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USG guided Paravertebral block with Dexmedetomidine in Percutaneous Nephrolithotomy surgeries for Post operative Analgesia - A Randomized Study

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Abstract

Background: Postoperative analgesia following renal surgeries is mandatory to allow early mobilization of the patients, effective coughing, to reduce the incidence of respiratory complications and shorten the hospital stay. Usage of NSAIDS has limitations as these patients may have potential renal problems. Paravertebral block (PVB) with local Anaesthetic, for renal surgeries is considered equivocal to epidural analgesia. PVB may facilitate smooth recovery, provide prolonged postoperative analgesia and reduce the requirement of postoperative opioid. Hence, for longer duration of analgesia we hypothesized that addition Dexmedetomidine to local Anaesthetic may provide longer duration of analgesia.

Methods: Elective Percutaneous Nephrolithotomy (PCNL) surgeries in ASA I/II patients belonging to the age group of 18-60 years, either sex were divided into two groups according to the postoperative analgesia received. Group B received bupivacaine and Group BD received Dexmedetomidine as an adjuvant to bupivacaine in ultrasound guided paravertebral block. Primary outcomes were to compare the time of request for rescue analgesia of both groups, total dose of rescue analgesic required in first 24 hours and postoperative pain relief. Hemodynamic parameters along with Visual Analog Scale and Ramsay sedation score were noted for the first 24 hours.

Results: A total of 72 surgeries were included in the study of which 70 were analysed on the listed parameters. It was concluded that the duration of analgesia obtained with Dexmedetomidine was (10.942 ± 0.725) hours compared to that achieved without it (7.228 ± 0.725) hours. The total dosage of rescue analgesia required (Tramadol) over first 24 hours postoperatively was (356.857 ± 72.872) mg with Group B, significantly higher than Group BD (252.285 ± 34.221) mg. Moreover, Hemodynamic parameters were significantly better maintained ($p<0.05$) with Dexmedetomidine.

Conclusion: Addition of Dexmedetomidine as adjuvant provides prolonged duration of analgesia with a better quality of pain relief postoperatively in PCNL surgeries.

Keywords: Paravertebral block, Dexmedetomidine, Postoperative analgesia, Ultrasound guidance.

Introduction

Percutaneous Nephrolithotomy (PCNL) is the most frequently performed surgical procedure for complex upper urinary tract calculi. Although the skin incision for PCNL appears to be small, the intensity of intraoperative and postoperative pain is significant owing to soft tissue injury [1]. Human body response towards the postsurgical pain has been proven to cause detrimental effect on the patient‘s homeostasis and recovery. The outcome of surgery is affected by the metabolic, hormonal and cardio-respiratory responses induced by pain. Therefore, intra and post-operative analgesia is an integral part of anaesthesia practice. Pre-emptive analgesia is superior than the similar analgesia provided postoperatively [2]. Appropriate and adequate treatment for this pain reduces the incidence of complications, hospitalization and costs. For postoperative analgesia in PCNL, systemic opioids, NSAIDS and Neuraxial methods like epidurals and paravertebral blocks may be used or local anaesthetics may be administered along nephrostomy tube [3]. Usage of opioids may lead to severe adverse effects such as respiratory depression, sedation, nausea, vomiting, constipation and opioid induced hyperalgesia. Moreover, tolerance and physical dependence, can occur even at prescribed doses [4] [5] [6]. Regional Anaesthetic measures protect the patient from such adverse effects by reducing the need and consumption of postoperative opioids, especially in a period of opioid epidemic [7] [6]. Usage of NSAIDS has limitations as these patients may have potential renal problems.

USG guided Thoracic Paravertebral Block is a feasible and superior option amongst the multimodal analgesic techniques. It can be supplemented with general anaesthesia to provide adequate surgical anaesthesia as well as postoperative analgesia. This technique provides stable hemodynamic status with unilateral somatic and sympathetic blockade.

Dexmedetomidine, a relatively new agent, is a highly selective alpha-2 receptor agonist, has been used widely for sedo - analgesia in diagnostic and therapeutic procedures, and also as an adjuvant to local Anaesthetic to provide postoperative analgesia.

