Original Article

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A Comparative Study of Dexmedetomidine and Tramadol for Prevention of Post-Spinal Anesthesia Shivering

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Abstract

Background: Shivering is an unpleasant and stressful symptom for the patient undergoing surgery. It occurs as a thermoregulatory response to hypothermia. Shivering obscures intraoperative monitoring. It can be detrimental to patients with low cardiorespiratory reserve as it increases oxygen demand, produces arterial hypoxemia and lactic acidosis. This study aimed to evaluate the relative efficacy of intravenously administered Inj. Dexmedetomidine 0.5µg/kg in 100 ml NS and Tramadol 0.5 mg/kg in 100 ml NS and 100 ml NS as a placebo group in controlling shivering posted for lower abdominal surgeries and lower limb general surgeries under spinal anaesthesia.

Method: 120 participants, aged 18 to 65 years, of ASA Physical status I and II, scheduled for lower abdominal surgeries and lower limbgeneral surgeries under spinal anaesthesia. The patients were randomly allocated into 3 groups of 40 each and were named as group D (Dexmedetomidine 0.5µg/kg), group T (Tramadol 0.5mg/kg) and group N (100ml Normal Saline) as aplacebo. Vital parameters of the patients such as heart rate, blood pressure, spo2, temperature and shivering score, sedation score were monitored at regular intervals as per protocol. Statistical tests like Chi square test, Student's t test (unpaired and paired) were applied to the data collected.

Results: Both the dexmedetomidine and tramadol were effective in the prevention of post-spinal shivering. Dexmedetomidine had better sedation profile (P value <0.0001) without any respiratory depression and had fewer incidences of nausea and vomiting when compared to Tramadol. Thus, it can be used as a better alternate for shivering prophylaxis for patients undergoing surgeries under regional anesthesia.

Conclusion: Dexmedetomidine is more effective in the prevention of shivering when compared with tramadol and placebo (normal saline). 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 with tramadol.

Keywords: Subarachnoid Block; Dexmedetomidine; Tramadol; hyperbaric Bupivacaine; Normal Saline; Sedation; Shivering; Lower abdominal surgeries and lower limb general surgeries.

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Introduction

Shivering is a common and distressing experience to many patients which occurs either during or immediately after the surgery. It is defined as an involuntary, repetitive activity of skeletal muscles. The incidence of shivering varies but is very high and the incidence is approximately[1] 40 – 50%.

Human core temperature normally ranges from 36.50C to 37.50C. Anterior hypothalamus integrates thermal inputs from different tissues of the body and compares peripheral information with a set point or threshold value.[8] Temperature lower than this set point will result in responses to warm the body while temperatures higher will trigger reflexes to cool the body.

Studies in recent years have shown that even mild hypothermia[2] (10C–20C) can triple the incidence of adverse cardiac outcomes. An increase in surgical blood loss and increase in need for blood transfusion by 20% is also noted. All these factors leads to a prolonged hospitalization.

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]. Both these effects predispose patients undergoing spinal anaesthesia to hypothermia andshivering.[5]

Shivering during surgery leads to an uncomfortable experience to the patient along with that leads to an increase in oxygen consumption and carbon dioxide production by two to three fold. Shivering can also increase catecholamine production, lactic acidosis, intraocular pressure, intracranial pressure. Mild shivering increases oxygen consumption like that produced[7] by light exercise but severe shivering can increase oxygen consumption and metabolic rate by 100–600%. This can prove detrimental to patients with limited cardiac reserve. Shivering also creates difficulty in monitoring the patients as most of the multi parameter monitors used for anaesthesia show erroneousvalues.

