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RESEARCH ARTICLE

A COMPARATIVE STUDY OF DEXMEDETOMIDINE AND TRAMADOL IN THEPREVENTION OF INTRAOPERATIVE SHIVERING IN PATIENTS UNDERGOING SURGERY UNDER SPINAL ANAESTHESIA

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Abstract

Background: Shivering is a common and distressing experience to patients which occurs either during or immediately after the surgery. It is defined as an involuntary, repetitive activity of skeletal muscles. Spinal anaesthesia impairs the thermoregulatory system by inhibiting vasoconstriction, and results in redistribution of core heat to the periphery from the trunk. Both these effects predispose patients to hypothermia and shivering. commonly used drugs for treatment of hypothermia are pethidine, tramadol, dexmedetomidine, clonidine.
Objective: To study the efficacy and side effects of dexmedetomidine and tramadol in the prevention of intraoperative shivering.
Materials and method: This study is on patients undergoing lower abdominal surgeries and lower limb general surgeries under spinal anaesthesia was done in basaweshwara teaching and general hospital, MR medical college gulbarga. It was a prospective study including 60 consented patients of age group 18 – 65 years belonging to American society of anesthesiologist's class I or II and posted for lower abdominal surgeries and lower limb general surgeries under spinal anesthesia were randomly allocated to Dexmedetomidine and Tramadol groups.
Results: This study included 60 patients, 30 in each group. There was statistically significant difference in group D and Group T at 15 min ($p<0.045$) and at 30 min ($p<0.003$). The rescue drug was used more in tramadol group which included 12 patient's and only 1 in dexmedetomidine group. p value for this is 0.001 which is highly significant.
Conclusion: Dexmedetomidine is more effective in the prevention of shivering when compared to tramadol. Dexmedetomidine has an added advantage of adequate reliable sedation. Hence, we conclude that Dexmedetomidine is most effective in the prevention of shivering when compared to tramadol.

Introduction:-

Shivering is defined as an involuntary, repetitive activity of skeletal muscles. The incidence of shivering varies but is very high and the incidence is approximately 40 – 50% 1.

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In patients undergoing neuraxial anaesthesia, shivering is a normal thermoregulatory mechanism as evidenced by the presence of vasoconstriction before shivering . Spinal anaesthesia impairs the thermoregulatory system by inhibiting vasoconstriction, which plays an important role in temperature regulation. Spinal anaesthesia results in redistribution of core heat to the periphery from the trunk [below the level of block] 2. Both these effects predispose patients undergoing spinal anesthesia to hypothermia and shivering.

Treatment of shivering consists of non-pharmacological and pharmacological methods. Non-pharmacological methods include use of blankets, forced air warmers and warmed fluids, maintaining operating room temperature etc. In Pharmacological methods Most commonly used drugs include meperidine, tramadol dexmedetomidine, clonidine, alfentanil, magnesium sulphate, nefopam etc.

Many studies on tramadol showed its efficacy in the treatment of shivering. Tramadol produces adverse effects like nausea, vomiting, dizziness etc., which can create further discomfort to the patient 3. Dexmedetomidine is a selective α2 adrenergic agonist and has 1600 times greater selectivity for the α2 adrenoceptor compared with the α1 receptor. It produces sedation, anxiolysis, hypnosis, analgesia, sympatholysis and has anti shivering properties .

Objective:-

1. To study the efficacy of dexmedetomidine, tramadol in the prevention of intra operative shivering.
2. To study the side effects caused by the study drugs like nausea , vomiting, sedation.

Materials and Methods:-

This study on patients undergoing lower abdominal surgeries and lower limb general surgeries under spinal anaesthesia at Basaveshwar Teaching and General Hospital, Kalaburagi during the period of 1st August 2022 to 31st January 2024[18 months], was approved by the Institutional Ethical Committee . This was a prospective study conducted on 60 patients over a period of 3 months. Pre-anaesthetic evaluation was done and written preoperative consent was obtained.

Sample Size= 60 [30 IN EACH GROUP]
The sample size was calculated as 60 based on the pilot study and statistical reports of previous studies. The patients were randomly allocated into 2groups of 30 each after applying inclusion and exclusion criteria and were named as
Group D (Dexmedetomidine 0.5µg/kg),
Group T (Tramadol 0.5mg/kg)

Inclusion Criteria:

1. ASA grade I or II
2. Age 18 to 65 years
3. Undergoing Spinal anaesthesia
4. Lower abdominal surgeries and lower limb general surgeries.

Exclusion Criteria

1. Known hypersensitivity or allergy to study drugs.
2. Cardio-pulmonary, renal , hepatic or thyroid impairment.
3. Known history of substance or alcohol abuse
4. An initial core temperature >37.5˚C or <35.5˚C
5. Blood transfusion during surgery
6. Convulsions or psychiatric disorder
7. Pregnancy and lactation

Procedure:-

Patients were shifted to the operation theatre and all monitors were connected The operation room temperature was maintained at 25 0C.