Its use is progressively increasing with more studies being published about its beneficial effects. Studies indicate that it reduces incidence of nausea, vomiting, agitation, and shivering in the postoperative period [8].

For postoperative analgesia in renal surgeries para vertebral block with local Anaesthetic is considered equivocal to epidural analgesia. But local Anaesthetic provides 6- 7 hours of pain relief in postoperative period. So for longer duration of analgesia we hypothesized that addition Dexme detomidine to local Anaesthetic may provide longer duration of analgesia. Therefore, the objective of the present study is to examine effect of addition of Dexmedetomidine (1µg/kg) to Bupivacaine (0.25%) in Thoracic PVB for postoperative analgesia after PCNL surgery.

Materials and methods

This prospective, randomized study was done after approval from Institute of Kidney Disease and Research Centre (IKDRC-ITS) Ethical Committee. Written informed consent was obtained from all the patients scheduled for routine PCNL surgery at the institute. Study was conducted for period of 1 year and 6 months, which includes 12 months for data collection and six months for data entry, data analysis and report preparation.

All patients belonged to the age group of 18-65 years with American Society of Anaesthesio logists physical status I or II posted for PCNL surgery. Patients were

excluded if they refused TPVB, were obese (BMI > 35kg/m^2), had infection at the site of block or a spine deformity, were hypersensitive to local Anaesthetic drugs or dexmedetomidine, or had a coagulopathy. Patients were also excluded if they had advanced Cardiovascular or respiratory disease, or a history of psychiatric illness. Preoperatively patients were taught how to evaluate their own pain intensity using Visual Analogue Scale (VAS). Scored from 0 to 10 (where 0 = no pain and 10 = worst pain imaginable). After arrival into operation theatre, basic monitors Spo2, NIBP and ECG were applied. Patient was explained about the procedure and informed consent was taken. General anesthesia was induced with Inj. Glycopyrrolate (0.004mg/kg) Inj. Fentanyl (1µg/kg) i. v, Inj. Thiopentone (4mg/ kg) and Inj. Scoline (1.5mg/kg) i. v. Intubation was done with cuffed portex ET tube and anesthesia was maintained with Isoflurane, Atracurium besylate (0.08-0.1mg/kg), nitrous oxide and oxygen keeping FiO2 0.5%. After induction of general anesthesia, the study subjects were randomised 1:1 into the two groups using closed envelope method. The patients and all staff involved in patient management and data collection were unaware of the group assignment. The researchers involved in preparing the study drugs were not involved in patient monitoring or outcome analyses.

A thoracic paravertebral block was performed with the patient in the prone position after PCNL was completed and nephrostomy tube inserted. Ultrasound probe was prepared by sterilization. High frequency Linear probe (L1,25) was placed on the spinal process of T10 vertebra, on the sagittal plane for imaging. The probe was lateralized and ribs and transverse process were imaged as hyper echoic structures along with the acoustic shadows under them. The superior costotransverse ligament and pleura were also visualised in the anterior aspect. A 22G 100mm block needle (Stumuplex ® Ultra, Braun, Germany) was used for injection. The needle tip was visualized real time using USG (in plane technique) and the needle was advanced until superior costotransverse ligament was passed. [9] To confirm the position of needle, a 2mL saline injection was made and anterior movement of parietal pleura was observed. No cerebrospinal fluid, blood or air was observed under negative aspiration and 20 mL of 0.25% Bupivacaine in Group B (n=35) and 0.25% Bupivacaine with 1µg/kg Dexmedetomidine diluted to total volume 20mL injected in Group BD (n=35). Both groups received 1000mg IV Paracetamol.

