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Comparison of Intravenous Dexmedetomidine and Tramadol for Post Spinal Anesthesia Shivering: A Randomized Controlled Study

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Abstract: ***Introduction: In patients undergoing neuraxial anesthesia, shivering is a normal thermoregulatory mechanism as evidenced by the presence of vasoconstriction before shivering. Spinal anesthesia impairs the thermoregulatory system by inhibiting vasoconstriction, which plays an important role in temperature regulation. Tramadol is a synthetic opioid. 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. Dexmedetomidine is a selective alpha 2 adrenergic agonist and has 1600 times greater selectivity for the alpha 2 adrenergic receptor compared with alpha 1 receptor. It produces sedation, anxiolysis, hypnosis, analgesia, sympatholysis and has antishivering properties. we compared the anti-shivering effect of dexmedetomidine with that of tramadol after spinal anaesthesia. In addition to evaluating any side effect of such medication. Methodology: 120 ASA grade I and II patients, 20-60 years old, scheduled for surgeries under spinal anaesthesia were included in this study. The patients were randomly assigned to two groups, Group D received inj. Dexmedetomidine 0.5mcg/kg and Group T received inj. Tramadol 0.5mg/kg after onset of shivering. Time taken to stoppage of shivering and recurrence were noted. The incidence of adverse effects such as nausea, vomiting, headache, bradycardia, respiratory depression, and hypotension were recorded. Results: The two groups were comparable in demographic data. Time to stopaage of shivering was earlier and recurrence was less in Group D. Group D patients were more haemodynamicaly stable than Group T. Conclusion: Dexmedetomidine is more effective in the prevention of shivering when compared with tramadol. Dexmedetomidine has an added advantage of adequate reliable sedation.***

Keywords: Shivering, Dexmedetomidine, Tramadol, Spinal Anaesthesia

1. Introduction

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.

Tramadol is a synthetic opioid developed and introduced in Germany in 1970. Many studies on tramadol showed its efficacy in the treatment of shivering. Tramadol has been shown to be effective in controlling post spinal shivering. Tramadol has got agonist properties on opioid receptors, with the mainopioid effect being mediated through μ receptors, with minimal effect on k (kappa) ands (Sigma) receptors. It activates the mono aminergic receptors of the descending spinal inhibitory pathway of pain. It also inhibits the synaptosomalnor- adrenaline and serotoninup take. The anti-shivering action of tramadolis probably mediated viaitsopiods or serotonergic and noradrenergic activity or both.1

The absolute bioavailability of tramadol is 68%. Tramadol is mainly metabolized by N and O demethylation by hepatic cytochrome P450 enzymes and by subsequent conjugation. Tramadol is demethylated to anactive metabolite, mono-O-desmethyltramadol (Ml). Peakplasma concentration of active metabolite (Ml) occur about 3 hours after an oral dose. Its elimination half time is 3-5hours.

Dexmedetomidine is a selective alpha 2 adrenergic agonist and has 1600 times greater selectivity for the alpha 2 adrenergic receptor compared with alpha 1 receptor. It produces sedation, anxiolysis, hypnosis, analgesia, sympatholysis and has antishivering properties. its role in the prevention of shivering is studies in a few trials [2, 3]. The antishivering effects of $\alpha_2$adrenoceptor agonists are mediated by binding to α2 receptors that mediate vasoconstriction and shivering. In addition to this, it has hypothalamic thermoregulatory effects[4]. Dexmedetomidine reduces the vasoconstriction and shivering thresholds. In other words, it prevents shivering by acting on the central thermoregulatory system rather than preventing shivering peripherally.

Dexmedetomidine is highly bound to plasma proteins (94%). Dexmedetomidine is extensively metabolised in the liver through glucuronide conjugation and biotransformation by the cytochrome P450 system without formation of toxic metabolites. The resulting methyl and glucuronide conjugates are excreted by the kidneys. Its elimination half time is 120-180 minutes.

The aim of the study to compare the anti-shivering effect of dexmedetomidine with that of tramadol after spinal anaesthesia. In addition to evaluating any side effect of such medication.

2. Material and Methods

The study included 120 patients undergoing surgery under

spinal an aesthesia. The study was conducted after the approval from ethical committee of the institution. Written formed consent was obtained from all patients. The patients were divided in two groups by sealed envelope method. Group–C (n=60) patients treated with inj dexmedetomidine 0.5mcg/kg, Group T-(n=60) patients treated with inj. Tramadol0.5mg/kg on post spinal intraoperative shivering. Preoperative PAC was done with all mandatory basic investigations were done. Only fit patients with ASA grade I/II, height ≥150 cms, age between 20-60 yrs, wt 50-80 kg with no known allergy to any substance were allowed to be included in study. Patients with refusal, H/O Acute infection, fever, sepsis, contraindications to spinal block, Pregnant, Chronichistory of headache and backache, Spinal deformity or infection at the local site, allergic to drug, Failed spinal block were excluded from study.

On the day of surgery randomisation was done in the preoperative patient waiting area and patient was explained about the procedure again and informed written consent was taken. Patients were shifted to operating room. On arrival, all standard monitoring techniques were attached, and baseline parameters were recorded. IV line was secured by 18 G cannula and 500 ml Ringer's Lactate solution were started. After preloading with Ringer's Lactate solution 10ml/kg, a subarachnoid block at L3-L4 intervertebral space by Quincke's 25 G spinal needle in sitting position were given, after confirmation of the subarachnoid space 3ml injection 0.5% bupivacaine heavy pushed in the space without any adjuvants.