Treatment of shivering consists of both non-pharmacological and pharmacological methods. Non-pharmacological methods of treatment include external heating like use of blankets, forced air warmers and warmed fluids, maintaining operating room temperature etc.[6]

Pharmacological methods for treatment of hypothermia is the next resort to treat all these patients. A number of drugs were studied and are being used. Most commonly used drugs include tramadol, dexmedetomidine, magnesium sulphate, etc.[4]

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 α2 adrenergic agonist and has 1600 times greater selectivity for the α2 adrenoceptor compared with the α1 receptor.[3] It produces sedation, anxiolysis, hypnosis, analgesia, sympatholysis and has anti shivering properties.

Material and Methods

This study on patients undergoing lower abdominal surgeries and lower limb general surgeries under spinal anaesthesia was approved by the Institutional Ethical Committee, [(IRB (HEC) No.888/2019) & (CTRI registration no. CTRI/2020/01/023040)] Government Medical College, Bhavnagar. This was a prospective study conducted on 120 patients over a period of 12 months. Pre-anaesthetic evaluation was done, recording a detailed history and performing a complete physical examination. Complete blood count, renal function test, random blood sugar, HBsAg, HCV and antiretroviral screening tests were done. After discussion of anaesthetic options, a written preoperative consent wasobtained.

Sample Size and Randomisation

The sample size was calculated as 120 based on the pilot study and statistical reports of previous studies. The group sizes (n=40) were calculated to find out the efficiency of study drugs in prevention of shivering with a power of 90% [assuming a variability (sd) of ±10%] and a significance level of 0.05. The patients were randomly allocated into 3 groups of 40 each and were named as group D (Dexmedetomidine 0.5µg/kg), group T (Tramadol 0.5mg/kg) and group N (100ml Normal Saline) as a placebo. The investigator prepared 120 lots numbered serially from 1-120. A coding sheet was also simultaneously prepared that allotted each number randomly to a group.[8] The observer is allowed to take a lot and the selected number was marked in the proforma. Then the observer is blinded for drug being infused and performs the procedure. At the end of the study coding sheet was revealed. For the serial numbers which were selected and excluded as per the exclusion criteria,

the same serial number was mixed again in the lot by the investigator.[10]

Inclusion Criteria

- ASA grade I orII
- Age 18 to 65 years
- Undergoing Spinalanaesthesia
- Patients scheduled for elective lower abdominal, lower limb, gynaecological procedures as well as caesarean section, orthopedics and plastic surgeriesunder spinal anaesthesia included in the study.

Exclusion Criteria

- known hypersensitivity or allergy tostudy drugs.
- Cardio-pulmonary, renal or hepaticim -pairment.
- known history of substance or alcoholabuse
- patients who received anypre-medication
- an initial core temperature >37.5˚Cor<35.0˚C
- blood transfusion duringsurgery
- hypo- orhyperthyroidism
- convulsions or psychiatricdisorder
- patientrefusal
- pregnancy andlactation

Materials

The following equipments, drugs and monitors were kept ready for the conduct of anaesthesia.

Equipments

- 18 Gauge IVcannula
- Sterile towels and gauze packs
- Sterile gloves
- Surgical Spirit Solution
- Sponge holding forceps
- 2 ml and 5 ml syringes
- 25G quincke needle
- IV fluids
- 100ml Normal saline with study drugs

Drugs

- Inj. Dexmedetomidine 0.5µg/kg
- Inj. Tramadol 0.5mg/kg
- Inj. 100ml Normal Salinepint
- Inj. Ondansetron 4mg
- 15 mg of 0.5% hyper baric bupivacaine
- 2ml of 2% lignocaine for local infiltration

Monitors

A multi parameter monitor with following was made available.

- Electrocardiography
- Non-invasive BloodPressure
- Pulse Oximetry
- AxillaryTemperature

An emergency drugs and all equipment as required was kept ready.

Methodology

120 consented patients of age group 18 – 65 years belonging to American society of anaesthesiologists class I or II and posted for lower abdominal surgeries and lower limb general surgeries under spinal anaesthesia were randomly allocated to any one of the three groups.