At the end of the operation, 0.05mg/kg Neostigmine and Inj. Glycopyrrolate 0.4mg administered for antagonism of muscle relaxant. When the patient satisfied extubation criteria in the operating room, they were shifted to Recovery Room after tracheal extubation. Patient was then transferred to post anesthesia care unit and monitored for vital signs. Visual analogue scale for pain immediately and then 1 hourly till first 4 hours, 2 hourly till 8th hour, 4 hourly till 12th hour, 12 hourly till 24 hour postoperatively. Rescue analgesia with Inj. Tramadol 2 mg/kg intravenously when (VAS $\geq$ 4) was given.

The primary outcome was- Time to the first request of analgesia (duration of postoperative analgesia) using Visual Analogue Scale, Total analgesic requirement in first 24-hour, Postoperative pain relief. The secondary outcomes were to observe Hemodynamic changes and side-effects.

Statistical analysis

Sample size was calculated by using Open EPI software. A pilot study was done with 20 patients, and considering the mean ± SD of time until request of rescue analgesia with confidence interval 95% and Power 80; sample size was calculated. On that basis, n=35 patients in each

group, we compared analgesic efficacy of dexme detomidine addition to bupivacaine and bupivacaine alone in thoracic paravertebral block.

Data was collected by using a structured pre-prepared case proforma to enter the patient details, detailed clinical history including presenting complaints, past history, family history, physical and systemic examination of patients.

The statistical analysis was done by chi square test for demographic data, independent t test for intergroup comparison with the use of SPSS software version 20.

Results

Out of the 74 individuals with eligibility to join the study, 2 declined to participate, 1 case was lost to follow up and one failed block was noted. The block evaluation was made by pin prick test, including T10, T11 and T12 segments. If the blockade did not include at least 2 segments, it was defined as a failed block and excluded from analysis. Patients participating in the study are shown in the CONSORT chart (Figure 1) followed by a comparison of demographic and clinical characteristics of the two groups (Table 1).

There were no significant differences between the two groups in terms of age, gender, weight, duration of surgery ($p>0.05$) **.** Figure 2 & 3 shows the variation of heart rate and mean arterial blood pressure in patients of both groups for 24 hours post operatively. It shows a trend of higher heart rate and blood pressure in Group B. Heart rate was not >100/min or <60/min in both the groups post operatively. So no tachyarrhythmia or bradyarrhy thmias were observed postoperatively.

The trend of oxygen saturation in post-operative period shows a dip in the first 2 hours amongst the patients of Group BD, which was statistically significant but did not require any active intervention. The SPO_2 did not fall below 97%, hence respiratory depression was not noted in any patient. Rest of postoperative period showed no significant differences.

Figure 4 depicts that there was no significant difference in mean VAS score among both the groups immediately after surgery. But it shows statistically significant higher VAS scores in Group B at 2hour onwards, upto 12 hours postoperatively in comparison to Group BD. Compared to Group B, the Patients in Group BD showed higher Ramsay Sedation Scores for a span of 1-12 hours postoperatively. The comparison has been found to be statistically significant.

The duration of analgesia was measured from the time at which drug was administered in the block to the demand for first additional analgesic (Rescue Analgesia). Group BD showed longer duration of analgesia from the block (10.942 ±0.725 hours) as compared to Group B (7.228 ± 0.725 hours) which was statistically significant. The total dose of Tramadol required in the first 24 hours was noted for patients of both groups. Group BD showed lower dose (252.285 ±34.221) mg as compared to Group B (356.857 ± 72.872) mg, which was statistically significant. ($P <0.05$)

There were no side effects such as respiratory depression, hypotension and bradycardia. No significant differences were seen in nausea and vomiting between two groups. Additionally, there were no complications- pleural puncture, pneumothorax, inadvertent vascular puncture related to PVB.

Discussion

In this study, we have demonstrated that patients who received PVB with 0.25% bupivacaine and 1 µg/kg dexmedetomidine in addition to general anesthesia experienced superior postoperative analgesia, pro long ation of the time to the first rescue analgesic requirement, and decreased mean total intravenous tramadol consumption as compared to those without PVB and

general anesthesia alone in the first 48 hours after PCNL surgery. This finding is similar to the meta-analysis review of 34 RCTs done by Vorobeichik et al [10]. Similar findings were affirmed by El-Boghdadly et al. [11]. He did a review of 20 RCTs and demonstrated that perineural dexmedetomidine, compared with clonidine, increased the mean duration of analgesia and sensory block. In a similar study, Boohwi Hong et al. examined the use of PVB in Video Assisted Thoracoscopic Surgery (VATS) [12] comparing: Ropivacaine 0.5% in 30mL alone and with Dexmedetomidine 50µg.

