

Original Article

A PROSPECTIVE RANDOMIZED CONTROL STUDY COMPARING POST-OPERATIVE ANALGESIA AFTER WOUND INFILTRATION WITH ROPIVACAINE ALONE AND ROPIVACAINE WITH DEXMEDETOMIDINE IN SPINE FIXATION SURGERIES WITH PROSTHESIS

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ABSTRACT

Objective: To compare postoperative analgesia after wound infiltration with ropivacaine alone and ropivacaine with dexmedetomidine in spine fixation surgeries with prosthesis. This is a prospective randomized double-blind clinical trial.

Methods: A total of 60 patients were recruited in this study based on inclusion and exclusion criteria. Written informed consent was obtained from every patient. Patients were randomized by computer-generated randomization into two groups. Group R received an injection ropivacaine 0.5% in a dose of 2 mg/kg for wound infiltration, while those in group RD received an injection dexmedetomidine 0.5mcg/Kg along with ropivacaine 0.5% 2 mg/kg for wound infiltration at the end of surgery. Patients were observed till 24 h postoperatively. VAS score, duration of analgesia, total rescue analgesic consumption, any side effects were observed and noted at specified time intervals.

Results: VAS score was found to be lower in group RD at any time interval till 24 h postoperatively, with a p value = 0.004. Time to first rescue analgesic demand was 281.43±11.1 min in group R while it was 912.57±52.61 min in group RD. This difference was found to be statistically significant (p value = 0.01). In group R, 200±39.39 mg of tramadol was consumed as rescue analgesic, while in group RD 136.67±28.42 mg of tramadol was consumed till 24 h post-operatively. Tramadol consumption was found to be significantly low in group RD (p =0.007). No significant side effect was observed in either of the groups.

Conclusion: Based on our study, we conclude that dexmedetomidine as an adjuvant to ropivacaine for local wound infiltration improves analgesic profile, increase analgesia duration and reduces opioid requirement in patients undergoing spine surgeries with prosthesis.

Keywords: Wound infiltration, Ropivacaine, Dexmedetomidine

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INTRODUCTION

The early success of pharmacologic endeavours in pain mitigation involved extensive use of opioids. Although reasonably successful, opioid were often associated with systemic complications like nausea, vomiting, respiratory depression, sedation, delayed recovery of bowel functions and hyperalgesia.

In the past decade, researchers have witnessed a significant shift towards multimodal analgesia, with a target of reducing opioid requirement for post-operative analgesia. Regional analgesia is gaining more and more attention as the primary technique in postoperative pain management. Single wound infiltration with local anesthetic or continuous local anesthetic infusion through catheters placed into the surgical wound have recently been re-introduced as integral parts of multimodal analgesia schemes for postoperative pain control following various surgical procedures under general or regional anesthesia [1].

Wound infiltration only with local anesthetic agent does not translate into major or consistent pain relief after lumbar fusion surgery [2]. Co-administration of adjuvants with local anesthetic drugs prolong the duration of sensory-motor block and limit the cumulative dose requirement of local anesthetics. Adjuvants have the potential to improve efficacy of perineural blocks and decrease local anesthetic toxicity. The armamentarium of local anesthetic adjuvants have evolved over time from classical opioids to a wide array of drugs including several groups having varying mechanisms of action.

Dexmedetomidine, an alpha-2 adrenoceptor agonist has sedative, anxiolytic and analgesic properties. Dexmedetomidine has shown to increase the duration of block and postoperative analgesia when added to local anesthetic in regional blocks [3]. Several studies are done on effect of adding dexmedetomidine to local anesthetic for

perineural blocks. There is a lack of data on post-operative analgesic effect of dexmedetomidine combined with local anesthetic for local wound infiltration for spine prosthesis surgeries.

Crippling postoperative pain linked with spine surgeries not only hampers patient's normal daily activities but also lengthens their hospital stay. Inadequately treated acute pain can lead to long standing pain. So, allaying postoperative pain in these patients has become a substantive component in neuroanesthesia to expedite neurological recovery [2].

Thus, we conducted this study to compare the analgesic efficacy of ropivacaine alone versus the combination of ropivacaine and dexmedetomidine for surgical wound infiltration in spine fixation with prosthesis surgeries. The primary objective of this study was to compare post-operative Visual Analog Pain Scale (VAS) Score. Also, we compared total opiate consumption during the first 24 h among the two groups, time to first rescue analgesia demand, and any side effects as secondary objectives.

