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A Study of Dexmedetomidine Vs Tramadol for Post Operative Analgesia in Patients Undergoing Spine Surgeries.

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Abstract

Background: Spinal procedures are generally associated with intense pain in the initial postoperative period. Adequate pain management in this period has been seen to correlate well with improved functional outcome, early ambulation, early discharge, and preventing the development of chronic pain. A multiple array of pharmacological options exists for the effective treatment of post spinal surgery pain, but each of these drugs possesses inherent advantages and disadvantages which restricts their universal applicability. In this study, we aim to evaluate and compare the analgesic effects of Dexmedetomidine and Tramadol in patients who are undergoing spine surgeries.

Materials and Methods: 50 patients posted for elective lumbar laminectomy and discectomy under general anesthesia were included in the study. Randomization was done using the sealed envelope technique; accordingly patients were allotted to group D (for dexemedetomidine) and group T (Tramadol) with 25 patients each. We evaluated the analgesic efficacy , pain intensity and quantify the requirement of rescue analgesia in the postoperative period in the two groups, hemodynamics in peri-operative period in patients using dexmedetomidine and tramadol for postoperative analgesia in spine surgeries.

Results: Comparison of intraoperative heart rate of both groups showed that there were no statistically significant differences in heart rates between the two groups (p value > 0.05). Comparison of intraoperative systolic blood pressure of both groups showed that there were no statistically significant differences in systolic blood pressure between the two groups. (p value > 0.05) . Comparison of intraoperative diastolic blood pressure of both groups showed that there were no statistically significant differences in diastolic blood pressure between the two groups. (p value >0.05) . Comparison of intraoperative Mean arterial blood pressure of both groups showed that there were no statistically significant differences in systolic blood pressure between the two groups. (p value > 0.05) . Comparison of intraoperative oxygen saturation of both groups showed that there were no statistically significant differences in oxygen saturation between the two groups. (p value > 0.05) . Comparison of VRS pain score in both group showed that it was statistically significant at 3,4,5,6,7,8,9,10 hours in the tramadol group,p value in these hours were < 0.05 . First dose rescue analgesic requirement were comparable on both the groups and was found statistically significant at 8 hour-3 patients (12%) in tramadol group required rescue analgesia and was found statistically significant .

Conclusion: Dexmedetomidine has superior analgesic efficacy when compared to tramadol in patient undergoing spine surgeries.

Keywords: Dexmedetomidine, Tramadol, postoperative pain, spinal surgeries.

Background

Post operative pain management is very essential for all the major surgical procedures. Post operative pain is more frightening for the patients. It increases hospital stay and poor surgical outcomes. Spinal procedures are generally associated with intense pain in the postoperative period, especially for the initial few days[1]. Adequate pain management is required in this period. Accurate measurement of postoperative pain is imperative to provide optimum pain relief. There are various methods to treat post operative pain like continuous infusion epidural analgesia, patient controlled analgesia, parenteral systemic opioids like fentanyl, remifentanil, morphine and tramadol, NSAIDS like paracetamol , alpha 2 agonists like dexmedetomidine ,NMDA receptor antagonist like ketamine and gabapentin. Spinal surgery encompasses a wide variety of procedures (elective and emergency) in a range of patients from the very young to the elderly. Patients may suffer from multiple co-morbidities and systemic diseases. Surgery imposes further stresses due to significant blood loss, prolonged anaesthesia, and difficulties in acute postoperative pain management. Despite improvements in pain management therapies and drugs, a single drug or therapy is yet to be labeled as the ―gold standard‖ for pain control following spinal surgery and wide-ranging differences exist in treatment modalities among different centers. Both clonidine and dexmedetomidine have emerged as effective agents for providing analgesia post spinal surgery. Use of these agents as adjuncts to local anesthetics, opioids or their combination enhances the analgesic properties. Hemodynamic stability and lack of respiratory depression are added advantages of these drugs. Clonidine has been utilized for providing postoperative analgesia through various methods. Dexmedetomidine presumably acts on the nociceptive cascade and prevents the sensitization of nociceptors present in the dorsal horn. Tramadol is frequently prescribed opioid for analgesia both intraoperatively and in postoperative period. Most importantly, unlike other opioids, tramadol has no clinically relevant effects on respiratory or cardiovascular parameters. Tramadol may prove particularly useful in patients with poor cardiopulmonary function, including the elderly, the obese and smokers, in patients with impaired hepatic or renal function, and in patients in whom non-steroidal anti-inflammatory drugs are not recommended or need to be used with caution. Parenteral or oral tramadol has proved to be an effective and well tolerated analgesic agent in the perioperative setting.

