

# Per Cutaneous Nephrolithotomy Under Spinal Anesthesia And The Efficacy Of Adding Adjuvant Clonidine To Intrathecal Hyperbaric Bupivacaine : A Comparative Study

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## Abstract

**Context:** Percutaneous nephrolithotomy (PCNL) is an established procedure of choice for renal stones > 2cm. However, there are few studies regarding the efficacy of spinal anesthesia for PCNL.

**Aim:** The purpose of present study was to evaluate the feasibility of doing PCNL under spinal anesthesia and whether addition of clonidine improves the quality of spinal block needed for PCNL.

**Setting and Design :** A prospective randomized double blind trial

**Methods and Material:** Sixty patients scheduled for PCNL were randomly divided into two groups of which group B received spinal anesthesia with hyperbaric bupivacaine (15 mg) and group BC received 45 microgram clonidine in addition to hyperbaric bupivacaine. Parameters recorded were onset of sensory and motor block, intraoperative analgesia, 2 segment regression of sensory block, sedation score, surgeon satisfaction score and postoperative analgesia. Hemodynamic parameters were recorded both intraoperative and postoperatively.

**Statistical analysis:** Student's t-test for parametric data and Chi-Square test for non-parametric data using SPSS 17.0.

**Results:** Although the onset of sensory and motor blockade was same in both the groups, but the two segment regression of sensory block was significantly prolonged in clonidine group ( $p=0.003$ ). The clonidine group also had good intraoperative analgesia. Time to first rescue analgesia post operatively was significantly more for BC group ( $p=0.003$ ). Both systolic and diastolic blood pressure was significantly lowered in the clonidine group and patients in this group had longer duration of post-operative analgesia.

**Conclusion:** Spinal Anesthesia using bupivacaine and clonidine offers a reliable block, excellent patient and surgeon acceptance and prolonged intraoperative and postoperative analgesia in patients undergoing PCNL.

## INTRODUCTION

Fernstrom and Johansson were the first to report the removal of a renal calculus through a nephrostomy tract in 1976[1], since then Percutaneous Nephrolithotomy (PCNL) has largely replaced open surgery in the management of renal stones.

Several changes and modifications have taken place in the last few years in an attempt to further refine the procedure and to lower the morbidity, analgesic requirements and duration of hospitalization. These include the use of regional blocks, single step dilatation, "Mini Perc" technique,

tubeless PCNL and sandwich therapy. [2][3][4]

PCNL is mostly performed under general anesthesia [5]. Published literature regarding the use of spinal anesthesia for PCNL is sparse.[ 6][ 7][ 8][ 9] The aim of the present study is to evaluate the feasibility of doing PCNL under spinal anesthesia and whether the addition of clonidine improves the quality of spinal block for PCNL.

## SUBJECT AND METHODS

After obtaining local ethical committee approval and written informed consent from the patients, sixty ASA I and II patients, aged 18–65yrs.scheduled for percutaneous

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nephrolithotomy (PCNL) were enrolled in the study. Those with any known contraindication for spinal anesthesia, such as increased intracranial pressure, neurological disorders, hemorrhagic diathesis, or infection at the puncture site, were excluded, as were those having any history of allergy to clonidine and bupivacaine.

A double-blind, randomized, placebo-controlled study design with two parallel groups was used. The patients were randomly allocated (a computer-generated allocation sequence) into two groups B and BC. Group B received 3ml of 0.5% hyperbaric bupivacaine plus 0.3 ml normal saline and group BC received 3ml of 0.5% hyperbaric bupivacaine plus clonidine 45µg in 0.3 ml. The total volume of the drug was 3.3 ml in both the groups. Both the patients and the person measuring the block spread were unaware of the injection used for spinal anesthesia.

All patients were kept fasting for 8 hrs. Premedication was given with tablet midazolam (7.5 mg) night before surgery and on the morning of surgery. Ringer's lactate 10ml/kg was given preoperatively to all patients about 15minutes before the intended time of intrathecal drug administration. Patient was shifted to operation theatre and non-invasive blood pressure monitoring was started. In addition, patient was monitored for SPO<sub>2</sub> and ECG. Lumbar puncture was performed with the patient in the sitting position at the L4–5 interspace, with a 25 gauge Quinke's needle. After a free flow of cerebrospinal fluid was ensured, the study drug was administered. The patient was then made to lie down supine and the table was slightly tilted head down to achieve a level of T4.

