Section Anaesthesiology

Original Research Article

COMPARATIVE EFFECTIVENESS OF TRAMADOL AND DEXMEDETOMIDINE FOR THE CONTROL OF SHIVERING IN PATIENTS UNDERGOING SPINAL ANAESTHESIA

Dugganapalli Sushma[1], Rashmita Behera[2], Jagadish Jena[3], Sheikh Mustak Ali[3]

[1]Senior Resident, Department of Anaesthesiology, Acharya Shree Bhikshu Government Hospital, New Delhi, India.
[2]Assistant Professor, Department of Anesthesiology, Institute of Medical Sciences and SUM Hospital, Bhubaneswar, Odisha, India.
[3]Associate Professor, Department of Anesthesiology, Institute of Medical Sciences and SUM Hospital, Bhubaneswar, Odisha, India.

Received : 02/11/2023
Received in revised form : 22/11/2023
Accepted : 11/12/2023

Keywords:
Dexmedetomidine, Tramadol, Shivering.

Corresponding Author:
Dr. Sheikh Mustak Ali,
Email: drmustakali@gmail.com

DOI: 10.47009/jamp.2023.5.6.233

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5 (6); 1137-1141

Abstract

Background: Spinal anaesthesia is widely used in modern anaesthesia and has been recommended for surgery below the umbilicus, although there are a number of absolute and relative contraindications. The purpose of this research was to determine how well dexmedetomidine and intravenous tramadol suppressed trembling during spinal anaesthesia. **Materials and Methods:** Patients were divided into two groups i.e. Group T (n=30)-Receiving iv Tramadol 0.5 mg/kg and Group D (n=30)-Receiving iv Dexmedetomidine 0.5mcg/kg. Grading of shivering was done. Drowsiness, low blood pressure, slow heart rate, nausea, and vomiting were all mentioned as negative side effects. Proforma data were imported into Microsoft® Excel 2019, and then exported to SPSS v21.0 for analysis (IBM, USA). In this study, a value of P 0.05 was considered statistically significant. **Results:** The results of the study showed that patients' average ages did not differ significantly between Group D and Group T (p=0.916). The distribution by age showed no statistically significant differences either. (p=0.929). The distribution of sexes was similar in both sets of participants (P=0.438) and had similar mean body weights (P=0.637). Patients in Group D received spinal anaesthesia for a shorter average time than those in Group T (P=0.471). The average time it took to perform surgery on patients in Group D versus those in Group T did not differ significantly (P=0.563). Statistical analysis showed that the ASA scores of the two groups were not significantly different from one another (P=0.432). In Group D, patients experienced shivering on average for a shorter period of time than Group T patients (P=0.258). No statistically significant difference was found between Group D and Group T in terms of the average severity of shivering (P=0.156). Patients in Group D recovered from their shivering faster than those in Group T (P<0.0001), on average. No statistically significant difference was seen between Group D and Group T in terms of the median time to recurrence. (P=0.518). There was no significant difference in mean pulse rate, mean SBP, mean DBP and mean SPO2 values did not differ significantly between Group D and Group T. Group D showed significantly lower sedation scores than group T at 5, 10, and 20 minutes. Three patients in group D and one in group T experienced bradycardia as a result of our investigation. **Conclusion:** In conclusion, dexmedetomidine efficiently reduces shivering and causes it to stop in approximately the same amount of time as tramadol. Furthermore, it offers intraoperative sedation without any risk of nausea or vomiting.

