

Research Article

A comparative study of ropivacaine 0.75% and bupivacaine 0.5% for segmental epidural anaesthesia in patients undergoing percutaneous nephrolithotomy

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ABSTRACT

Background: Percutaneous nephrolithotomy (PCNL) is used for fragmentation and removal of stones from pelvicalyceal system using a nephroscope passed into the kidneys through a track created in the patients back. PCNL is the treatment of choice for larger renal stones of size more than 20 to 30 mm, staghorn stones and stones that are multiple or resistant to extra corporeal shock.

Methods: This prospective, randomized, open, controlled trial was carried out in 60 adult patients undergoing elective surgical procedure. The patients were randomly divided into two groups of 30 each. Each group underwent PCNL under segmental epidural.

Results: Both the groups were comparable with respect to their demographic data, duration of surgery, size of stone and baseline vital parameters. Nine patients in Ropivacaine group and seven patients in Bupivacaine group developed clinically significant hypotension. The incidence of complications was similar in both the group. The fall in haemoglobin was similar in both the groups and none of the patients required blood transfusion.

Conclusions: Segmental epidural anaesthesia is a safe alternative technique to general anaesthesia for PCNL. Both the drugs ropivacaine and bupivacaine were safe and clinically comparable in segmental epidural for PCNL.

Keywords: PCNL, Bupivacaine, Ropivacaine, Hypotension

INTRODUCTION

Management of nephrolithiasis has been revolutionized by the advent of shock-wave lithotripsy (SWL) and percutaneous nephrolithotomy (PCNL). PCNL is a minimally invasive endoscopic technique and is used for the fragmentation and removal of stones of size more than 20 to 30 mm, staghorn stones or multiple stones resistant to ESWL.^{1,2}

General anaesthesia is the gold standard for this surgery.³ The advent of new drugs has refined the technique of general anaesthesia. However there are several issues

related to prone position still to be addressed like accidental extubation and difficult reintubation, nerve injuries and post-operative respiratory complications.⁴ Bupivacaine is a well-established drug for epidural anaesthesia and post-operative pain relief.⁵

Ropivacaine is a new drug, which is structurally related to bupivacaine, having less cardio toxicity and almost equal potency as that of Bupivacaine^{6,7}

There exists no published literature with regard to the use of Ropivacaine in segmental epidural anaesthesia for PCNL.

Aim and objectives

- To study safety of segmental epidural for PCNL.
- To compare segmental level of anaesthesia achieved by using ropivacaine 0.75% and bupivacaine 0.5% epidurally.
- To evaluate and compare technical difficulties faced by the surgeon during the procedure in the form of positioning and locating the pelvicalyceal system.
- To compare the incidence of postoperative complications, if any related to surgery during PCNL.
- To evaluate safety of ropivacaine 0.75% in epidural anaesthesia.

METHODS

This prospective, randomized, open, controlled trial was carried out in 60 adult patients undergoing elective surgical procedure. The study was reviewed and approved by research and ethics committee of our hospital LTMMC and LTMGH. Study was carried out in 60 adult patients who were randomly divided in to two groups of 30 each. Each group underwent PCNL under epidural anaesthesia by using Ropivacaine 0.75% or Bupivacaine 0.5%

Inclusion criteria

- ASA I/II
- Age 18 to 65 years
- Either sex
- BMI <30kg/m²

Exclusion criteria

- Unwilling for consent
- ASA ≥ 3
- Obesity with BMI >30kg/m²
- Contraindications for epidural anaesthesia
- Undilated pelvicalyceal system.

A test dose of 3 ml lidocaine 2% with 1:200,000 adrenaline through the catheter was given to exclude intravascular or intrathecal catheter placement. A loading dose of the study drug approximately 6ml (1.5 ml/segment) was injected epidurally with regular negative aspiration to achieve a epidural block of T6-T12 segments.

After injecting study drug the sensory block level was checked every minute with an ether swab for first 15 min and if not adequate then additional dose of study drug 1ml/ spared segment was given to achieve T6-T12 level.