Materials and methods

This present study was a prospective, randomized comparative double blinded study; randomization was done using closed envelops method. The study was initiated after obtaining permission from the Institutional Ethical Committee. It was carried out on 50 patients within the age group of 18-60 years of both sex with ASA (American Society of Anesthesiologist) status I or II undergoing various elective spine procedures under general anaesthesia in Yenepoya Medical College & Hospital, Mangalore, from October 2017 to december 2017.Patients of ASA physical status III ,IV, emergency cases, heart rate <60, severe pulmonary, hepatic, renal disease, heart disease, not willing to participate in study are excluded.

As a part of preoperative preparation patients were asked to be nil per oral ,adequate premedication was given and patient was educated about pain scale which will be used postoperatively .Study drug preparation was done using Tramadol in 2ml ampoule containing 50mg/ml diluted in 0.9% Normal saline 48ml to get tramadol 2mg/ml strength in 50 ml syringe used for group T and dexemedetomidine in 2ml ampoule containing 50mcg/ml diluted in 0.9%

Normal saline 48ml to get dexemedetomidine 2mcg/ml strength in 50 ml syringe.

Anaesthetic Technique

When the patient arrived into operation theatre pre-induction monitors (ECG, SPO2, NIBP) were attached and baseline vitals were recorded and patient is kept under monitoring. Two 18G I.V cannula were secured, one IV access for Dexmedetomidine/Tramadol infusion and other for i.v anaesthetic drug and fluid administration. In both group, patients were preoxygenated with 100% Oxygen for 3 minutes and 2mcg/kg of IV fentanyl was given. Anaesthesia will be induced with inj. Propofol 2-3 mg/kg IV titrated to the loss of verbal response. Mask ventilation were assessed and if adequate proceeded with neuromuscular blockade of inj. vecuronium 0.1 mg/kg IV. After 3 minutes of assisted ventilation with oxygen, endotracheal intubation done with an appropriate-sized endotracheal tube. Post induction capnograph and temperature monitor were attached. General anesthesia will be maintained with nitrous oxide: oxygen 1:1 and sevoflurane 1-2% titrated to achieve a MAC of 1 with controlled ventilation using a closed circuit. Patients hemodynamic parameters were noted 10 min after induction and just prior to turning prone. After turning prone patients vitals were recorded. In Group D, Dexmedetomidine diluted with 0.9% Normal saline to a concentration of 2mcg/ml in 50 ml was administered as IV infusion by a syringe pump at a dose of 0.2 mcg /kg/hr. In Group T, Tramadol diluted with 0.9% Normal saline to a concentration of 2mg/ml in 50 ml was administered as IV infusion by a syringe pump at a dose of 0.2 mg /kg/hr. Muscle paralysis will be maintained with intermittent bolus of 0.01 mg/kg of IV vecuronium. Intraoperatively Systolic blood pressure(SBP),Diastolic blood pressure(DBP) Mean arterial blood pressure (MAP),Heart Rate, Spo2 were monitored and noted in proforma every 30minutes till end of surgery. For both groups, intraoperative side effects like bradycardia (HR < 60 beats/min), hypotension (systolic blood pressure decrease more than 20% from the baseline and/or SBP< 80 mm Hg), hypertension (systolic blood pressures increase more than 20% from baseline and/or SBP > 150mmHg) were noted. Bradycardia will be treated with Inj Atropine 0.6 mg IV. Hypotension will be treated initially with I.V. crystalloids followed by titrated boluses of phenylephrine 1-2mcg/kg and patients going in for refractory hypotension not responding to fluids/ phenylephrine boluses will be excluded from the study, infusions discontinued and treated with inj. Dopamine 5-20 mcg/kg/hr titrated according to blood pressure. Intraoperatively Inj. Acetaminophen 20mg/kg IV were given to both groups 45 minutes after the start of surgery as adjuvant analgesia. Additional analgesia will be given with IV fentanyl 1-2mcg/kg. At the end of the surgery, patient is made supine with due care and precautions, residual paralysis were antagonised with Inj. Neostigmine 0.05 mg/kg IV and Inj. Glycopyrrolate 0.02 mg/kg IV. The patient was extubated once the standard criteria for extubation have been met. Vitals were recorded. The study drug were continued. The patient is then transported to the post anaesthesia care unit under ECG, SPO2 monitoring with study drug infusion. In the Postoperative ICU, patient will be monitored for 7hr for analgesic requirement and hemo-dynamics. Postoperative pain will be evaluated at 1hr intervals using a 10 point verbal rating scale (VRS) (0: no pain; 10: severe pain) and dexmedetomidine /Tramadol infusion were stopped after 7hrs of continuous infusion. Rescue analgesia (Inj.Paracetamol 15mg/kg IV if interval between last dose more than 6 hours or Inj Diclofenac 1mg/kg IV diluted in 100ml normal saline over 30 min) which will be administered if pain score >3 or if the patient requested

analgesia during pain assessment. Postoperatively time for first dose rescue analgesia and total dose rescue analgesia were noted. If any side effects like Nausea, vomiting were treated and noted.