INTRODUCTION

Spinal anaesthesia is widely used in modern anaesthesia because it has been shown to be effective, predictable, increase patient satisfaction, have a low complication rate, and provide better pain control than intravenous narcotics, allow for earlier bowel function recovery, reduce the need for systemic opioids, make breathing easier, and allow for easier participation in physical therapy.[1] Spinal anaesthetic

is commonly utilised for procedures that take place below the umbilicus, such as genital and prostate surgeries, caesarean sections, hysterectomies, and hysterectomy.[2,3] A spinal anaesthetic block is a potentially dangerous invasive procedure.[4] You can classify these problems as either minor, moderate, or major. Minor side effects include shivering, mild hypotension, nausea, vomiting, and urine retention. Post-dural puncture headache and poor spinal blocking are examples of mild effects; vertebral canal hematoma, direct needle trauma, total spinal, cardiovascular collapse, meningitis, paralysis, and death are examples of severe complications.[5,6] Twenty percent to seventy percent of patients who undergo general anaesthesia experience postoperative shivering.[7] Shivering is a common and challenging side effect of anaesthesia and temperature regulation because it involves involuntary rhythmic contractions of the skeletal muscles".[8] Post-spinal anaesthesia shivering is an involuntary, oscillatory muscle activity that occurs in the early phases of recovery. When the hyperactivity or fasciculation of the muscles of the face, jaw, or skull lasts for more than 15 seconds, we call it shivering.[9] There are several methods available for preventing and treating shivering during spinal anaesthesia. Because of its centrally acting alpha 2-adrenergic agonist property, dexmedetomidine has been used as a sedative and is known to reduce the shivering threshold. After surgery, dexmedetomidine has been shown effective in reducing or eliminating the occurrence of tremors in several investigations.[10] Tramadol, an opioid receptor agonist, inhibits the reuptake of serotonin (5-hydroxytryptamine) and norepinephrine in the spinal cord. 5HTP is stimulated, and its effects on body temperature are felt. It's a common medicine used today for the treatment of trembling. However, tramadol can also cause nausea and vomiting, which can be distressing for the patient. Therefore, a better medicine that is equally effective as tramadol but has fewer side effects needs to be developed.[11] The purpose of this research was to determine how well dexmedetomidine and intravenous tramadol suppressed trembling during spinal anaesthesia.

MATERIALS AND METHODS

The present randomized comparative study was conducted among 60 Patients who were getting spinal anaesthesia for any type of surgery in IMS & SUM Hospital, Bhubaneswar over a period of 2 years i.e. June 2020 to July 2022. Patients were divided into two groups i.e. Group T (n=30)-Receiving iv Tramadol 0.5 mg/kg and Group D (n=30)-Receiving iv Dexmedetomidine 0.5mcg/kg. Patients of age 18 to 50 years, Grades 1 and 2 of ASA, patients getting spinal anaesthesia for lower abdomen and lower limb procedures and weight 30 to 70kgs were included in the study. Patients of ASA 3,4, who refused to participate in the study, allergic reaction to study drugs, contraindications to the use of study drug, conditions where neuraxial blockade was contraindicated, patients who had received opioid analgesics before surgery, patients on anti-coagulant therapy and on emergency surgeries, patients with history of seizure and significant systemic illness.

Methodology

All patients were informed of the surgery's impending date one day beforehand. Before surgery, patients were kept off of any oral sustenance starting at midnight. After receiving written informed consent, patients were randomly allocated to either Group S or Group D using a computer-generated randomised sequence. All patients were thoroughly checked up before surgery. The patient was transferred to the elective surgery theatre, where one large bore (18 G) intravenous access was established, and 500 ml of ringer lactate IV fluid was preloaded before spinal anaesthesia was administered. At this time, vital signs such as pulse oximetry, noninvasive blood pressure, and a 5-lead electrocardiogram were being monitored to keep tabs on the patient's heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and oxygen saturation (SpO2). Using a 25G spinal needle and 0.5 percent strong Bupivacaine, spinal anaesthesia was given in the L3–4 region under aseptic conditions. Patients were continuously monitored by multipara monitors during the procedure.

Grading of shivering was done as follows:

Grade 0: No shivering

Grade 1: Piloerection, peripheral vasoconstriction, peripheral vascular cyanosis without apparent muscle activation but without further etiology

Grade 2: one muscle type only showing visible muscle activity

Grade 3: multiple muscle groups that are clearly active

Grade 4: All-over body movement using large muscles.