They proved similar results that Adjuvant Dexme detomidine lengthened the duration of analgesia obtainable with Ropivacaine alone. This can be attributed to the affinity of Dexmedetomidine for α_2 receptors- nearly eight folds in comparison to clonidine, its faster duration of action, prolonged duration of analgesia, rapid occurrence of sensory blockade, dose sparing action of local anaesthetics and stable hemodynamics [13].

We administered 20ml 0.25% Bupivacaine (with or without dexmedetomidine) as a single injection at the level of T10. Cheema et al. [14] injected 15 ml 0.5% Bupivacaine in thoracic PVB and noted somatic block of at least five dermatomes and a sympathetic block of eight dermatomes. Thus, we believe that multilevel injections would unnecessarily expose patients to additional risks related to multiple punctures, Fatma Nur Kaya evaluated single injection vs multiple injection in thoracic PVB. In terms of efficacy, they concluded, the single puncture technique was potentially superior to multiple puncture, since the patients were more satisfied, the procedure took less time and there was a lower risk of developing complications [15]. Cowie Brian also concluded that If PVB is performed in awake patients, a single injection may be preferable to multiple injections. Their research on cadavers demonstrated that the spread of infiltrated Anaesthetic was no different, whether injection occur singly or at two levels [16]. The total dose of rescue analgesic required in first 24 hours in our study, was significantly lower in group BD. Similar results were obtained by Kalpana Kulkarni et al. [17], Boohwi Hong et al. [12] M. Mohta et al [18].

The reason behind this can be the intrinsic analgesic property of dexme detomidine and the synergism of dexme detomidine with local Anaesthetic agents that prolongs their duration of action in comparison to that of local Anaesthetic alone [10].

Unlike our study, Bhattacharya et al [19] did a comparison of spinal anaesthesia and unilateral landmark guided single shot thoracic paravertebral block with 20 mL 0.5% Bupivacaine; using nerve stimulator technique. Their results stated that no significant difference was found in analgesic intake post operatively. Moawad et al. [20] compared epidural analgesia with unilateral single shot landmark guided thoracic paravertebral block at T10 using Loss of resistance technique with 0.5% bupi vacaine in open renal surgeries. They found that no significant difference in pain scores was seen for the first 24 hours. Also, analgesic intake for first 24 hours did not show any statistical difference either. In these studies, however, plain Bupivacaine was used and compared with neuraxial analgesia. Hence, PVB is comparable to epidural analgesia.

The reason for this difference might be the technique of PVB used. Block failure rate has been shown to be highest with loss of resistance technique [11]. Ultra sonography guidance can improve success rate, shorten the puncture time and reduce the complications of pneumothorax and vascular puncture [21] [22]. Our study used USG guidance and as a result we had precise drug delivery in paravertebral space and better postoperative analgesia that led to lesser requirement of rescue

analgesics, without complications. Although the patients in Group BD had higher sedation scores, the patients were comfortable and easily arousable. In our study no patient had respiratory distress in the postoperative period. These results pass in agreement to previous studies done by Reem Abdel Raouf et al. [23], Chen et al. [24].