Statistical analysis

The Statistical software namely SPSS 18.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc. Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven1s test for homogeneity of variance has been performed to assess the homogeneity of variance. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher Exact test used when cell samples are very small. Suggestive significance (P value: 0.05<P<0.10).

Results and observations

The patients participating in the study were between 18-60 yrs of age. The mean ages of patients were 47.92 ± 10.75 and 45.04 ± 11.39 years respectively in Group D and Group T. The student t test (p> 0.05) showed that the groups were comparable based on their age. The mean weight of the patients were 67.28±9.73 kg and 65.32±6.60 kg respectively in Group D and Group T. The student t test (p> 0.05) showed that the groups were comparable based on their age. Comparison of intraoperative heart rate of both groups showed that there were no statistically significant differences in heart rates between the two groups (p value > 0.05) . Comparison of intraoperative systolic blood pressure of both groups showed that there were no statistically significant differences in systolic blood pressure between the two groups. (p value > 0.05) . Comparison of intraoperative diastolic blood pressure of both groups showed that there were no statistically significant differences in diastolic blood pressure between the two groups. (p value >0.05) . Comparison of intraoperative Mean arterial blood pressure of both groups showed that there were no statistically significant differences in systolic blood pressure between the two groups. (p value > 0.05) . Comparison of intraoperative oxygen saturation of both groups showed that there were no statistically significant differences in oxygen saturation between the two groups. (p value > 0.05) . Comparison of VRS pain score in both group showed that it was statistically significant at 3,4,5,6,7 hours in the tramadol group,p value in these hours were < 0.05 as shown in table 2. First dose rescue analgesic requirement were comparable on both the groups and was found statistically significant at 8 hour-3 patients (12%) in tramadol group required rescue analgesia and was found statistically significant .

Discussion

The present study prospective randomised comparative study was designed to evaluate the analgesic efficacy of dexmedetomidine and tramadol in postoperative opioid for patient undergoing spine surgeries under general anaesthesia. Analgesic efficacy was evaluated using VRS pain scale and need for first dose rescue analgesia. Along with analgesic efficacy intraop hemodynamics like Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure, Oxygen saturation and 12hr postoperative hemodynamics studied and also sedation using Ramsay sedation score noted50 patients ASA 1 & 2 were included in the study, 25 in each group, group D received Dexmedetomidine infusion , at a dose of 0.2mcg/kg/hr without loading dose and was continued postoperatively for first 12 hours. There were no significant difference with respect to Age , Sex, Weight

and ASA status, both groups baseline demographic data were comparable In both the group 99st intraoperative and postoperative hemodynamic parameters like Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure, Oxygen saturation were comparable and no significant changes seen. Other studies, fischer et al [2] conducted similar study and concluded that repetitive bolus group requested more analgesic than continuous infusion group. Arain et al [3] conducted prospective randomised study for 34 patients scheduled for major in patient elective surgery randomised study for 34 patients scheduled for major inpatient elective surgery randomised to get Dexmedetomidine or Morphine, study concluded that statistically significant postoperative pain reduction in the early postoperative hours and also says that Dexmedetomidine has a potential advantage of reducing myocardial work and beneficial effect in ischemic heart disease patients, similarly in our study postoperative pain intensity as evaluated by VRS pain scale, there was statically significant changes between the groups with respect to postoperative pain at 3hr,4hr,5hr,6hr,7hr.Dexmedetomidine was found superior than tramadol with respect to postoperative analgesic efficacy in the early postoperative hours.

Hwang et al [4] conducted a randomised control study to compare postoperative analgesic efficacy of Dexmedetomidine versus Remifentanyl in patients undergoing post lumbar interbody fusion and study concluded that VAS score in Remifentanyl group was significantly higher than that in the dexmedetomidine group at immediate and late postoperative period, similarly in our study VRS score was significantly higher in Tramadol group at postoperative 3-10 hours.

Blaudzen et al [5] conducted a meta analysis on effect of perioperative systemic a agonist on postoperative morphine consumption and pain intensity and found that there was statistically significant decrease in opioid consumption in dexmedetomidine group from the second postoperative hour until 24 hr with clonidine decrease was from 12th hr until 24 hr postoperatively.At 24 hr the decrease in cumulative morphine equivalents was approximately 25 percent with clonidine, it was 30 percent with dexmedetomidine.This degree of morphine sparing is stronger than what has reported with acetamiophen but weaker than with ketamine or NSAIDs, they also found that α agonist administration reduced early postoperative nausea.similarly in our study need for rescue analgesia for tramadol group compared to Dexmedetomidine group was statistically significant at 8 hours.