Subjects in the study included those who reported shivering of Grade 3 or higher. Patients who experienced shivering of Grade 3 or 4 were considered. In the case of a recurrence, we used the same scale to quantify the degree of shaking. When a patient was observed to be clearly shivering, the time at which the shivering began was recorded, and then the patient was given one of two drugs over the course of several hours. There was a careful recording of how long it took for the shivering to subside after medication was given. Additional Tramadol, Ondansetron, or Dexmedetomidine dosages were given to patients who experienced a recurrence of shivering. Drowsiness, low blood pressure, slow heart rate, nausea, and vomiting were all mentioned as negative side effects.

Statistical Analysis

Proforma data were imported into Microsoft® Excel 2019, and then exported to SPSS v21.0 for analysis (IBM, USA). Frequency and percentages were provided to help visualise the distribution of the

ISSN (O): 2687-5365; ISSN (P): 2753-6556

categorical data that was analysed using the Chi-square test. Quantitative data were expressed using mean and standard deviation, and comparisons were made using the Student t-test. In this study, a value of P 0.05 was considered statistically significant.

RESULTS

The average ages of the patients in Group D and Group T were not significantly different from each other. (36.20±8.04 years vs. 36±9.24years; P=0.916). The distribution by age similarly showed no statistically significant variation between the groups. (p=0.929). In Group D, 56.67% were male and 43.33% were female while there were 46.67% male and 53.33% female patients in Group T. The distribution of sexes did not differ significantly (p>.05) between the two groups. (P=0.438). There was no discernible variation in the patients' mean weight between Group D and Group T. (48.80±13.27 Kg vs 50.33±11.74 Kg; P=0.637).

In this study, there was no discernible difference between Group D and Group T patients' mean spinal anesthetic duration. (125.20±31.64 vs 120.40±32.29; P=0.471). Between Group D and Group T, there was no discernible variation in the patients' mean surgical duration. (72.30±22.17 vs 76.40±21.62; P=0.563). In this study, 63.33% of the patients ASA were grade 1 in Group D and the remaining 36.37% patients grade 2, similarly 53.33% patients in Group T ASA grade were 1 and remaining 46.67% patients in grade 2. Between the two groups, there was no statistically significant difference in ASA grade. (P=0.432)

There was no discernible difference between Group D and Group T patients' mean onset of shivering (68.93±33.88 vs 78.20±28.72; P=0.258). There was no discernible difference between Group D and Group T participants' mean shivering severity. (2.47±1.18 vs 2.90±1.14; P=0.156). The mean time for the patients' shivering to stop differed significantly between Group D and Group T in this study (161.23±11.45 vs 261.34±18.76; P=<0.0001). In this study, there was no discernible difference between Group D and Group T patients' mean times between recurrences. (65.45±15.65 vs 68.32±18.45; P=0.518).

There was no discernible difference between Group D and Group T participants' mean pulse rates in this investigation. (78.36±6.28 vs 80.83±6.70; P=0.147). There was no discernible difference between Group D and Group T patients' mean SBP in this study. (124.46±6.84 vs 121.46±8.40; P=0.135), Similarly, there was no discernible change in the patients' mean DBP between Group D and Group T. (75.03±5.95 vs 74.86±4.55; P=0.904). There was no discernible difference between Group D and Group T participants' mean SPO2 in this trial. (99.13±0.68 VS 99.23±0.56; P=0.539).

In our study, sedation score in group D was significantly lower at 5-, 10-, and 20-min compared to group T. In our study, 3 patients in group D and one patient in group T had incidence of bradycardia.

