea & cardiac output. Apart from physical warming for shivering, many drugs have been used for prevention of these events. We conducted a study with primary objective to evaluate the effect of Granisetron on prevention of perioperative shivering.

MATERIAL AND METHODS: A prospective randomised comparative study was conducted after institutional ethical committee's approval. A total of 60 parturients of ASA grade I & II posted for elective caesarean section were randomly allocated in two groups, 30 Patients each group, Group G (Granisetron), Group N - (Normal saline Patients were randomly allotted in to two groups, namely group G(n=30) who received Granisetron 3mg i.v. and group N (n=30) who received normal saline 3 ml i.v. Vital parameters of the patient such as Heart rate, Blood pressure, SPO2, RR and temperature were monitored at regular intervals APGAR score in neonate at 1 min and 5 min were noted.

RESULTS: Out of all, 10% (3/30) of patients in Group N and 54% (16/30) of patients in the Group G had shivering during the perioperative period that was treated with Tramadol. Six patients (20%) in Group G and 15 patients (50%) in Group N had nausea.1 and 5 minutes APGAR scores of neonates were not statistically different in the groups.

CONCLUSION: Granisetron 3mg I.V. is an effective way to prevent shivering, nausea and vomiting during cesarean delivery under spinal anesthesia with no effect on APGAR score.

KEYWORDS

INTRODUCTION

Shivering is defined as an involuntary, spontaneous, oscillatory mechanical activity of skeletal muscle associated with increased oxygen consumption, this can be as much as 600% .Shivering is bodily defence mechanism in response to early core hypothermia in an attempt to raise metabolic heat production

Shivering is a frequent complications following anaesthesia , with an incidence of between 40 to 60 %[1] and 56.7% following general and neuralgia anaesthesia respectively.

Two types of shivering occurs

a)Thermoregulatory

b)Non thermoregulatory

Thermoregulatory shivering occurs as a consequence of hypothermia and in order to maintain normothermia, vasoconstriction and shivering occurs.

Non thermoregulatory shivering is less well understood and maybe associated with

Postop - pain, release of endogenous pyrogens, uninhibited spinal reflexes and adrenal suppression. Shivering is also seen in normo thermic individuals following surgery.

RISK FACTORS

Younger age, Male sex, longer duration of surgery and anaesthesia and type of anaesthesia are associated with increased risk of PAS.

Shivering is unpleasant for the patient, anaesthesiologist and the surgeon besides being physiologically stressful for the patient. The physiologic[12] role of shivering is to provide heat, but its occurrence in relation to anaesthesia is inconsistent and incompletely understood.

Spinal anaesthesia significantly impairs the thermoregulation system by inhibiting tonic vasoconstriction, which plays a significant role in temperature regulation[2]. It also causes a redistribution of core heat from the trunk (below the block level) to the peripheral tissues. These factors predispose patients to hypothermia and shivering.[1] Spinal anaesthesia may not trigger sensation of cold as the cutaneous vasodilatation resulting from sympathetic blockade increases skin temperature leading to a sensation of warmth although accompanied by thermoregulatory shivering.[2]

Various methods are available for the control of shivering. These may be non-pharmacological or pharmacological. Intra-operative hypothermia can be minimized by any technique that limits cutaneous heat loss to the environment such as those due to cold operating room, evaporation from surgical incisions and conductive cooling produced by administration of cold intravenous fluids.

The non-pharmacological management is by external heating like the use of radiant warmer, pre warming of patients, warm fluids [3] etc. Various pharmacological treatments like i.v. opioids (i.e. Alfentanil and pethidine), cholinomimetic agent physostigmine, nalbuphine and meperidine, 5-HT3 antagonist[6] (ondansetron, dolasetron) have been used; however, side effects like hypotension, sedation, respiratory depression, nausea and vomiting, limit their use.

Our study was designed to know the efficacy of I.V. Granisetron[6] 3mg for prevention of intra op shivering.

AIM AND OBJECTIVES

Primary objective: To evaluate the effect of I.V. Granisetron on prevention of perioperative shivering.

Secondary objective: To evaluate effect of granisetron on fetus by APGAR score.

MATERIALS AND METHODS

This prospective randomised study was conducted at the **JHALAWAR MEDICAL COLLEGE, JHALAWAR (RAJASTHAN).** After approval of The Institutional Ethical Committee, written informed consent was taken from each patient. 60 patients of ASA grade II undergoing caesarean section under subarachnoid block, were included in this prospective randomized controlled study.