Following parameters were noted

- Onset of block: Time taken to achieve adequate level of anaesthesia i.e. (T6-T12). Onset of block is

defined as time taken to achieve T6 level from the time of injection of drug.

- Number of segments blocked.
- Total volume of drug injected.
- Heart rate.
- Blood pressure:-systolic, Diastolic and mean arterial pressure.
- Oxygen saturation.
- Segmental Level of anaesthesia every 15 minutes after the first one hour.
- Bromage Score

Motor blockade of lower limb was assessed by Bromage scale where 0=no block; 1=impaired movement at the hip, normal knee, and ankle movements; 2=impaired movement at hip and knee, but normal ankle Movements; and 3=impaired movement at the hip, knee, and Ankle; Surgeons satisfaction score (0 – unsatisfied, 1- satisfied, 2- excellent satisfaction).

Statistical analysis

The data thus obtained was expressed as mean and standard deviation. Difference in demographic data between the two groups was sought with Chi square test and Student ‘t’ test. The hemodynamic variables were analyzed using paired ‘t’ test for within the group comparisons and unpaired ‘t’ test for between the group comparisons. Time of requirement of first rescue analgesia was analyzed using Chi-square test. Incidence of complications was analyzed with Chi-square test and Student ‘t’ test wherever appropriate. For all statistical comparisons, P<0.05 was taken as significant.

RESULTS

The present study was conducted on ASA I –II patients undergoing percutaneous nephrolithotomy (PCNL) under segmental epidural anaesthesia using Ropivacaine 0.75% or Bupivacaine 0.5%. Sixty patients were randomly allocated into two groups. Table 1 shows comparison of demographic data between group B and group R. The two groups were comparable with respect to age, weight, height and sex. Table 2, depicts duration of surgery and Mean stone size were comparable in both the groups.

Table 1: Demographic data.

Parameters	Group B Mean±SD	Group R Mean±SD	P value
Age (years)	44.50±16.62	44.70±15.64	0.962
Weight (kg)	57.43±4.76	57.70±5.17	0.836
Height (cm)	166.03±7.54	166.07±7.77	0.987
Sex (M:F)	17:13	18:12	0.793

From Table 3 it can be seen that, total number of single punctures were 25 in Group R and 23 in Group B, four patients in Group R and six patients in Group B required two punctures and only one patient required three

punctures in both the groups. Table 4 shows that, two groups were comparable in terms of position of puncture (Chi square test). In present study, none of the patients were having plueral injuries.

Table 2: Surgical parameters.

	Group B	Group R	'P' value
Duration of surgery* (Min)	109±29.96	106.67±30.2	0.887 (NS)
Mean stone size* (Cm)	3.75±1.51	3.83±1.72	0.855 (NS)

*ANOVA test; NS - Not significant.

Table 5 shows, time taken to achieve T6-T12 segment (Min) for Group B was more (12.13+2.18) as compared to Group R (10.60+2.04) and it is statistically significant.

There was no statistical significance between the time taken for two segment regression and total volume of drug for both drugs and the two groups were comparable.

Table 6 shows, that only 8 patients in Group B required one epidural top up whereas in Group R, 7 patients required one epidural top up and only one patient required two epidural top ups. So the two groups were comparable in terms of Epidural top ups.

Table 3: Number of punctures required.

Number of punctures	Group B	Group R	Total	Chi- Square test	Z- Value	P-value
1 Puncture	23	25	48	0.483	0.695	0.785
2 Punctures	6	4	10			

Table 4: Position of puncture.

Groups	Supra-costal puncture	Infra-costal puncture	Total	Chi- square test	Z statistics	P- Value
Group B	4	33	37	3.171	1.780	0.075
Group R	10	27	37			
Total	14	60	74			

Table 5: Drug parameters.

	Group B	Group R	P-Value
Onset of Block.			
Time taken to achieve T6-T12 segment (Min)	12.12±2.18	10.60±2.04	0.007 (Significant)
Time Required for 2 segment regression (Min)	93.33±8.84	89.67±8.84	0.268 (NS)
Total volume of drug in ml (First dose)	9.93±1.84	10.00±1.70	0.885

Table 6: Epidural top ups required during surgery.