MATERIALS AND METHODS

This is a prospective randomized double-blind clinical trial. After obtaining due approval from the institutional ethical review board, we approached the patients fulfilling our inclusion criteria to participate in this study. The patients of either sex of age group 18 y to 50 y weighing 50-80 kgs undergoing spine prosthesis surgery under general anaesthesia were recruited for this study. Patients with a history of allergy to study drugs, long-term use of analgesic medication (2 mo for narcotic medication and 3 mo for NSAIDS), tramadol or anti-epileptic drugs as pregabalin, patients who refused consent, patients with coagulopathies, patients with history of thromboembolic events, patients with altered mental status or serious psychiatric disorders, dural breach were excluded from this

study. A thorough pre anaesthetic check-up (PAC) and review of investigations was done well ahead of the surgery. The PAC time was also utilised to explain VAS score to the patients. Patients who granted consent for participation were randomized by computer-generated randomization into two groups. Group R received an injection ropivacaine 0.5% in a dose of 2 mg/kg for wound infiltration, while those in group RD received injection dexmedetomidine 0.5mcg/Kg along with ropivacaine 0.5% 2 mg/kg for wound infiltration at the end of surgery. Each group had 30 patients each. The surgeries were done under general anaesthesia in prone position with endotracheal tube and control ventilation. Intraoperatively, injection fentanyl and injection paracetamol were used for analgesia. The study drugs were prepared by anesthesiologist and administered by the operating surgeon before final wound closure. The patients were reversed and extubated and shifted to post-operative care unit. This time point was considered as 0 h and VAS score was noted, following at 1, 3, 6 12 and 24 h post operatively. Time to first rescue analgesic demand was noted in minutes. At the end of observation period amount of total rescue analgesic consumed was noted. Patients were also observed for any side effects like sedation, bradycardia, hypotension, nausea, vomiting, etc. This was a double blinded study as neither the patient nor the data collector were aware of the group allocated.

Statistical analysis

Sample size was calculated to be 30 patients for each group at 95% confidence interval with 80% power to verify expected minimum

difference of 2.0 (1.67-2.33) in mean visual analog score in both groups at 6 h post-operative period. Statistical analyses were done using SPSS Trial version 23 and primer. The qualitative data were expressed in form of proportion and the quantitative data expressed as mean and standard deviations. The difference in proportion was analyzed by using chi square test and the difference in means was analyzed using the student's t' test (difference in differential analysis). The level of significance were kept 95% for all statistical analysis.

RESULTS

In this study, a total of 60 patients were recruited, divided in two groups of 30 each. Both groups were identical in demographic profile (table 1). In Group RD, 24 out of 30 (80%) patients had an average VAS score of 1 for 6 h after surgery; while in Group R, 60% patients had an average VAS score of 2. Group R had 10 patients with VAS score more than 3 while Group RD had none of them for 6 h postoperatively. VAS score was found to be lower in group RD at any time interval till 24 h postoperatively, with a p value = 0.004. Time to first rescue analgesic demand was 281.43±11.1 min in group R while it was 912.57±52.61 min in group RD. The difference was found to be statistically significant (p value =0.01). In group R, 200±39.39 mg of tramadol was consumed as rescue analgesic while in group RD 136.67±28.42 mg of tramadol was consumed till 24 h post-operatively. Tramadol consumption was found to be significantly low in group RD (p = 0.007). No significant side effect was observed in either of the groups.

Table 1: Demographic profile of two groups

Parameter	Group R	Group RD	P Value
Age (years)	39.17±15.64	36.00±18	0.22
Gender (% Male)	43.33	53.33	0.6
Weight (kgs)	68.30±11.68	64.57±9.71	0.06