- Inj. Dexmedetomidine 0.5µg/kg in 100 mlNS
- Inj. Tramadol 0.5mg/kg in 100 mlNS
- Inj. Normal Saline 100ml

Shivering was monitored by a grading system as described by 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 musclegroup.

Grade 3: Visible muscle activity in more than 1 muscle group.

Grade 4: Gross muscle activity involving the whole body.

Sedation was assessed by a four point scale as per Filoset al

Grade 1: Awake and alert

Grade 2: Drowsy, responsive to verbal stimuli

Grade 3: Drowsy, arousable to physical stimuli

Grade 4: Unarousable

Patients 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.

Statistical Analysis

The statistical analysis was done by statistical software package SPSS 22.0 using chisquare test and ANOVA.

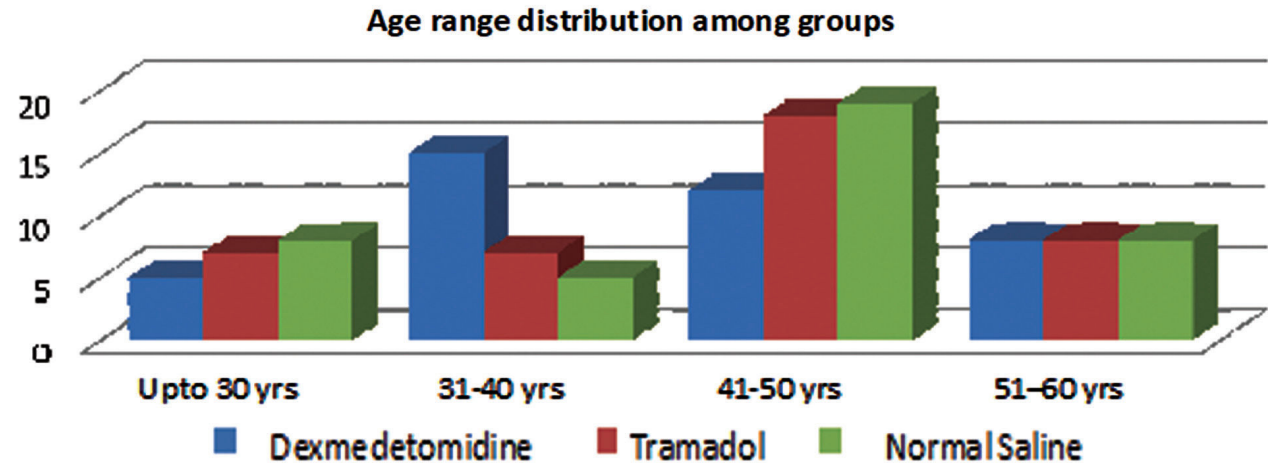

Fig. 1: Age distribution between study group.

Observation and Results

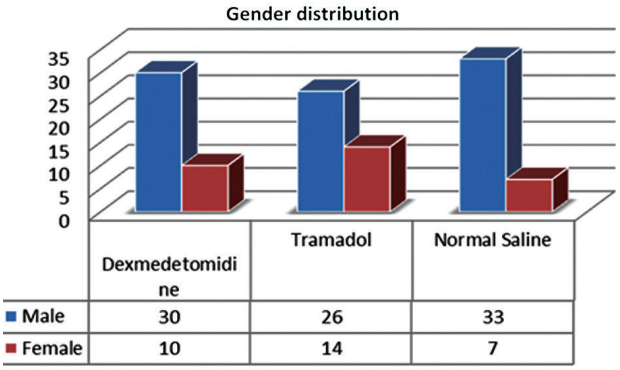

Fig. 2: Sex distribution between groups.