Study group	Epidural top ups (number)			Total
	No	Yes (1)	Yes (2)	
Group B	22	8	0	30
Group R	22	7	1	30
Total	44	15	1	60

Motor blockade was checked by Bromage score at three different positions i.e. 1) Before lithotomy; 2) at time of log rolling and 3) At end of the procedure. Complete motor blockade (Bromage score 3) was not seen in any of the patients (Table 7).

In Table 8, T4-L2 block in Group B was seen in 4 patients and in Group R, 5 patients whereas T6-T12 block in Group B was seen in 15 patients and in Group R, 11

patients. T4-T12 block in Group B was seen in 3 patients and in Group R, 4 patients. T6-L2 block in Group B was seen in 8 patients and in Group R, 10 patients.

Table 7: Bromage score.

Bromage score	Group B		Group R		P value
	Mean	SD	Mean	SD	
Before lithotomy	0.33	0.48	0.30	0.47	0.786 (NS)
Log role	0.97	0.18	1.00	0.26	0.570 (NS)
At end of procedure	1.00	0.00	1.03	0.18	0.321 (NS)

Table 9 shows that only 8 patients out 30 in Group B and only 4 patients out of 30 in Group R required sedation for ureteric catheterization. When compared statistically it was found that the two groups were comparable.

Heart rates throughout the procedure in both groups were comparable and there was no statistical difference between the two groups. None of our patients had bradycardia (Figure 1).

Table 8: Number of segments blocked.

Number of segments blocked		T4-T12	T4-T12	T6-L2	T6-T12	Total
Group B	Number	4	3	8	15	30
	Percent	13.3%	10%	26.7%	50.0%	100%
Group R	Number	5	4	10	11	30
	Percent	16.7%	13.3%	33.3%	36.7%	100%
Total		9	7	18	26	60
		15%	11.7%	30%	43.3%	100.0%

Chi Square test-0.779.

Table 9: Sedation required for ureteric catheterization.

Study group	Sedation required for ureteric catheterization	Sedation required for ureteric catheterization		Total
		Yes	No	
Group B	Number	8	22	30
	Percent	26.7%	73.3%	100.0%
Group R	Number	4	26	30
	Percent	13.3%	86.7%	100.0%
Total		12	48	60
		20.0%	80.0%	100.0%

Pearson Chi Square-0.197; Fisher’s exact test-0.333.



Figure 1: Pulse rate at various time interval among study group.

Figure 2 shows changes in mean arterial pressure. Pre operatively baseline MAP was 95.70 ± 20.71 mm Hg in group B and 98.27±10.81 mm Hg in group R which was comparable and the difference was not statistically significant. In both groups, there was a fall in MAP after induction (at 0 minutes) which returned at near the baseline after fifteen minutes. The MAP was within normal limits, the difference being statistically significant (*) however clinically insignificant.

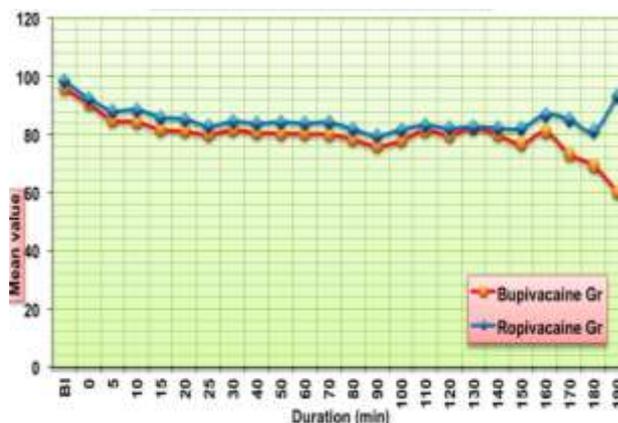


Figure 2: Mean arterial pressure at various time intervals among study group.

DISCUSSION

Per cutaneous nephrolithotomy (PCNL) is used for the fragmentation and removal of stones from the renal pelvis and renal calyceal system by means of a nephroscope passed into the kidney through a track created in the patients back.