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Table 1: Demographic and Clinical Data

	Group B (n= 35) Mean ± SD	Group BD (n= 35) Mean ± SD	P Value
Age (In Years)	44.57 ± 12.01	39.28 ± 12.62	0.0769
Weight (In Kg)	60.31 ± 13.19	63.42 ± 9.88	0.2682
Gender (F/M)	15/20	11/24	0.979
Duration Of Surgery	1.546 ± 0.464	1.457 ± 0.475	0.4306

Table 2: Duration of analgesia & Rescue analgesic requirement

	Group B (n = 35) Mean ± SD	Group BD (n = 35) Mean ± SD	P value
Duration of analgesia achieved (in hours)	7.228 ± 0.689	10.942 ± 0.725	<0.0001
Rescue analgesia require ment in 24 hours (Tramadol, mg)	356.857 ± 72.872	252.285 ± 34.221	<0.0001

Figure 1: CONSORT Flow diagram of the study (Consolidated Standards of Reporting Trials)

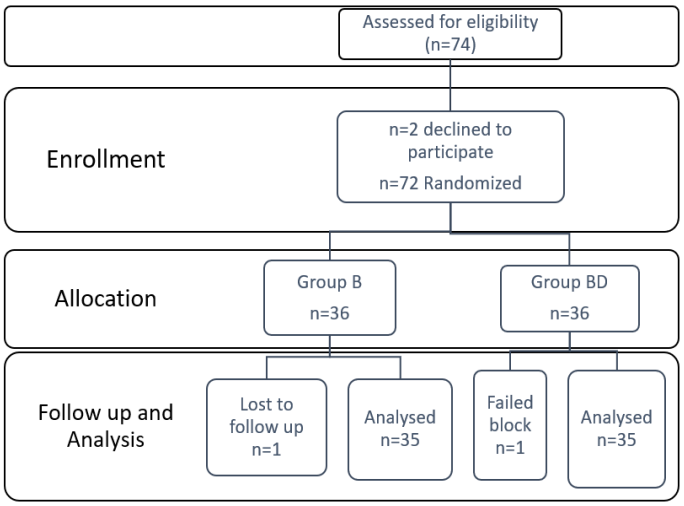
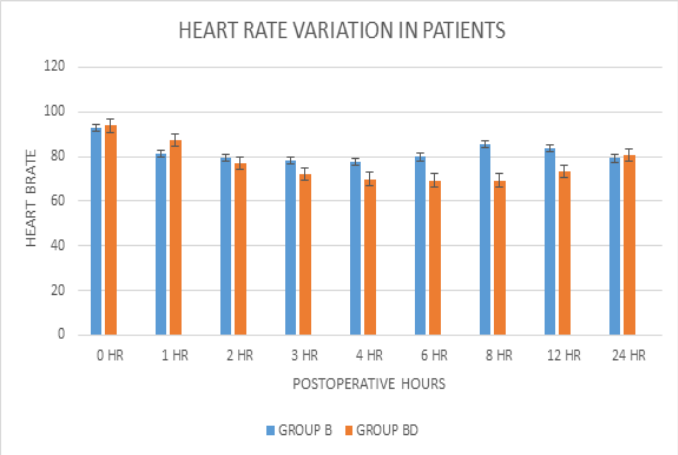
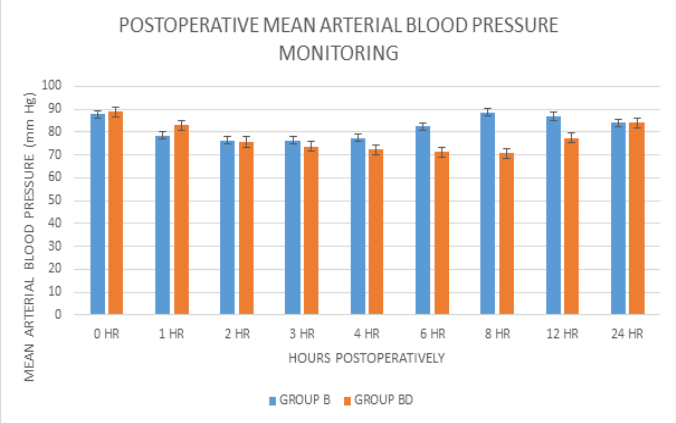


Figure 2: Post-operative Heart rate (beats per minute) noted over 24 hours postoperatively