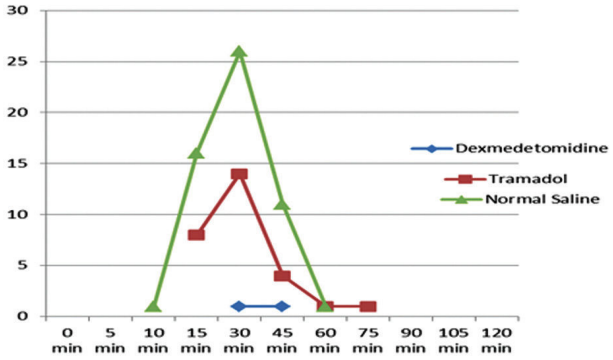

Fig. 4: No. of patients who had shivering.

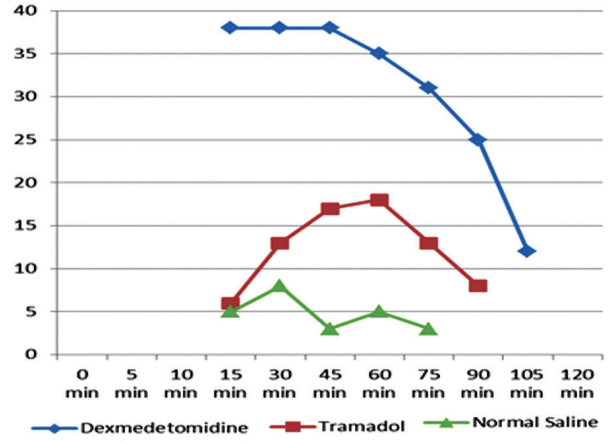

Fig. 6: No of patients sedate.

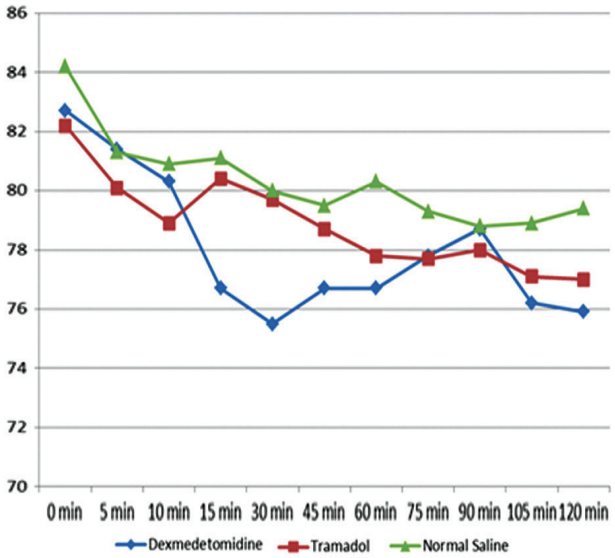

Fig. 7: Heart rate variation between the groups.

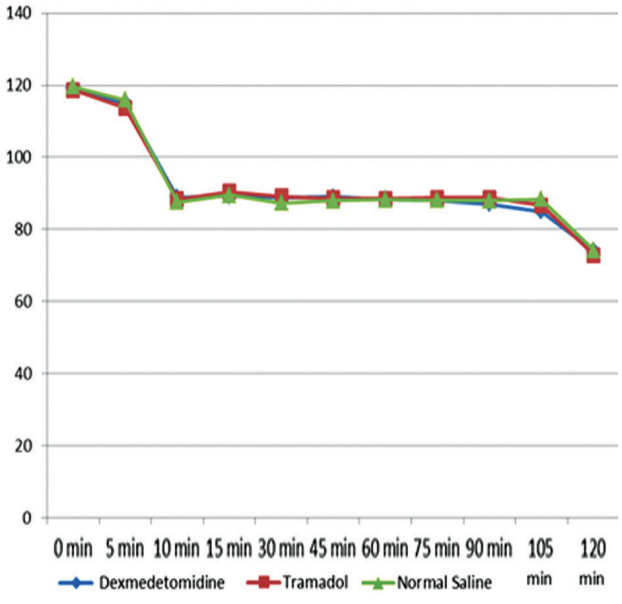

Fig. 8: Mean arterial pressure variation between the groups.