The spread of sensory block was tested with a pinprick method at midline and the time to reach the T4 dermatome was noted. Motor block was tested with the modified Bromage scale:

Bromage 0, the patient is able to move the hip, knee and ankle;

Bromage 1, the patient is unable to move the hip but is able to move the knee and ankle;

Bromage 2, the patient is unable to move the hip and knee but able to move the ankle;

Bromage 3, the patient is unable to move the hip, knee and ankle; and the time to reach Bromage 3 was recorded.

Sedation was assessed on a modified Wilson's sedation scale

(1 – Oriented, 2 – Drowsy, 3 – Arousable to mild physical stimulation, 4- unarousable to mild physical stimulation).

During surgery, the surgeon assessed the quality of anesthesia as 4=excellent, 3=acceptable, 2=poor, or 1=unacceptable. The same surgeon performed all procedures.

Quality of intraoperative analgesia was evaluated by the patient using the following 4 point scale

1 – Perfect analgesia, no sensation at all from the surgical site

2- Adequate analgesia, sensation of motion only

3- Inadequate analgesia, discomfort, but the patient declines additional analgesic

4-Major discomfort, additional analgesic or general anesthesia required

Duration of surgery was taken as time interval from positioning of patient in lithotomy position to putting of nephrostomy tube.

Adverse effects like hypotension, bradycardia, nausea and vomiting and dryness of mouth were recorded.

Noninvasive arterial blood pressure, heart rate, and oxygen saturation were assessed at baseline and every 1 min for the first 20min after spinal injection and thereafter, every 5 minutes during the surgery.

Hypotension was defined as 20% reduction in systolic blood pressure from the baseline. In case of hypotension the patient was administered 6mg of intravenous mephentermine. Following which the blood pressure was monitored and the dose repeated if required.

Bradycardia was defined as 20% reduction in the heart rate from the baseline. In case of bradycardia, 0.3 mg of intravenous atropine was administered immediately and which was repeated as per the need.

Sensory and motor blocks and sedation score were assessed at every 2 minutes for first 20minutes after spinal injection, every 15 minutes till end of surgery and thereafter every 15 minutes in post anesthesia care unit (PACU) for 2 hours. In PACU, patient was administered inj. Diclofenac 1.5 mg/kg IM for rescue analgesia if the patient complained of pain. Duration of post-operative analgesia was taken as the time

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period till demand of first rescue analgesic.

The time to reach T4 dermatome, Bromage score of 3, the time to regression of the sensory block by two dermatomes, total time duration of the surgery, intraoperative analgesia as assessed by the patient, surgeon satisfaction score, sedation score and the time to the first rescue analgesic were recorded. In cases with inadequate intraoperative analgesia incremental doses of fentanyl 25µg or general anesthesia was administered. These cases were designated as failed spinal anesthesia and were excluded from the study.

**Statistical analysis**

The various data obtained were analyzed using IBM SPSS Software using student’s t-test for parametric data and Chi-Square test for non-parametric data. The sample size calculation was based on the assumption of a minimum difference of 25% in the duration of sensory block between the two groups. The level of significance was set at P < 0.05, and 95% confidence intervals were calculated for the main outcome measures.

Statistical analysis: The various data obtained were analyzed using IBM SPSS Software using student’s t-test for parametric data and Chi-Square test for non-parametric data. The sample size calculation was based on the assumption of a minimum difference of 25% in the duration of sensory block between the two groups. The level of significance was set at P < 0.05, and 95% confidence intervals were calculated for the main outcome measures.

**RESULTS:**

Demographic variables such as Age , Body Mass Index (BMI) , Gender , Duration of surgery and Stone bulk was comparable in both the groups and non significant on statistical analysis Table no.1.