All cases were divided into two groups:

Group - G (n=30) inj. Granisetron 3mg[6] I.V. 5 min before spinal block.

Group - N (n=30) inj. Normal saline 3 ml I.V. 5 min before spinal block.

EXCLUSION CRITERIA:-

- Contraindication to Spinal Anesthesia
- Patient refusal
- Cradiovasular disease

- Fever or hypothermia
- Hypo or Hyperthyroidism
- Patient requiring blood transfusion
- Hypertensive disorder of pregnancy

PROCEDURE

All patients were thoroughly examined pre-operatively which included history, physical examination, all routine investigation, vital parameters of the patients (blood pressure, pulse rate, respiratory rate, temperature), examination of respiratory, cardiac, CNS and alimentary system.

The procedure was explained to the patients and a written informed consent for spinal anaesthesia and operation was taken.

Patient was taken to the OT, fasting status was confirmed, monitors were attached to the patient; base line HR, SBP, DBP, ECG and SpO2, and temperature were recorded. All operation theatres in which the operations were performed maintained at constant humidity (70%) and an ambient temperature of around 21ºC to 23ºC.

In the preoperative preparation room, nearly 500-ml crystalloid (lactated ringer's) was given intravenously (i.v.) after insertion of i.v. 18 G cannula in nondominant hand.

On arrival in the operating room, patients were monitored for mean arterial blood pressure (MAP), ECG, and pulse oximeter, and this becomes baseline monitoring.

Group G received 3mg I.V. granisetron and Group N received 3 ml normal saline 5 min before spinal block.

After sterilization of the back, spinal anesthesia was induced at L3–L4, with the patient in the sitting position, with 3. ml (15 mg) of 0.5% hyperbaric bupivacaine after confirmation of free flow of cerebrospinal fluid through a 25-G Quincke spinal needle. The patients were then placed in the supine position.

Supplemental oxygen was administered through facemask at 5 l/min. Maintenance fluids (10 ml/kg in the first 1 h and 5 ml/kg in the subsequent hours) were given at room temperature. Hemodynamic data (MAP, heart rate, SaO2 and ECG changes), sensory block, motor block, nausea, vomiting, and shivering were recorded at 5 min interval in the first 15 min and then every 15 min until the end of procedure and then every 1 h for 6 h postoperatively.

Hypotension, defined as a decrease of mean blood pressure by more than 20% from baseline, was treated with incremental IV doses of mephentermine 5 mg and IV fluid as required. Bradycardia, defined as heart rate < 50 bpm, was treated with IV atropine 0.3-0.6 mg. After the end of surgery patients were shifted to recovery room and sedation score was noted.

The grade of shivering was graded on four point scale as per wrench et al[4], which is as follows:
Grade 0: No shivering
Grade 1: One of the following: piloerection, peripheral vasoconstriction, peripheral cyanosis, but without visible muscles activity
Grade 2: Visible muscle activity confined to one muscle group
Grade 3: Visible muscle activity in more than one muscle group
Grade 4: Gross muscle activity involving the whole body

Following parameters were noted
1. Level of sensory block
2. Duration of anaesthesia and surgery
3. Skin body temperature
4. Shivering score
5. 1st and 5th minute APGAR score for neonates

INTRA OPERATIVE MONITORING -

Pulse rate, blood pressure, oxygen saturation and body temperature (in axilla) recorded before administration of spinal anaesthesia and at various time intervals throughout the surgery.

RESULTS

Both the groups were comparable with respect to age, weight, duration of surgery, duration of anaesthesia (**Table 1**).

Table 1

Parameters	Group G	Group N	p value
Age (in years)	24.9±3.82	25.1±3.97	0.8431
Weight (in kgs)	59.8±7.48	56.4±6.41	0.0637
Height (cms)	155.2±4.85	156.7±3.74	0.0516
Duration of surgery (in minutes)	42.1±7.34	44.8±9.3	0.217
Level of sensory block	T5(T5- T8)	T6(T4-T6)	

Demographic data and median of sensory block level were not statistically different between the study groups [Table 1].

There was no difference in mean core body temperature in groups. Shivering at Grade IV was not observed in any patient. 10% (3/30) of patients in granisetron and 53% (16/30) of patients in saline group had Grade III of shivering during perioperative period that was treated with tramadol.