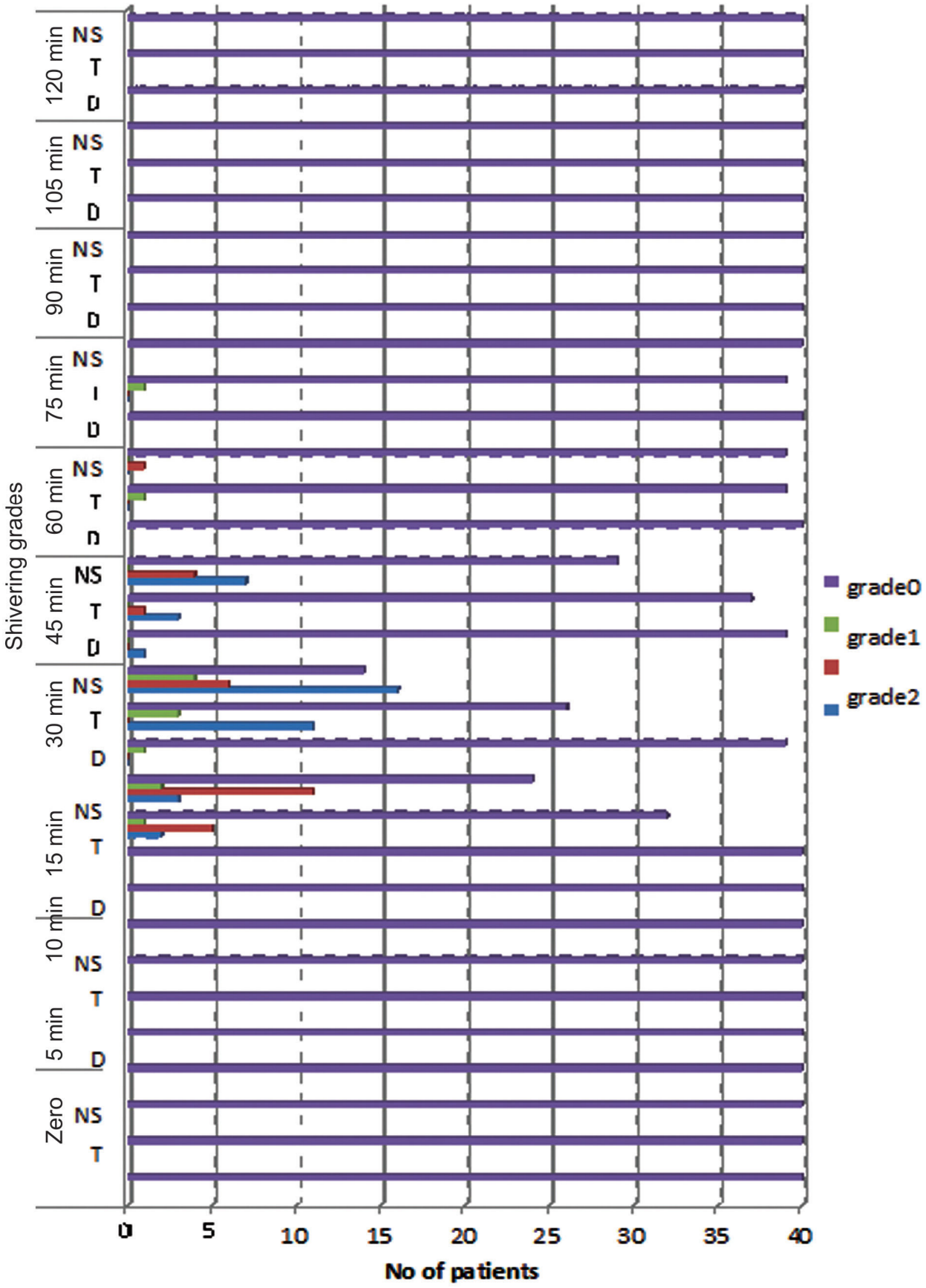

Fig. 3: Grades of Shivering in three groups.

