ORIGINAL RESEARCH PAPER

Medical Science

PREVENTION OF POST-SPINAL SHIVERING IN CAESAREAN SECTION WITH GRANISETRON: A RANDOMIZED CONTROLLED STUDY

KEY WORDS:

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INTRODUCTION

- Spinal anaesthesia is a safe and popular technique for the various surgeries including caesarean section
- Around 40-60% of patients under spinal anaesthesia develops shivering which may increase the metabolic rate and oxygen consumption by 100-600% and may induce arterial hypoxemia, lactic acidosis, increased ICP and IOP and may interfere with the hemodynamic monitoring.
- The primary mechanism of peri-operative hypothermia and shivering during spinal anaesthesia is because of redistribution of the intravascular volume from the core to peripheral compartment below the level of sympathetic block, predisposing body to radiant heat loss.
- Evidence suggests that serotonergic system is involved in thermo-regulation of the body.
- Granisetron a serotonergic anagonist known for treating nausea and vomiting has been studied for treating post-anaesthetic shivering.
- Study done by Sajedi et al, included three drugs comparison namely Tramadol, Meperidine, and Granisetron and a placebo group, for the prevention of post-anaesthetic shivering in patients undergoing elective orthopedic surgeries under general anesthesia.

AIMS AND OBJECTIVE

- To evaluate the efficacy of Granisetron when used as prophylaxis in the prevention of post-spinal shivering in parturient undergoing caesarean section under spinal anesthesia.

MATERIALS AND METHODS

- After obtaining approval from the Research Ethics Board, RIMS, a double blinded randomized control study was done on 86 parturients who underwent caesarean section under spinal anaesthesia .
- After obtaining written informed consent, the study group were divided into two groups of 43 participants in each group
- Randomization was done by computer generated randomization table.

Inclusion Criteria

- Pregnant women of age 18 to 45 years.
- ASA I and II

Exclusion Criteria

- Patients with history of allergy to the study drug & refusal to participate
- Cardiac, respiratory diseases and kidney disorder, neurological deficit
- Local site infection
- Spinal deformity
- Bleeding disorder-platelet count <50.000/micro litre, prothrombin time>14 sec, International normalised ratio(INR)->1.5

Sample Size Calculation

Sample size is calculated using the formula ,

$$N = \frac{(U+V)^2 [P_1(100-P_1) + P_2(100-P_2)]}{(P_1 - P_2)^2}$$

Where

N = sample size
U = 0.84 (at power 80%)
V = 1.96 (at 95% confidence interval)

P_1 and P_2 is complete response of shivering 27% and 57% respectively to granisetron and 0.9% normal saline, according to Sajedi et al[4].

So, sample size calculated is 38.5.

After adding 10% dropout rate, Total sample size = 38.5+3.85 = 42.3 = 43.

Hence in each group 43 participants were recruited.

- Intervention
- Group A received IV Granisetron 2 mg diluted with 3ml 0.9% Normal Saline.
- Group B received IV 0.9% of Normal Saline 5 ml.

- Baseline vital parameter such as HR, BP (including SBP,DBP & MAP), axillary body temperature were recorded.
- Operation theater temperature were maintained at 24-28° C and recorded.
- Spinal anesthesia was performed using 25G Quincke's spinal needle keeping the patient in left lateral position with the drug Inj. Hyperbaric bupivacaine 0.5%(ANAWIN HEAVY) 2ml.
- Monitoring of the vital parameters were done at intervals of every 5 minutes for upto 20minutes than every 10 minutes for rest of the observation period.
- Patients were closely monitored for the appearance of shivering and the shivering was graded using the four point scale as per Wrench.[11]
- Inj. Tramadol 0.5mg/kg was used as rescue drug for grade 3 and 4 shivering.
- Adverse events such as nausea and vomiting and any other intra-operatively were also noted.

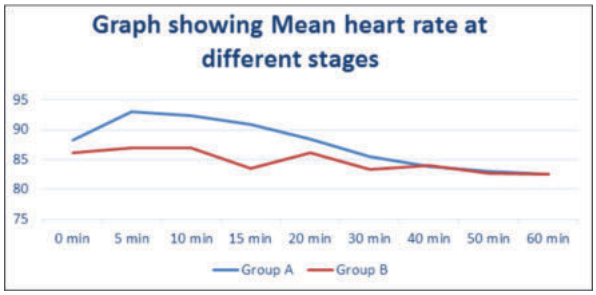
Four Point Scale Grading Of Shivering As Per Wrench.