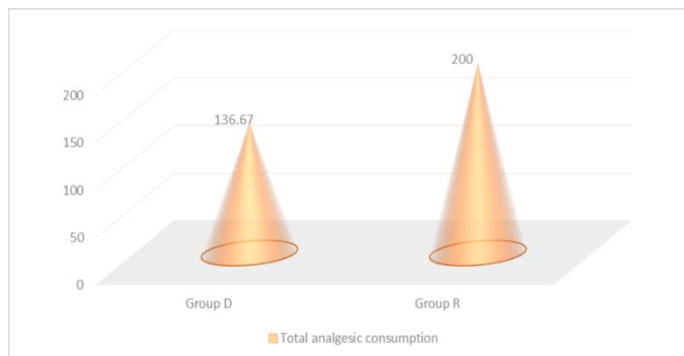


Fig. 1: Comparison of analgesic consumption between the study groups

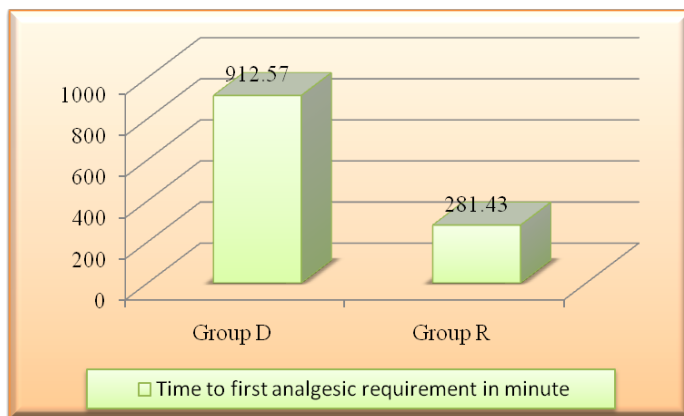


Fig. 2: Comparison of time to first analgesic requirement in minutes between the study groups

Table 2: Comparison of time to first analgesic requirement in minutes between the study groups

	Group D		Group R				p-value		
	Mean	SD	Minimum	Maximum	Mean	SD		Minimum	Maximum
Time to first analgesic requirement in min	912.57	52.61	855.00	995.00	281.43	11.10	260.00	300.00	<0.001

Table 2 depicts the time to first rescue analgesia among the groups. The mean time to first rescue analgesia was significantly shorter in the R group 912.57±52.61 min than D group 281.43±11.10 min (P<0.001).

DISCUSSION

We conducted this study with an aim to evaluate if addition of dexmedetomidine to ropivacaine for local wound infiltration in spine prosthesis surgery improves analgesia and reduces opioid requirement in the postoperative period. In this study, a total of 60 patients were included, who were randomly allocated in two groups. Group R received an injection of ropivacaine 0.5% alone at the end of surgery for local infiltration while group RD received an injection of dexmedetomidine in addition to the injection ropivacaine. Results of this study showed that the mean VAS score was lower at all the time intervals in the combination group i.e., group RD as compared to ropivacaine alone group i.e., group R. Our findings corroborated with those of Daiki M *et al.* [4] who conducted a study comparing analgesic efficacy of ropivacaine alone with the combination of ropivacaine and dexmedetomidine for wound infiltration in lumbar discectomies. In our study, the time of first rescue analgesic demand was significantly shorter in group R (281.43±11.10 min) as compared to that in group RD (912.57±52.61 min). Similar findings were observed in various studies done on patients undergoing various other surgeries [1-5]. The mean total rescue analgesic consumption in our study was found to be significantly lower in group RD (136.67±28.67 mg) as compared to group R (200±39.39 mg), with *p* value<0.001 (fig. 1). This was consistent with a study done by Bhardwaj S *et al.* [5] in which they found that adding dexmedetomidine to ropivacaine for surgical incision infiltration decreases the total rescue analgesic demand by 72% in 24 h postoperative period.

No significant adverse effects, such as bradycardia or hypotension, were noted in any of the group, and none of them required any medical intervention of any type. Similar observations were found by Mitra S *et al.* [1]

Though our study showed better results of adding dexmedetomidine with ropivacaine for local wound infiltration, we had certain limitations. Ours was a single-center study with small sample size. Surgeries were conducted by different surgeons, thus causing differences in tissue handling and local anesthetic infiltration. A control group receiving placebo injection was lacking, and we did not follow the patient for the incidence of chronic pain.

CONCLUSION

Based on our study, we conclude that dexmedetomidine as an adjuvant to ropivacaine for local wound infiltration improves the analgesic profile, increases analgesia duration and reduces opioid requirement in patients undergoing spine surgeries with prosthesis.

FUNDING

Nil

AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICT OF INTERESTS

Declared none

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