**Table 1**

Statistical comparison of demographic variables such as age , bmi , gender , duration of surgery and stone bulk in the two groups

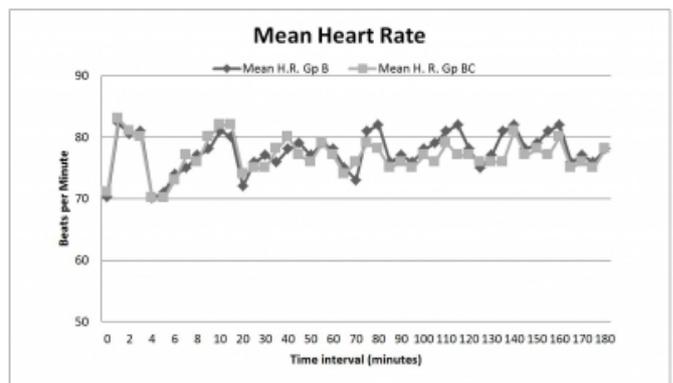
Parameter	Group B	Group BC	P Value
Age (Yrs)	42.0 ± 2.33	44.3 ± 1.91	0.553
BMI	28.9 ± 2.00	27.6 ± 0.30	1.343
Sex (M:F)	16:14	17:13	0.994
Duration of Surgery (mins)	118.33 ± 6.83	114.09 ± 5.66	0.923
Stone size (cms)	2.8±0.8	3.0± 0.9	0.34

Heart Rate was recorded every minute for the first 10 minutes and there after every 10 minutes till the end of surgery. Between groups, the mean heart rates (Fig 1) did

not vary significantly at any interval (P>0.05). However, a significant difference in between two groups with regard to the SBP was recored at 35 min (P=0.02), which persisted till end of the procedure and thereafter (Fig 2). The number of patients who required intravenous mephentermine for hypotension were significantly higher in group BC (N= 5) when compared to group B (N = 2). Nevertheless, number of patients who required intravenous atropine for bradycardia did not vary between these two groups.

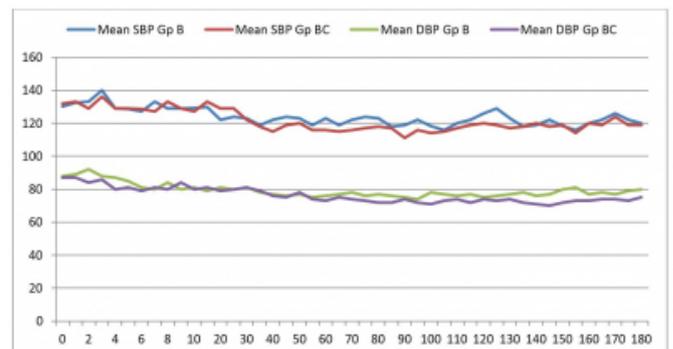
**Figure 1**

Mean Heart Rate recorded in two groups every minute for the first 10 minutes and there after every 10 minutes till the end of surgery.



**Figure 2**

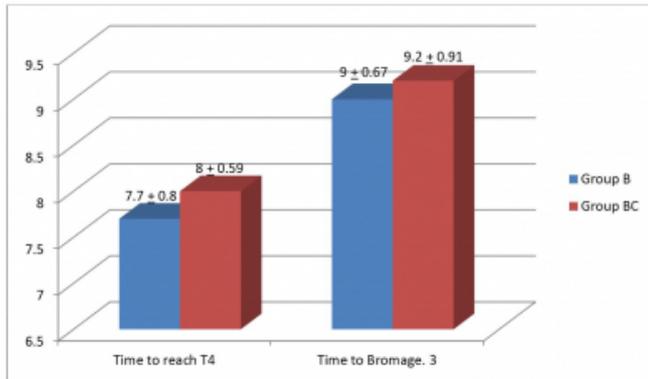
Systolic and Diastolic Blood Pressure recorded every minute for the first 10 minutes and there after every 5 minutes till the end of surgery.



The difference with regards to time taken for the sensory level to reach T4 dermatome was compared between the two groups. No doubt, patients in Group BC took longer time to reach a sensory level of T4 dermatome but this difference was not statistically significant (P>0.05). Similar observations were recorded with regard to time to attain Bromage score of 3 (Fig 3).