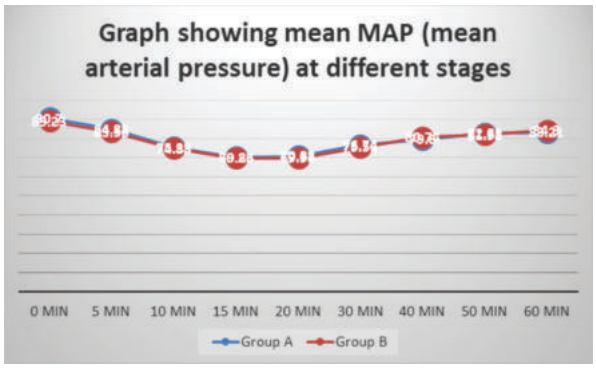
Grade 0	No shivering
Grade 1	One or more of the following:- Piloerection Peripheral vasoconstriction Peripheral cyanosis but without visible muscle activity.
Grade 2	Visible muscle activity confined to one muscle group.
Grade 3	Visible muscle activity in more than one muscle group.
Grade 4	Gross muscle activity involving the whole body

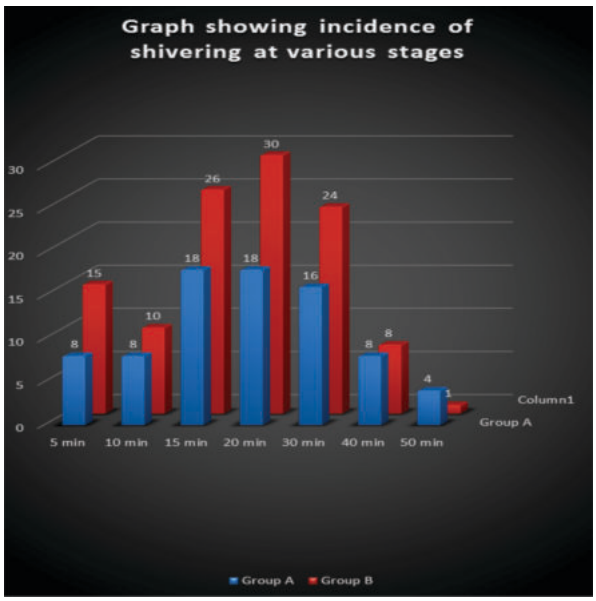
RESULTS

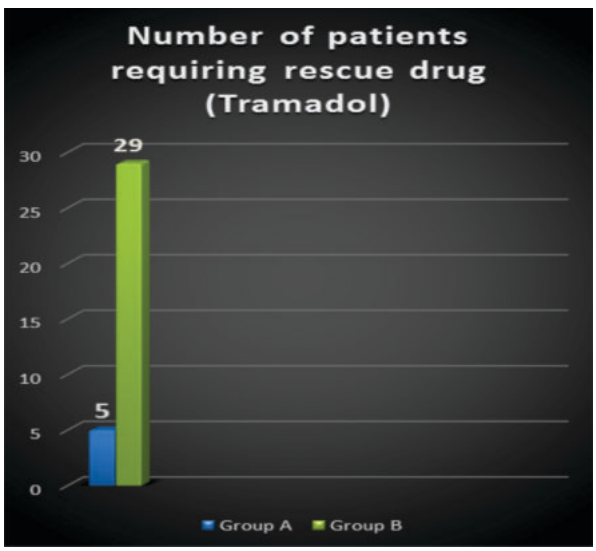
- ✓ Number of patients requiring rescue drug in Group A – 5.

✓ Number of patients requiring rescue drug in Group B – 29.









DISCUSSION

- There was no statistically significant difference between the two groups in terms of demographic parameters such as, age, weight, body temparature. The hemodynamic parameters such as heart rate, blood pressure and SpO_2 were also comparable between the two groups.
- Incidence of shivering after spinal anesthesia were found to be more in Group B compare to Group A
- The P-value of <0.05 was noticed only at observation period of 20minutes, with 49.9% of patients having shivering in Group A and 69.9% in Group B
- The grades of shivering noticed were also of 1-2 grades in Group A and less number of cases required rescue therapy with Inj.Tramadol.
- Similar finding were found also in the study done by Abdel et al[3] comparing Granisetron two dosage with placebo Normal saline0.9%.

LIMITATION

- Short duration of the surgeries as the mean duration of the surgeries were less than one hour in both the groups
- A positive control group using an agent with established anti-shivering properties, such as meperidine was not included.

CONCLUSION

- Prophylactic intravenous granisetron significantly reduced the incidence and severity of post-spinal shivering as well as prevented nausea and vomitting

Future Direction

- Effects of these drug in lengthy operations needs to be investigated in prevention of post operative shivering.
- Further studies are needed to conclude on the appropriate effective dose of Granisetron for the prevention of post spinal shivering in parturients undergoing caesarean section.
- Also, the efficacy of granisetron in the paediatric population in the post anaesthetic shivering needs to be evaluated.

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