In 2006, Papadopoulos et al investigated the safety and efficacy of epidural anaesthesia in elective lumbar

microdissectomies in prone position.⁸ They concluded that epidural anaesthesia is a good alternative to general anaesthesia in surgeries performed in prone position.

Epidural block characteristics

In 1990, Brown DL et al in Virginia Mason Medical Centre, Seattle, Washington investigated a randomized, double-blind study to compare the clinical effectiveness of ropivacaine and bupivacaine for epidural anaesthesia in patients undergoing lower-extremity surgery.⁹

Forty-five patients were randomized to receive 20 ml of 0.5% ropivacaine or bupivacaine. The quality and extent of sensory and motor blockade between groups were comparable, although bupivacaine was slightly longer acting.

Christelis N et al compared epidural ropivacaine 0.75% and bupivacaine 0.5% with fentanyl for elective caesarean section.¹⁰ Eighty women having elective caesarean section under epidural anaesthesia were randomly allocated to receive 20 mL of either 0.75% ropivacaine or 0.5% bupivacaine plus fentanyl 100 micrograms. Times were recorded for onset of sensory block, density and duration of motor block, and the need for supplementation.

There was no difference between the groups in the time (mean [SD]) to achieve sensory blockade too cold to T4 (ropivacaine 15.8 [5.6] min, bupivacaine/fentanyl 18.7 [9.1] min, $P=0.13$) or to S1 (ropivacaine 18.3 [4.6] min, bupivacaine/fentanyl 17.4 [7.6] min, $P=0.59$), or in the need for supplementation.

However, ropivacaine produced a motor block that was denser (median Bromage score ropivacaine-3, bupivacaine/fentanyl-1.5, $P=0.0041$), and of longer duration (ropivacaine 237 [84] min, bupivacaine/fentanyl 144 [76] min, $P<0.0001$). This study suggests that epidural 0.75% ropivacaine without opioid may be used as an alternative to bupivacaine 0.5% with fentanyl for elective caesarean section.

In our study time taken for onset of sensory block (T6-T12), for ropivacaine was 10.6 ± 2.04 min and for Bupivacaine it was 12.13 ± 2.18 min. Bupivacaine required slightly longer time than ropivacaine to achieve adequate level of anaesthesia. This was statistically significant; however this time difference was clinically comparable.

Bromage score and positioning

The mean bromage score for Group B before lithotomy was 0.33 ± 0.48 , at time of log rolling to prone position was 0.97 ± 0.18 and at the end of procedure it was 1 ± 0.0 . Similarly for Group R before lithotomy was 0.30 ± 0.47 , at time of log rolling to prone position was 1.00 ± 0.26 and

at the end of procedure it was 1.03 ± 0.18 , which were comparable.

Ureteric catheterisation

Wuethrich PY et al hypothesized that lower urinary tract function re- mains unchanged during thoracic epidural analgesia (TEA) within segments T4 –T11 after open renal surgery.¹¹ In a prospective, open, observational, follow-up study, 13 male patients with no pre-existing lower urinary tract symptoms and post void residual less than 100 ml underwent urodynamic investigations the day before open renal surgery (lumbotomy) and 2-3 days postoperatively during TEA. They observed that the detrusor activity was significantly impaired during TEA after open renal surgery.

In our study, we are unable to explain why most of the patients (48 patients) did not require any sedation for ureteric catheterization. It could be because of the application of lignocaine jelly well in advance (pre-emptive anaesthesia) to the catheterization or because of possible lumbar spread of anaesthesia and preferential blockade or neuromodulation of susceptible small thinly myelinated fibers by the local anaesthesia compared with larger A-alpha fibers.

Haemodynamics

Mehrabi et al evaluated 160 consecutive patients who underwent PCNL under spinal anaesthesia (15 mg bupivacaine 0.5 % heavy and 25 µg fentanyl).¹² They reported hypotension in 18 patients, 3 to 10 minutes after regional anaesthesia that was controlled by injecting 10 mg ephedrine intravenously.