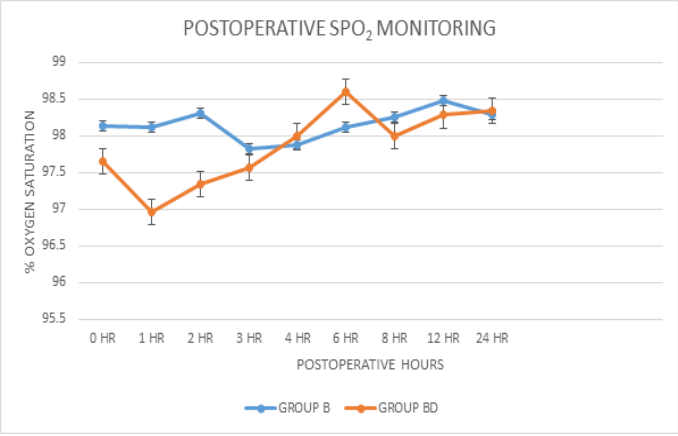
(P<0.05) = Significant

Figure 3: Mean Arterial Blood Pressure Variation



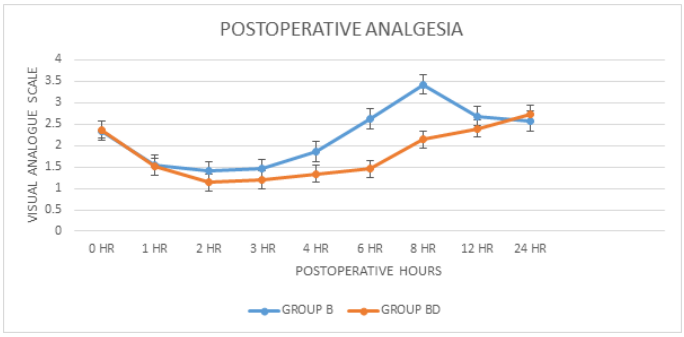
(P<0.05) = Significant

Figure 4: Postoperative oxygen saturation (SPO_2) monitoring.



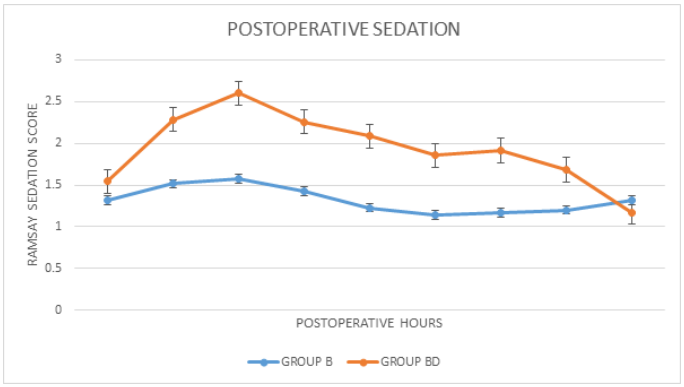
(P<0.05) = Significant

Figure 5: Postoperative analgesia achieved



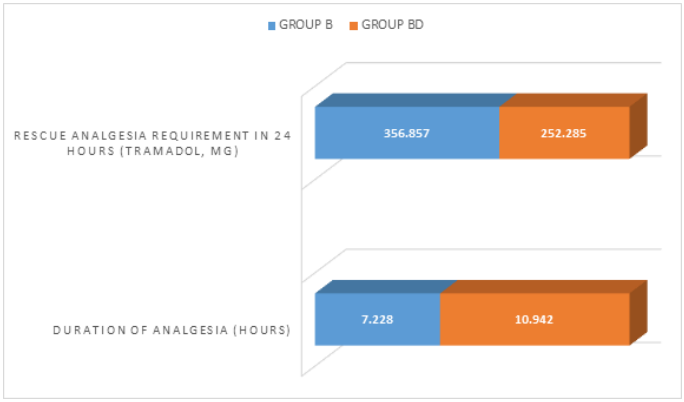
(P<0.05) = Significant

Figure 6: Postoperative sedation



(P<0.05) = Significant

Figure 7: Duration of analgesia obtained and total rescue analgesia requirement in 24 hours (mg)



(P<0.05) = Significant