Table 1: Demographic data

Variable			
Age Group	**Group D (n=30)**	**Group T (n=30)**	**P value**
≤20	1	2	0.916
21-30	6	5	
31-40	12	13	
41-50	11	10	
Mean Age	36.20±8.04	36±9.24	0.929
Gender			
Male	17 (56.67%)	14 (46.67%)	0.438
Female	13 (43.33%)	16 (53.33%)	
Weight (kg)	48.80±13.27	50.33±11.74	0.637

Table 2: Data related to Spinal Anesthesia

	Group D (n=30)	**Group T (n=30)**	**P value**
Mean Duration of Spinal Anesthesia (min)	125.20±31.64	120.40±32.29	0.471
Duration of Surgery (min)	72.30±22.17	76.40±21.62	0.563
ASA grade			
Grade I	19 (63.33%)	16 (53.33%)	0.432
Grade II	11 (36.67%)	14 (46.67%)	

Table 3: Data related to Shivering.

	Group D (n=30)	**Group T (n=30)**	**P value**
Duration of onset of Shivering	68.93±33.88	78.20±28.72	0.258
Severity of Shivering	2.47±1.18	2.90±1.14	0.156
Time of Disappearance of shivering	161.23±11.45	261.34±18.76	<0.0001
Time of Recurrence	65.45±15.65	68.32±18.45	0.518

Table 4: Vital Signs

	Group D (n=30)	**Group T (n=30)**	**P value**
Pulse rate	78.36±6.28	80.83±6.70	0.147
BP			
SBP	124.46±6.84	121.46±8.40	0.135

ISSN (O): 2687-5365; ISSN (P): 2753-6556

DBP	75.03±5.95	74.86±4.55	0.904
SPO2	99.13±0.68	99.23±0.56	0.539

Table 5: Sedation score

	Group D (n=30)	Group T (n=30)	P value
0-min	2±0.0	2±0.0	-
5-min	2.02±0.181	2±0.0	<0.05
10-min	2.26±0.460	2±0.0	<0.05
20-min	2.26±0.460	2±0.0	<0.05
40-min	2.16±0.347	2.16±0.256	0.732
60-min	2±0.0	2±0.0	-
90-min	2±0.0	2±0.0	-

Table 6: Side effects

	Group D (n=30)	Group T (n=30)	P value
Bradycardia	3	1	NS
Hypotension	0	0	-
Respiratory depression	0	0	-
Nausea and vomiting	0	7	<0.05

DISCUSSION

Post-spinal shivering is a typical, unpleasant, and extremely uncomfortable after effect of spinal anaesthesia and surgery. Symptoms range from mild skin eruptions to severe, continuous spasms of the skeletal muscles. Fifty to eighty percent of the population is affected.[12]

The frequency of shivering in our sample was 46.15 percent. Our results are consistent with Kundra et al estimates of a 41% prevalence of shivering.[13] The frequency of shivering in patients undergoing surgery under regional anaesthetic has been recorded by Shukla et al.[14] Recent RCT meta-analysis indicated that the overall incidence of shivering was 34%.[15]

We found no significant difference between Group D and Group T in the time it took for patients to start shivering (68.9333.88 vs. 78.2028.72; P=0.258). In the study conducted by Mittal et al., researchers found no significant difference in the onset of shivering between the two groups.[16]

Patients in Group D shook for a much longer average period of time than those in Group T. (161.23±11.45 vs 261.34±18.76; P=0.0001). Our findings in the Kundra et al. experiment showed that dexmedetomidine was just as effective as theirs. Blaine Easley et al. looked into using dexmedetomidine to treat children's postoperative trembling.[17] In the past, research has shown that all children can stop shivering after waiting 3.50.9 minutes, however in our study, it only required 2.90.23 minutes (174.1214.366 s). Possible causes of this variation include using contrasting criteria to establish when shivering should cease. While Blaine Easley et al. recorded their results as the percentage of patients who had stopped shivering after one minute, two minutes, etc., and then extrapolated the time needed for cessation of shivering from these data.[17] In our research, however, we timed how long it took before participants stopped shivering (in seconds). In addition, our sample size of 60 patients was significantly bigger than that of 24 employed by Blaine Easley et al.[17] Few studies have utilised dexmedetomidine, so we don't know for sure when the shaking will end. Patients experiencing post-spinal anaesthesia shivering can be effectively treated with either dexmedetomidine (0.5 g/kg) or tramadol (0.5 mg/kg), as reported by Mittal et al. While both drugs were effective in halting shivering, dexmedetomidine's effect was more rapid.16 As an added bonus, our results have been supported by the work of Sarwer et al.[18]