**Figure 3**

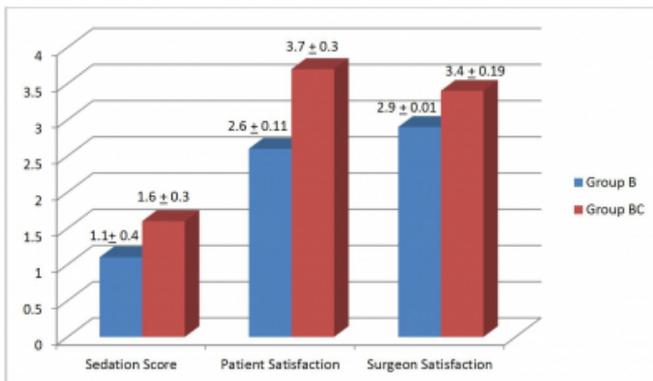
The time to reach T4 dermatome sensory block and Bromage 3 motor block in the two groups .



Patients in Group BC had higher sedation score as compared to those in Group B ( Fig 4). The difference among both groups was statistically significant (P=0.022). The patient satisfaction in Group BC was significantly higher as compared to Group B (P=0.0001). Surgeon satisfaction score was also higher in Group BC (3.4) which was statistically significant (P=0.001). A significant difference between the groups for sensory blockade regression time was noticed. Group BC had significantly higher regression time for sensory blockade (P=0.003) when compared with Group B (Fig 5)

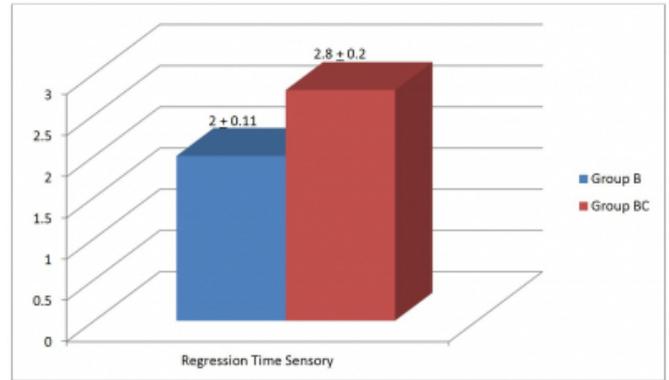
**Figure 4**

Sedation score, patient satisfaction and Surgeon satisfaction in two Groups.



**Figure 5**

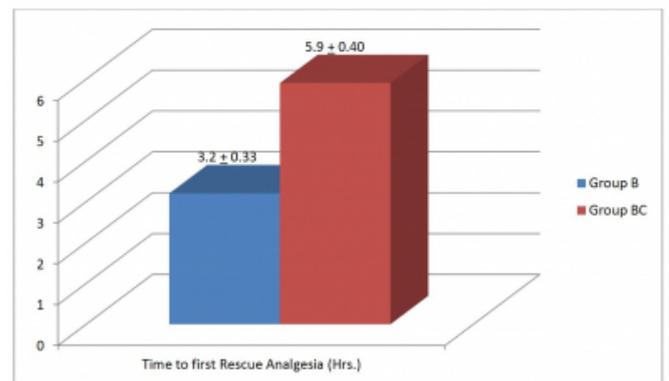
Regression times for sensory in two groups.



Time to first rescue analgesia (Fig 6) post-operatively was significantly prolonged (P=0.0001) in Group BC (5.9 hrs.) as compared to Group B patients (3.2 hrs)

**Figure 6**

Time to first rescue analgesia post-operatively in two groups.



**DISCUSSION**

PCNL is the procedure of choice for managing kidney stones. The practice of PCNL, having been refined over time, continues to evolve and has largely replaced open stone surgery. This has been aided by advances in technology and equipment resulting in stone removal with less morbidity, shorter convalescence and reduced cost compared with open surgery [10].

Regional anesthesia for PCNL was first described in 1988 [11]. Since then few studies have been done regarding use of regional anesthesia for PCNL.[6][7][8][9][12] Mehrabi et al evaluated the intraoperative and post-operative anesthetic and surgical outcomes in patients who underwent PCNL under spinal anesthesia in prone position. They found that spinal anesthesia is safe and effective for performing PCNL

and is a good alternative for general anesthesia in adult patients[6]. Borzouei et al did a largest study regarding the use of spinal anesthesia in PCNL and reported that spinal anesthesia is feasible, safe and well tolerated especially in elderly patients with significant co morbidities such as pulmonary disease [13]. In our experience too PCNL under spinal anesthesia is safe and feasible.