Jose R et al [6] investigated the effect of postoperative sedation on development of delirium in patients undergoing cardiac procedures randomly compared with Dexmedetomidine, Propofol or Midazolam and they suggest that postoperative sedation with Dexmedetomidine was associated with significantly lower rates of postoperative delirium and lower care cost, similar in our study we compared Dexmedetomidine and tramadol for postoperative sedation for 1st 12 hr, we found lower Ramsay sedation score in Dexmedetomidine than tramadol which was not statistically significant.

Tobias et al [7] conducted a study to evaluate the effect of Dexmedetomidine on intraoperative motor and somatosensory evoked potential monitoring during spinal surgery and they concluded after obtaining baselineSSEP and MEP, bolus dose of Dexmedetomidine caused significant decrease in MEP amplitude that there was no significant change in MEP or SSEP following Dexmedetomidine administration. They also suggest that monitoring depth of anaesthesia was very important as it may adversely effect SSEP and MEP value.

Mohamed Amr Abusabaa et al [8] conducted a study comparing epidural dexmedetomidine, tramadol, or neostigmine for postoperative pain after major breast surgeries.They concluded that dexmedetomidine is superior to tramadol and neostigmine in providing hemodynamic stability, excellent attenuation of stress response, prolonged postoperative analgesia, and early mobilization with minimal undesirable side effects.

MS Saravana Babu et al [9] conducted a study comparing epidural ropivacaine with dexmedetomidine and ropivacaine with clonidine for post-operative analgesia in patients undergoing spine surgeries .They concluded thatepidural route provided acceptable analgesia in spine surgeries and avoided the need of IV analgesics in either group. Dexmedetomidine is a better neuraxial adjuvant compared with clonidine for providing early onset and prolonged post-operative analgesia and stable cardiorespiratory parameters.

Neeta Abhay Kavishva et al [10] conducted a comparative study of intravenous patient-controlled analgesia with tramadol alone and tramadol plus dexmedetomidine for major lower abdominal surgery.They concluded that the combination of dexmedetomidine with tramadol reduces the tramadol requirement for postoperative analgesia.

Conclusion: we conclude that dexmedetomidine has superior analgesic efficacy when compared to tramadol in patient undergoing spine surgeries .

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Table 1:

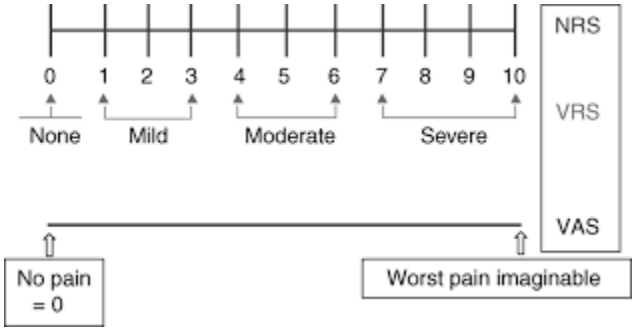

Table 2

VRS(Pain)	Group D(N=25)	Group T(N=25)	P Value
1 hr			
1.	**20(80%)**	**21(84%)**	**0.713**
2.	**5(20%)**	**4(16%)**	
2hr			
1.	**24(96%)**	**23(92%)**	**0.552**
2.	**1(4%)**	**2(8%)**	
3 hr			
1.	**24(96%)**	**18(72%)**	
2.	**0(0%)**	**7(28%)**	**0.12**
3.	**0(0%)**	**0(0%)**	
4.	**1(4%)**	**0(0%)**	
4hr			
1	**23(92%)**	**16(64%)**	
2	**1(4%)**	**6(24%)**	**0.054**
3	**0(0%)**	**0(0%)**	
4	**1(4%)**	**3(12%)**	
5hr			
1	**24(96%)**	**14(56%)**	**0.001**
2	**1(4%)**	**11(44%)**	
6hr			
1.	**23(92%)**	**14(56%)**	
2.	**2(8%)**	**9(36%)**	**0.013**
3.	**0(0%)**	**0(0%)**	
4.	**0(0%)**	**2(8%)**	
7hr			
1.	**25(100%)**	**19(76%)**	
2.	**0(0%)**	**5(20%)**	**0.033**
3.	**0(0%)**	**0(0%)**	
4.	**0(0%)**	**0(0%)**	
5.	**0(0%)**	**1(4%)**	