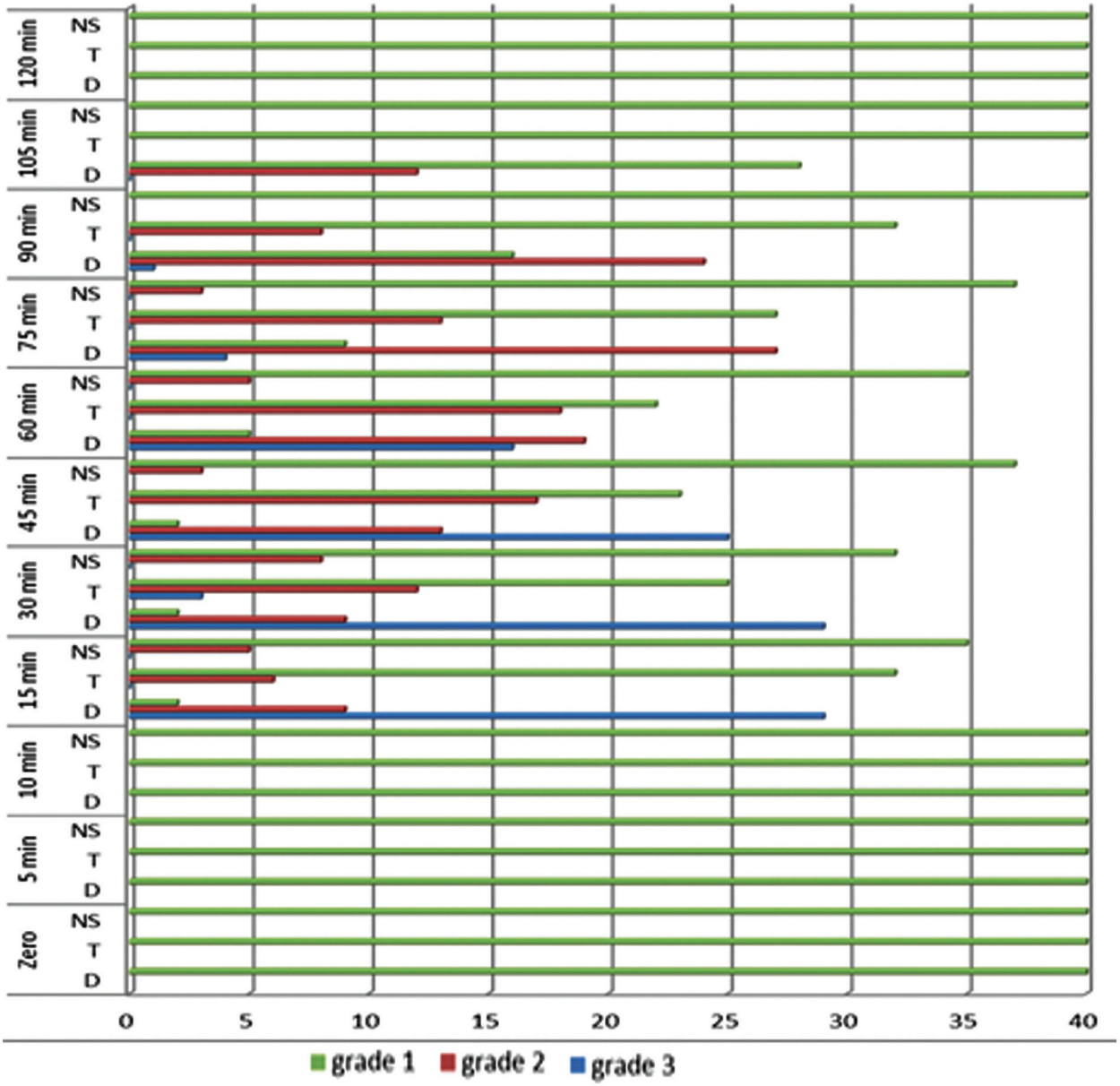

Fig. 5: Grades of Sedation.