We found that 17% (n=5) of people on tramadol experienced shivering, while 13% (n=4) of people taking dexmedetomidine did. Data from our study showed a slightly higher frequency of shivering recurrence in the tramadol group compared to that of Maheshwari et al,[19] significantly higher for dexmedetomidine, as reported by Bajwa et al.20 who discovered that patients given 1 mcg/kg of dexmedetomidine intraoperatively still experienced trembling 5% of the time. Having the patient sedated during surgery is beneficial for the surgeon as well as the patient.

In our investigation, patients who were given dexmedetomidine had widely varying levels of sedation. The Ramsay sedation score at 5, 10, and 20 minutes post-medicament administration showed a statistically significant difference between the two groups. This finding is consistent with that of earlier research by Bajwa et al,[20] and Mittal et al,[16] who noted a strong sedative effect in the dexmedetomidine-treated group. One outcome that defies logic was reported by Karaman et al,[21] by low-sedation (dex) morphine substitute. The tramadol group showed no evidence of drowsiness, which is in line with the results of the aforementioned studies.

Anesthesiologists work to keep patients' hemodynamics within a safe range so that they can do surgery. That's really important for the patient's well-being. We found that this attribute stayed within the specified range throughout our study. Both groups-maintained blood pressure, heart rate, oxygen saturation, and respiratory rate readings within 20% of their respective starting points. frequency of bradycardia There was one person in the tramadol

ISSN (O): 2687-5365; ISSN (P): 2753-6556

group and three in the dexmedetomidine group. Studies by Al-Mustafa et al. and others found that patients given dexmedetomidine were more likely than those given a placebo to experience bradycardia and require treatment with atropine.[22] However, the incidence reported by them was higher, being 16%.

CONCLUSION

In conclusion, Dexmedetomidine efficiently reduces shivering and causes it to stop in approximately the same amount of time as tramadol. Furthermore, it offers intraoperative sedation without any risk of nausea or vomiting.