Spinal anaesthesia was given .Oxygen via face mask at 5L/min was administered to all the subjects. Inj.Ondansetron 4mg IV was given to all the patients. Surgery will commence when the level of sensory block reaches T8. Patients were monitored for a period of 120 minutes or the end of the surgery whichever was longer.

Shivering was monitored by a grading system as described by wrench
1. Grade 0: No shivering,
2. Grade 1: One or more of the following: Piloerection, peripheral vasoconstriction, peripheral cyanosis, but without visible muscle activity,
3. Grade 2: Visible muscle activity confined to one muscle group,
4. Grade 3: Visible muscle activity in more than 1 muscle group
5. Grade 4: Gross muscle activity involving the whole body

Sedation was assessed by a four point scale as per Filos et al
1. Grade 1: Awake and alert,
2. Grade 2: Drowsy, responsive to verbal stimuli,
3. Grade 3: Drowsy, arousable to physical stimuli,
4. Grade 4: Unarousable

Patient's baseline Heart rate, Blood pressure, Temperature and SpO2 was monitored and monitoring of all these parameters were done for every 5 minutes till 15 minutes and then every 15 minutes till 120 minutes.

Patients who developed shivering during the study period were given Inj.tramadol 0.25mg/kg IV bolus as rescue drug. Any other adverse effects during the study period was noted.

Statistical Analysis:
Collected data was analysed by using IBM SPSS 20.0 version software. T test and ANOVA test was used as test of significance. P value <0.05 IS CONSIDERED STATISTICALLY SIGNIFICANT.

Results:-

Most of the patients in the study belonged to age group 41-50 years. Mean age of patients in tramadol group was 39.97 years, in dexmedetomidine group it was 38.70 years

Age group	No of pts in Tramadol group	No of pts in Dexmedetomidine group
<30yrs	8	5
30-40yrs	6	10
40-50yrs	11	8
50-60yrs	5	7
Total	30	30

Number of male and female patients were 21 and 9 in tramadol group respectively.and in dexmed group 25 and 5 respectively.

The number of patients who belong to ASA I were 23 and ASA I I were 7 in tramadol group and in dexmedetomidine group ASA I 24 and ASA I I 4 patients.

None of the patient in any of the groups had shivering at 0,5 and 10 minutes. In tramadol group, at 15 minutes, 2 patients had shivering of grade 3, 3patients had shivering of grade 2 and 1 patient had shivering of grade 1. In dexmed group, there was no shivering.

At 30 minutes, 8 patients in tramadol group had grade 3 shivering and 3 patients had grade 1 shivering, and in dexmedetomidine group, 1 patient had grade 1 shivering.

At 45 minutes, 2 patients in tramadol group had grade 3 shivering and 1 had grade 1 shivering, 1 patient in dexmedetomidine group had grade 3 shivering.

At 60 minutes, 1 patient in tramadol group had grade 1 shivering, no patients in dexmed group had shivering.

At 75 minutes, 1 patient in tramadol group had grade 1 shivering, and no patient in dexmedetomidine group had shivering.

At 90 minutes,105 minutesand at 120mins no patient had shivering.

P value at 15 minutes is 0.045 which is <0.05 and is statistically significant. P value at 30 minutes is 0.003 which is <0.01 and so, highly significant. P value at other duration are not significant.

At 5 minutes, no patients in tramadol had sedation but in dexmedetomidine group, 20 patients had grade 2 sedation and 5 had grade 3 sedation scores. At 10 minutes, no patients in tramadol had sedation but in dexmedetomidine group, 10 patients had grade 2 sedation and 17 patient had grade 3 sedation. At 15 minutes, 5 patients in tramadol group had grade 2 sedation. In dexmedetomidine group, 8 and 20 patients had grade 2 and 3 sedation respectively. At 30 minutes, in tramadol group, 12 and 1 patient had grade 2 and 3 sedation respectively, In dexmedetomidine group, 7 and 22 patients had grade 2 and 3 sedation respectively.

At 45 minutes, in tramadol group, 14 patient had grade 2 sedation.in dexmedetomidine group, 7 and 22 patients had grade 2 and 3 sedation respectively. At 60 minutes, 15 patients in tramadol group had grade 2 sedation. in dexmedetomidine group, 10 patient had grade 2 and 18 grade 3 sedation scores.