Karacalar S et al conducted a prospective study on 180 patients undergoing PCNL under GA and CSE and concluded that haemodynamics were comparable in both the groups.¹³ They encountered hypotension in both the groups.

In the present study, segmental epidural anaesthesia was the anaesthesia technique using Ropivacaine 0.75% or Bupivacaine 0.5%. To prevent hypotension and bradycardia due to the high sympathetic block, all the patients in our study were preloaded with 5 ml/kg of crystalloid and Inj. Atropine was given as premedication. In our study, the haemodynamics were comparable in both the groups.

Nine patients in Ropivacaine group and seven patients in Bupivacaine group developed clinically significant hypotension. But they responded immediately to a 250 ml bolus of intravenous fluid and a single dose (6 mg) of ephedrine. After this there was no further episode of hypotension. This was attributed to high level of block upto T4 in these patients.

Complications

Blood loss

Mehrabi et al found fall in mean haemoglobin postoperatively of 2.1 ± 0.4 g/dl and 6.3% of patients required blood transfusion.¹²

Kukreja et al concluded that stone surface area did significantly affect blood loss ($P=0.03$) and correlated more with transfusion rate ($P=0.0001$).¹⁴ Diabetes, multiple-tract procedures, prolonged operative time, and intraoperative complications are associated with significantly greater blood loss during PCNL.

In our study we did not encounter any severe bleeding. The mean haemoglobin pre and post operatively in both the groups were comparable and none of the patients required blood transfusion. For group B pre and post op hemoglobin was 11.96 ± 1.36 (pre-operative) and 11.04 ± 1.34 (post-operative) and for group R it was 11.94 ± 1.34 (pre-operative) and 10.95 ± 1.26 (post-operative).

Pleural injury

No complications were noted both intra and post operatively in these patients. Another potential complication of supracostal access is the risk of injury to the lung, leading to tension pneumothorax.¹⁵⁻¹⁷ No such injury was encountered in the present study. R Gupta et al in 2002 did a prospective study to evaluate the safety and efficacy of supra costal puncture in patients undergoing PCNL and concluded that supra costal approach provides high clearance rates with acceptable complications.¹⁸

Shivering

Shivering can occur during PCNL surgery, this could be because of central neuraxial block, cold solutions used for irrigation during surgery, low ambient temperature of theatre and prolonged duration of surgery. Shivering was seen in 9 patients of group B and 7 patients of Group R, which was comparable in both groups.

Patient compliance

The lack of sedation and prolonged procedure time under SE may be demanding on patient's compliance. In our study we encountered four patients in group B and one patient in group R complained of discomfort and shoulder tip pain during the surgery which was tackled by confirming the sensory level, reassuring the patient and Injection fentanyl 25 micrograms i.v.

Surgeons satisfaction

In our study we have noted surgeons satisfaction regarding locating the stone, taking puncture and scored. (It was graded as 0-Not satisfied, 1-satisfied, 2- excellent

satisfaction.) The score in group B it was 1.17 ± 0.38 and in group R it was 1.21 ± 0.42 which were comparable.

Postoperative nausea and vomiting (PONV)

Postoperative nausea and vomiting (PONV) are important side effects that influence readiness for discharge from a hospital.¹⁹ In our study, 14 patients of group B and 9 patients of group R were having Nausea. Similarly 13 patients of Group B and 10 patients of group R, were having vomiting.

CONCLUSION

Percutaneous nephrolithotomy (PCNL) is used for fragmentation and removal of stones from pelvicalyceal system using a nephroscope passed into the kidneys through a track created in the patients back. Hence we conclude segmental epidural anaesthesia is a safe alternative technique to general anaesthesia for PCNL. Both the drugs Ropivacaine and Bupivacaine were safe and clinically comparable in segmental epidural for PCNL

This is a preliminary study in ASA I-II patients, whether this technique can be used in high risk patients requires further studies. Positioning of the patient is very easy due to the segmental block. Surgeons were comfortable and supra and infra costal punctures were possible without complications.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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