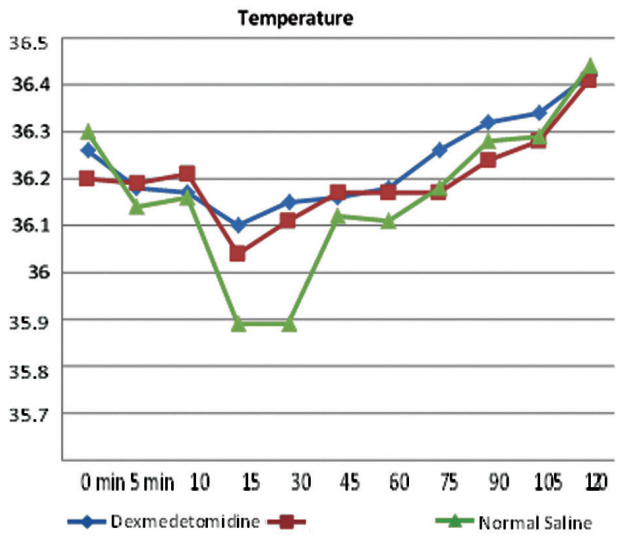

Fig. 9: Mean axillary temperature between the three groups.

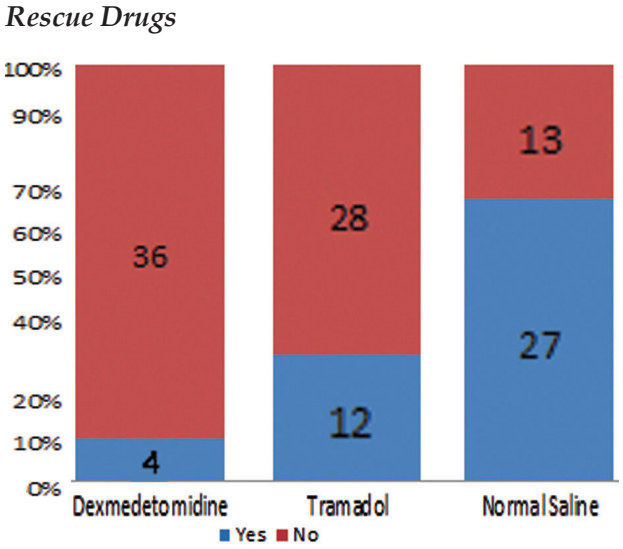

Fig. 10: Rescue drug usage.

Hypotension

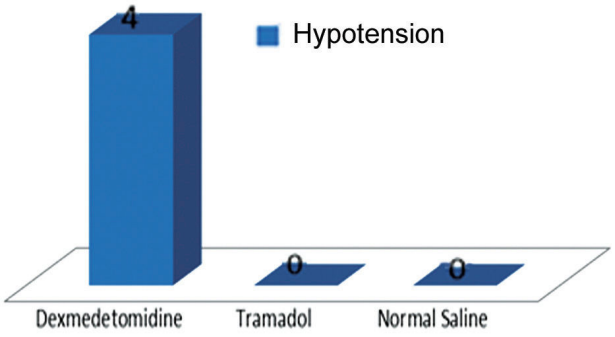

Fig. 11: Hypotension during the study.