REFERENCES

1. Sinha R, Gurwara AK, Gupta S. Laparoscopic surgery using spinal anesthesia. JSLS: Journal of the Society of Laparoendoscopic Surgeons. 2008 Apr;12(2):133.
2. Kokki H. Spinal blocks. Pediatric Anesthesia. 2012 Jan;22(1):56-64.
3. Bors E, Comarr AE, Moulton SH. The role of nerve blocks in management of traumatic cord bladders: spinal anesthesia, subarachnoid alcohol injections, pudendal nerve anesthesia and vesical neck anesthesia. The Journal of Urology. 1950 Apr 1;63(4):653-66.
4. Wedel DJ, Horlocker TT. Regional anesthesia in the febrile or infected patient. Regional Anesthesia & Pain Medicine. 2006 Jul 1;31(4):324-33.
5. Sonras SA, Komplikasyon GN. Spinal subdural hematoma: a rare complication of spinal anesthesia: a case report. Turk Neurosurg. 2008 Jul;18(3):324-6.
6. Pugely AJ, Martin CT, Gao Y, Mendoza-Lattes S, Callaghan JJ. Differences in short-term complications between spinal and general anesthesia for primary total knee arthroplasty. Jbjs. 2013 Feb 6;95(3):193-9.
7. Eberhart LH, Döderlein F, Eisenhardt G, Kranke P, Sessler DI, Torossian A, Wulf H, Morin AM. Independent risk factors for postoperative shivering. Anesthesia & Analgesia. 2005 Dec 1;101(6):1849-57.
8. Choi KE, Park B, Moheet AM, Rosen A, Lahiri S, Rosengart A. Systematic quality assessment of published antishivering protocols. Anesthesia & Analgesia. 2017 May 1;124(5):1539-46.
9. Crossley AW. Six months of shivering in a district general hospital. Anaesthesia. 1992 Oct;47(10):845-8.
10. Usta B, Gozdemir M, Demircioglu RI, Muslu B, Sert H, Yaldız A. Dexmedetomidine for the prevention of shivering during spinal anesthesia. Clinics. 2011 Jul 1;66(7):1187-91.
11. Kundra TS, Kuthiala G, Shrivastava A, Kaur P. A comparative study on the efficacy of dexmedetomidine and tramadol on post-spinal anesthesia shivering. Saudi J Anaesth. 2017 Jan-Mar;11(1):2-8. doi: 10.4103/1658-354X.197344. PMID: 28217045; PMCID: PMC5292846.
12. Begum R, Islam R, Sarker PC, Karmakar KK, Alam AM. Prophylactic use of ketamine hydrochloride for prevention of post-operative shivering. Journal of BSA. 2008 Jan;21(1):29-35.
13. Kundra TS, Kuthiala G, Shrivastava A, Kaur P. A comparative study on the efficacy of dexmedetomidine and tramadol on post-spinal anesthesia shivering. Saudi J Anaesth. 2017;11(1):2-8. doi:10.4103/1658-354X.197344.
14. Shukla U, Malhotra K, Prabhakar T. A comparative study of the effect of clonidine and tramadol on post-spinal anaesthesia shivering. Indian journal of anaesthesia. 2011 May;55(3):242.
15. Park SM, Mangat HS, Berger K, Rosengart AJ. Efficacy spectrum of antishivering medications: meta-analysis of randomized controlled trials. Critical care medicine. 2012 Nov 1;40(11):3070-82.
16. Mittal G, Gupta K, Katyal S, Kaushal S. Randomised double-blind comparative study of dexmedetomidine and tramadol for post-spinal anaesthesia shivering. Indian J Anaesth. 2014;58(3):257-262. doi:10.4103/0019-5049.135031
17. Blaine Easley R, Brady KM, Tobias JD. Dexmedetomidine for the treatment of postanesthesia shivering in children. Paediatr Anaesth. 2007;17(4):341-346. doi:10.1111/j.1460-9592.2006.02100.x
18. Sarwer F, Jha AK, Raman A, et al. Comparative study of dexmedetomidine and tramadol for control of post-spinal anesthesia shivering. Eastern Journal of Medical Sciences. Published online 2016:54-58.
19. Maheshwari BS, Shah SK, Chadha IA. Tramadol And Butrophanol For Control of Shivering: Randomised Double Blind Comparative Study. Journal of Anaesthesiology Clinical Pharmacology. 2008;24(3):343-346.
20. Bajwa SJS, Gupta S, Kaur J, Singh A, Parmar S. Reduction in the incidence of shivering with perioperative dexmedetomidine: A randomized prospective study. J Anaesthesiol Clin Pharmacol. 2012;28(1):86-91. doi:10.4103/0970-9185.92452
21. Karaman S, Günüşen İ, Ceylan M, et al. Dexmedetomidine infusion prevents postoperative shivering in patients undergoing gynecologic laparoscopic surgery. Turkish Journal of Medical Sciences. 2013;43(2):232-237. doi:10.3906/sag-1204-80
22. Al-Mustafa MM, Badran IZ, Abu-Ali HM, Al-Barazangi BA, Massad IM, Al-Ghanem SM. Intravenous dexmedetomidine prolongs bupivacaine spinal analgesia. Middle East J Anaesthesiol. 2009;20(2):225-231.

ISSN (O): 2687-5365; ISSN (P): 2753-6556