Patients were made in supine position immediately after the subarachnoid block. The ideal level of blockade needed for the surgery was noted. All vital parameters were connected with oxygen. Vitals like BP, PR, SPO2, Temperature monitoring was done at predesigned intervals. Patients who developed shivering during surgery were given study drugs according to their group. Response to study drug and side effects if any, were noted. After completion of surgery, patients were shifted to post op ward in stable condition.

Parameters of Observation

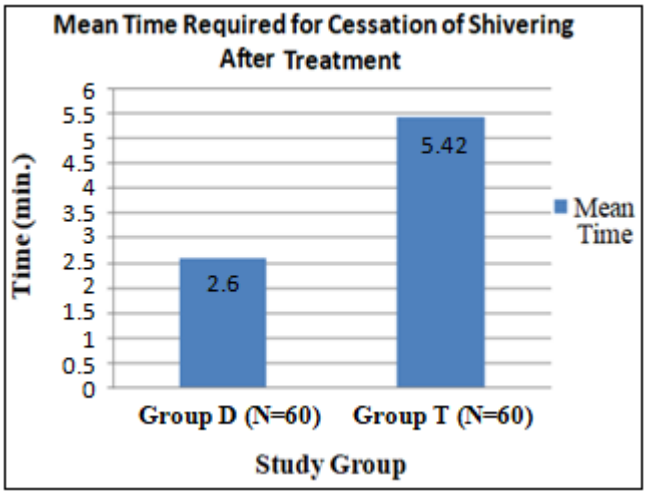
Intraoperatively patients who developed shivering were immediately given study drug according to their group and the following parameters were noted in both the croups. (**1) Mean Time Required for Cessation of Shivering after Treatment:** the duration time was noted from the time study drug was given to the time shivering stopped. (**2) Recurrencerate:** the numbers of patients who developed shivering again were noted. (**3) Side Effects:** Number of patients who developed side effects like nausea, vomiting, hypotension, bradycardia, ≥3 filo's sedation grade were noted.

3. Results

Baseline characteristics such as Age, Weight and Gender were not significantly different between the groups. Haemodynamic Parameters such as Heart rate, SpO2, respiratory rate, and Systolic, Diastolic and Mean arterial Blood Pressure at baseline were similar. Mean time of onset of shivering was 22.012 (±2.3) min in group D while in group T it was 22.414 (±2.108) min with p value of 0.320 which is statistically not significant. Mean time required for cessation of shivering was 2.60 (±0.34) min in group D while in group T it was 5.42 (±0.436) min with p value of 0.001 which is statistically significant.

Mean Time Required for Cessation of Shivering after Treatment

Group	Number of patients	Mean Time Required for Cessation of Shivering (min)		P value
		Mean	SD	
Group D	60	2.60	0.34	0.0001
Group T	60	5.42	0.436	



Nausea and vomiting was reported in Group T (n=21) when compared to Group D (n=0). Grade 3 or 4 sedation as per Filo's sedation score was found in group D (n=11) when compared to Group T (n=5).

Complication	Group D (n=60)	Group T (n=60)
Nausea	0	13 (21.66%)
Vomiting	0	8 (13.33 %)
Hypotension	0	0
Bradycardia	0	0
Filo's Sedation grade ≥3	11 (18.33%)	5 (8.33 %)

4. Discussion

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, randomized double blind manner to study the efficacy of these two drugs in the prevention of shivering. The study was double blinded wherein the patient and observer were blinded. In our study the sample size was calculated as 60based on previous studies to obtain results of the study with a power of 90% and a significance level of 0.05.

Patients between the age of 20 and 60 were selected as the paediatric patients are not suitable for spinal anaesthesia and the geriatric patients will have age related changes which can confound the variables. On analysing the demographic profile, the distribution of age, sex and height of the patients in both the groups are comparable.

Shivering

The primary outcome measure in the study included was the ability of the drugs in the study to control of shivering among the study population. The mean time required for cessation of shivering in Group D was 2.60 min with compared to Group T where it was 5.42 min. Response rate was 100% in both the groups. While recurrence rate was 3.33% (n=1) in group D as compared to group T where it was 13.33% (n=8). So Group D drug was superior in controlling shivering as compared to Group T drug.

This result is in accordance with the report by **Geeta Mittal et al (2014)** [5]study which also had a similar outcome. They also used same dosage of dexmedetomidine and Tramadol as iv injection for control of shivering. And concluded that time taken for cessation of shivering is less with dexmedetomidine when compared to tramadol. **Venkatraman R et al (2018)** [6] also concluded the same results stating shorter time required for dexmedetomidine when compared with Tramadol in control of shivering.

Side Effects

The secondary outcome measure of the study was to note the comparision of both the groups in terms of side effects like nausea/vomiting, hypotension, bradycardia, sedation. In our study there were no cases reported with hypotension or bradycardia. Nausea and vomiting was reported in Group T (n=21) when compared to Group D (n=0). Grade 3 or 4 sedation as per Filo's sedation score was found in group D (n=11) when compared to Group T (n=6). So we concluded that dexmedetomidine was better in terms of side effects when compared with tramadol. Dexmedetomidine had more arousable sedation profile than Tramadol which is in favour of patient. Our results were in accordance with **Mittal G et al (2014)** [54,] **Venkatraman R et al (2018)** [6].

5. Conclusion

It can be concluded from the study that Dexmedetomidine is more effective in the treatment of shivering when compared with tramadol in post spinal anaesthesia shivering cases. Dexmedetomidine has an added advantage of adequate reliable sedation.

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