Bradycardia

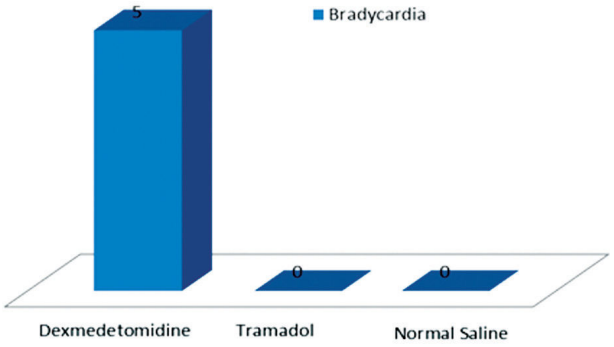

Fig. 12: Bradycardia during the study.

Discussion

Lower abdominal and lower limb surgeries are usually done under spinal anaesthesia. The most common surgical procedures done under spinal anaesthesia include inguinal hernioplasty, Trendelenburg procedure for varicose veins, excision and eversion of sac for hydrocele, split skin grafting in lower limbs, appendicectomy, hemorrhoidectomy, lateral anal sphincterotomy, lower limb debridement, VAAFT, abdominal hysterectomy, vaginal hysterectomy, LSCS, laparotomy, tubal recanalization, Orthopedic surgery like patella TBW, calcanium plate, calcanium CC screw, distal and proximal tibia plate, femur nail, femur plate, PFN, tibia nail, MM tbwetc.[6] In our current study, most of the surgeries done were hernioplasty, excision and eversion of sac for hydrocele, Trendelenburg procedure for varicose veins, STSG, lower limb debridement, appendicectomy, Orthopedic surgery like patella TBW, calcanium plate, calcanium CC screw, distal and proximal tibia plate, femur nail, femur plate, PFN, tibia nail .

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. The reason for shivering during spinal anaesthesia is multiple.[10] If patients are uncomfortable it will lead to agitation of the patient. A number of steps are usually taken to prevent shivering during the surgery and one important step is administration of drugs to prevent shivering during surgery.

Since the time the technique of spinal anaesthesia was discovered by August bier in 1898, one of the most common reason for failure of the procedure continues to be anxiety and fear from the patient which leads to failure of block and so, it is essential to adequately sedate the patient after administration of spinal anaesthesia. Most of the sedatives have problems like hypotension, bradycardia and also provides unreliable sedation.

This study was formulated in such a way to address these two problems. Dexmedetomidine, a selective α 2 agonist produces arousable sedation, hypnosis, anxiolytic and antishivering properties. It can cause decrease in heart rate and blood pressure. Tramadol is a semi synthetic opioid which controls shivering and also sedation. It has a high incidence of vomiting and in various studies, it is found to be approximately 70% 7. So, all the patients in our study were given Inj. Ondansetron 4mg I.V. irrespective of the study group.

We planned a study to find out the efficiency of study drugs in the prevention of shivering. Our study was planned in a prospective, randomized double blind manner to study the efficacy of these three drugs in the prevention[8] of shivering. The study was double blinded wherein the patient and observer were blinded. In our study the sample size was calculated as 120 based 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 18 and 65 were selected as the pediatric patients are not suitable for spinal anesthesia 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 weight of the patients in both the groups are comparable.

Conclusion

Dexmedetomidine is more effective in the prevention of shivering when compared with tramadol and placebo (normal saline). 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 with tramadol at 0.5 mg/kg. Success in any work can only be achieved by blessings, proper guidance and support given by a teacher. At the end of this task, with great sincerity and deep sense of gratitude, I thank my guide Dr. Komal S Shah, Associate Professor Department of Anesthesiology Government Medical College, Bhavnagar, who has guided me with her vast experience. I am especially thankful for her constant inspiration and suggestion during the entire phase of my work. I can never thank her enough for her advice, constructive criticism and novel suggestions throughout my study.

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I also take the privilege to express my sincere thankfulness to Dr. Hemant B. Mehta, Dean, Govt. Medical College, Bhavnagar for permitting me to carry out this study in our institution.

And I am indebted to all my subjects without whom this study could not be possible. I am also thankful to God Almighty for his blessings.

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