At 75 minutes, 11 patients in tramadol and in dexmedetomidine group, 19 had grade 2 and 5 had grade 3 sedation. At 90 minutes, in tramadol group, 7 patients had sedation score of 2and in dexmedetomidine group, 21 patients had score 2 and 1 had score of 3. At 105 minutes, all patients in tramadol group had sedation score of 1 and 13 patients in dexmedetomidine group had a score of 2. At 120 minutes, no patient had sedation score greater than one. The P value was highly significant from 15 minutes till 105 minutes.

The mean heart rate was similar in both groups with mean heart rate around 80 bpm. The P value is > 0.05 and hence, not significant.

The systolic blood pressure(SBP) and DBP was comparable between in both groups with insignificant P values.

The axillary temperature measured during the study in all the three groups showed comparable values with insignificant P values.

In this study we used Inj Tramadol 0.25mg/kg IV bolus as Rescue drug. In our study 12 patients (40%) needed additional rescue anti shivering drug in tramadol group and1 patient in dexmedetomidine group required rescue drug. The P value for this is 0.001 which is highly significant.

In this study, 2 patients from dexmedetomidine group had a fall in systolic blood pressure to less than 90 mm Hg during the study period. Patients in other group did not have any hypotension. The P value for this is 0.715 which is not significant.

In this study, no patient from tramadol group had bradycardia, but, three patients from dexmedetomidine group had bradycardia. The P value is 0.067 which is not statistically significant.

Discussion:-

Lower abdominal and lower limb surgeries are usually done under spinal anaesthesia. One of the least addressed and a very distressing complaint in many of the patients is shivering during the surgery and in the immediate postoperative period. it is crucial to sufficiently sedate the patient following spinal anesthesia administration. The majority of sedatives cause hypotension, bradycardia, and inconsistent sedation.

Many studies were conducted in patients who underwent general anaesthesia. The number of studies conducted after spinal anaesthesia are relatively less. Various studies were conducted after the onset of shivering for its treatment. We planned a study to find out the efficiency of these drugs in the prevention of shivering. Our study was planned in a prospective and randomized manner to study the efficacy of these three drugs in the prevention of shivering. The study was double blinded. In our study the sample size was calculated as 60 .

Patients between the age of 18 and 65 were selected .

Of the two medications used in the trial, dexmedetomidine was found to be more effective than the other two in preventing shivering, as evidenced by the fact that only one patient out of 30 who received dexmedetomidine experienced shivering. This result is in accordance with the report by Lim fern et al 4 study which also had a similar outcome. Tramadol group patients had the highest incidence of shivering with 12 patients in that group had shivering grade >2. When compared with Mittal et al 5 study, which was a 2 drug comparison between dexmedetomidine and tramadol, showed that both drugs were equally effective but dexmedetomidine had a faster onset of action. Again, it was an intraoperative study where drugs were given after the onset of shivering.

Drugs used in the study for prevention of shivering can cause sedation to varying degrees. So no other sedatives or hypnotics or anxiolytics were given during the study. Undoubtedly, dexmedetomidine stood far superior to tramadol. The onset of sedation was almost 5 minutes and had a sedation score of 3 (Drowsy, arousable to physical stimuli) in most of the patients. Sedation after the bolus dose lasted for over 90 minutes and patients were comfortable during the surgery. In tramadol group, only 40% of the patients were sedated and the sedation scale was also 2. The onset of sedation was also slower and was around 15 minutes. Mittal et al 5 concluded the study as sedation due to dexmedetomidine provides additional comfort to the patient. The sedation caused by dexmedetomidine causes the patient to be in a tranquil state but follows oral commands as seen in Elvan et al 6. The sedation score was higher in dexmedetomidine group starting from 5 minutes as observed in Bozgeyik et al 7 as this has the similar result in our study too.

Side effects

Side effects	**Tramadol**	**Dexmed group**
Bradycardia	0	3
Hypotension	0	2
Respiratory depression	0	0

Hypotension and bradycardia are known hemodynamic effects of dexmedetomidine but only few patients have those side effects which is acceptable as concluded by Lim fern et al 8. Hypotension and bradycardia were seen in dexmedetomidine group but is of lesser incidence as concluded by Usta B et al9 which was the similar observation in our study also.

There are limitations in our study. Different doses of dexmedetomidine and difference between use as infusions and bolus doses are to be evaluated for preventing shivering as to which is ideal with minimum haemodynamic adverse effects, which needs further studies. The dose of tramadol used for the study at 0.5mg/kg proved to be insufficient and higher doses of tramadol at 1mg/kg may be needed to prevent shivering and further studies on different dosing of the drug in similar conditions will help in sorting out the same.

Conclusion:-

Dexmedetomidine is more effective in the prevention of shivering when compared to tramadol.

Dexmedetomidine has an added advantage of adequate reliable sedation.

Hence we conclude that Dexmedetomidine at 0.5µg/kg is most effective in the prevention of shivering when compared to tramadol.

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