6 patients (20%) in granisetron and 15 patients (50%) in saline group had nausea (P = 0.002). No patients in both groups needed rescue medication.

Table 2

	Group G	Group N
Shivering	3/30	16/30
Nausea – Vomiting	6/30	15/30

Table 3

Study group	Grade 0	Grade 1	Grade 11	Grade 111	Grade1V
G no (%)	24(80)	2(7)	1(3)	3(10)	0
N no (%)	3(10)	5(16)	6(20)	16(54)	0

First minute APGAR scores were 10 ± 2 and 10 ± 1 and fifth minute APGAR scores were 10 ± 1 and 10 ± 1 in granisetron and saline group, respectively (P = 0.17, P = 0.16). There were no adverse effects of granisetron on fetus after delivery as compared to saline group in regard to APGAR score.

Both the groups were comparable in terms of intra operative hemodynamic parameters. Mean heart rate was comparable in both the groups at all times and there was no incidence of significant bradycardia. Mean arterial blood pressure was also comparable in both the groups.

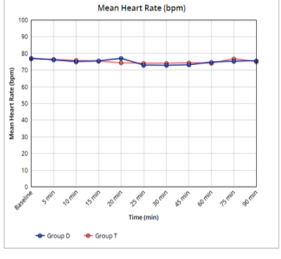

Figure:- showing comparison of mean heart rate in both the groups.

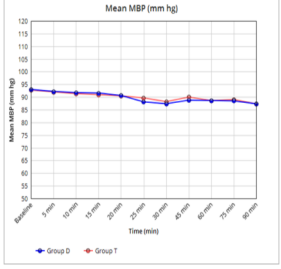

Figure:- showing comparison of mean MBP in both the groups.

DISCUSSION

The monoamine theory of thermoregulation by Feldberg and Myers in 1963 that balance of 5HT3 (hydroxytryptamine) and nor epinephrine in pre optic anterior hypothalamus controls the body temperature set point. 5HT3 can cause shivering and vasoconstriction, influences heat production and heat loss.

Shivering increases metabolic activity and oxygen consumption. It may induce hypoxemia, lactic acidosis, increased intraocular, and ICP.

It may interfere with patient monitoring such as ECG, NIBP, and SpO2. Hence, prevention of shivering is essential for better perioperative patient outcome. Various drugs have been used to treat or prevent postoperative shivering, but the ideal drug has not yet been found.[7-11]

Shivering interfere with monitoring NIBP, SPO2, PR.

Various drugs have been used for treating shivering as tramadol, pethidine, doxapram, ketamine, nefopam but with side effect as respiratory depression, sedation hypotension, post operative nausea & vomiting.

Our study show that 3 mg granisetron[6] intravenously is a effective way of preventing post spinal anaesthesia shivering during elective caesarean section as compared to normal saline. Nausea and vomiting were also reduced in these patients.

In study by mohammadi et al.[13] found that granisetron 3 mg intravenously is an effective method for prevention of spinal anesthesia induced shivering during cesarean delivery; it also reduced nausea, vomiting and no adverse effect on APGAR score.

In a study by Sagir et al[14]. on 160 patients undergoing urological surgery under spinal anesthesia with bupivacaine, the patients were randomly allocated to receive saline (Group P, n = 40), ketamine 0.5 mg (Group K, n = 40), granisetron 3 mg (Group G, n = 40) or ketamine 0.25 mg + granisetron 1.5 mg (Group KG, n = 40). The number of patients with observed shivering was 22 in Group P, 6 in Group G, 7 in Group GK and 0 in Group K. The number of patients with a shivering score of 3 was statistically significantly higher in Group P compared with the other groups. They study showed that prophylactic use of ketamine and granisetron separately and in combination was effective in preventing shivering developed during regional anesthesia that emphasize the effect of a serotonin 5-HT3 receptor antagonist on the prevention of shivering.

In a study by Kim et al[15] on 52 patients who had undergone knee arthroscopy under spinal anesthesia, romasetron, a selective serotonin 5-HT3 receptor antagonist effectively prevent shivering during spinal anesthesia that was correlated with our study.

CONCLUSION

Granisetron 3mg I.V. is an effective way to prevent shivering, nausea and vomiting during cesarean delivery under spinal anesthesia with no effect on APGAR score. Only one single drug is effective for preventing shivering nausea and vomiting.

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