However literature regarding the use of spinal anesthesia with bupivacaine and clonidine for PCNL is sparse and this forms the basis of our study.

Clonidine is a selective agonist for alpha 2 adrenoreceptors and acts by inhibiting norepinephrine release from presynaptic terminals. Clinical studies have found that use of intrathecal clonidine is associated with prolonged sensory as well as motor block of spinal anesthesia [14].

Clonidine improves the onset time of sensory and motor block [15]. However this is not our observation . In our study the time to reach T4 dermatome sensory block was 7.7 minutes in group B vs 8 minutes in group BC and Bromage 3 motor block was 9 and 9.2 minutes respectively. It was statistically not significant ( $p>0.05$ ).

In our study, there was significant difference in between the two groups with regard to systolic and diastolic blood pressures. Patients in group BC had significantly lower systolic and diastolic blood pressure as compared to group B and this difference was observed 35 minutes after spinal anesthesia and thereafter it remained significant( $p=0.02$ ). However this did not have any adverse morbidity for the patients in group BC. This is in accordance with other similar studies done by Thakur[16] et al and Dobrydnjov et al.[17] Thakur et al observed that a significant fall in the arterial blood pressure occurred after 15 – 240 minutes after intrathecal clonidine administration. Clonidine, after neuraxial or systemic administration affects arterial blood pressure in a complex manner because of opposing action at multiple sites. It produces sympatholysis and reduces arterial blood pressure through effects at specific brainstem nuclei and on sympathetic preganglionic neurons in the spinal cord[18]. These are the effects that are counteracted by direct vasoconstriction resulting from alpha 2 adrenergic agonist actions on the peripheral vasculature. Combining alpha 2 adrenergic receptor antagonists with local anesthetic can potentially increase the degree of sympatholysis and resulting Hypotension [18].

Heart rate did not show a statistically significant variation

among both the groups and our this finding is consistent with various other studies[16,17]

Intrathecal clonidine increases both the quality and the duration of the anesthesia provided by local anesthetics. The analgesic effect following its intrathecal administration is mediated spinally through the activation of post synaptic alpha 2 receptors in substantia gelatinosa of the spinal cord [17]. In our study the time to regression of sensory block by two dermatomes was more in the BC group as compared to the B group and the difference was statistically significant( $p=0.003$ ). This prolongation of sensory block by clonidine was beneficial to us in cases of prolonged PCNL surgery.

Intraoperative analgesia as judged by the patient was excellent in the BC group. Patients in the BC group had higher sedation score as compared to those in B group. However, despite a higher sedation score they were responsive to simple verbal commands. The combined property of sedation and analgesia of clonidine helped to keep the patients pain free and comfortable.

Surgeon satisfaction score regarding anesthesia was higher in clonidine group and was statistically significant ( $p=0.01$ ).

Patients undergoing PCNL usually experience considerable pain postoperatively once the effect of regional block wanes off. In our study the time to first rescue analgesic requirement post operatively was significantly prolonged in BC group as compared to the B group patients ( $P=0.00$ ). So the use of clonidine as an adjuvant to intrathecal bupivacaine prolongs the duration of post-operative analgesia in patients undergoing PCNL. This is in accordance with various other studies [15][16][17]

The operation specific advantage of regional anesthesia is easier and safer tilting of the patient from the lithotomy to prone position. Complications of turning the patient to prone position during general anesthesia like endotracheal tube dislodgement and brachial plexus nerve injuries are avoided when patient is under spinal anesthesia[6]. Further it has been reported that patients who are positioned prone and receive general anesthesia have an increased risk for development of postoperative visual loss and pressure necrosis of face [19]. Another advantage of spinal anesthesia is decreased intraoperative blood loss which consequently improves operating conditions.

The main concern regarding surgery in prone position under

spinal anesthesia is the risk involved in repositioning of the patients during critical events. Sudden cardiac arrest during PCNL under epidural anesthesia was reported in a 52 year old man with successful resuscitation[20]. In our study, we did not encounter any cardiac complication during the procedure.

The use of spinal anesthesia in patients undergoing PCNL is safe and effective. Addition of adjuvant clonidine along with bupivacaine provides better intraoperative analgesia, prolongs the time to two segment regression of block, good intraoperative sedation, acceptable surgeon satisfaction score and a prolonged post-operative analgesia.

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