

Is segmental epidural anaesthesia an optimal technique for patients undergoing percutaneous nephrolithotomy?

Address for correspondence:

Dr. Devangi A Parikh,
Parijat, Pushpa
Colony, Manchhubhai
Road, Malad (East),
Mumbai - 400 097,
Maharashtra, India.

E-mail: sdevangi10@gmail.com

**Devangi A Parikh, Geeta A Patkar, Mayur S Ganvir, Ajit Sawant¹,
Bharati A Tendolkar**

Departments of Anaesthesiology and ¹Urology, Lokmanya Tilak Municipal General Hospital,
Lokmanya Tilak Municipal Medical College, Mumbai, Maharashtra, India

ABSTRACT

Background and Aims: Neuraxial anaesthesia has recently become popular for percutaneous nephrolithotomy (PCNL). We conducted a study comparing general anaesthesia (GA) with segmental (T₆-T₁₂) epidural anaesthesia (SEA) for PCNL with respect to anaesthesia and surgical characteristics. **Methods:** Ninety American Society of Anesthesiologists Physical Status-I and II patients undergoing PCNL randomly received either GA or SEA. Overall patient satisfaction was the primary end point. Intraoperative haemodynamics, epidural block characteristics, post-operative pain, time to rescue analgesic, total analgesic consumption, discharge times from post-anaesthesia care unit, surgeon satisfaction scores and stone clearance were secondary end points. Parametric data were analysed by Student's *t*-test while non-parametric data were compared with Mann-Whitney U-test. **Results:** Group SEA reported better patient satisfaction ($P = 0.005$). Patients in group GA had significantly higher heart rates ($P = 0.0001$) and comparable mean arterial pressures ($P = 0.24$). Postoperatively, time to first rescue analgesic and total tramadol consumption was higher in Group GA ($P = 0.001$). Group SEA had lower pain scores ($P = 0.001$). Time to reach Aldrete's score of 9 was shorter in group SEA ($P = 0.0001$). The incidence of nausea was higher in group GA ($P = 0.001$); vomiting rates were comparable ($P = 0.15$). One patient in group SEA developed bradycardia which was successfully treated. Eight patients (18%) had hypertensive episodes in group GA versus none in group SEA ($P = 0.0001$). One patient in GA group had pleural injury and was managed with intercostal drain. Stone clearance and post-operative haemoglobin levels were comparable in both groups. **Conclusion:** PCNL under SEA has a role in selected patients, for short duration surgery and in expert hands.

Key words: General anaesthesia, percutaneous nephrolithotomy, segmental epidural anaesthesia

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INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is a minimally invasive endoscopic surgery usually performed under general anaesthesia (GA).^[1] However, there are several concerns related to GA such as stress response during induction, prone positioning, post-operative nausea and vomiting (PONV) and respiratory complications.^[2] Regional anaesthesia (RA) is associated with lower morbidity and mortality than GA^[3] and can be an alternative to GA. PCNL surgeries have been conducted under

spinal anaesthesia (SA) and combined spinal-epidural (CSE) anaesthesia^[4,5] and only epidural anaesthesia (EA).^[6,7]

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Segmental epidural anaesthesia (SEA)^[8] selectively blocks pain fibres from the surgical site. It limits sympathetic and motor block which could probably avoid hypotension and aid in easy positioning in PCNL surgery.^[9] Considering the potential advantages, the basis of the current study was to selectively block thoracic epidural segments from T₆ to T₁₂ for PCNL surgery. In this randomised controlled trial, our aim was to compare SEA and GA for PCNL with overall patient satisfaction as the primary end point.

METHODS

This prospective, randomised controlled single blind study was conducted from May 2012 to April 2013 after Institutional Ethics Committee approval. Ninety American Society of Anesthesiologists (ASA) physical status grade I/II patients of either sex, between 18 and 60 years were included. Patients were examined a day before surgery according to the institute protocol. They were counselled in detail regarding both the types of anaesthesia and operative procedure. Written informed consent was obtained. Exclusion criteria were body mass index >30, contraindication to EA, allergy to local anaesthetics and undilated pelvic/lyceal system. The visual analogue scale (VAS) for quantification of pain was explained. Patients were randomly divided into two equal groups, group GA and group SEA on basis of computer generated randomisation scheme. Random group assigned was enclosed in a sealed opaque envelope to ensure concealment of allocation sequence. The sealed envelope was opened by the anaesthesiologist conducting the case to administer either GA or SEA. The anaesthesiologist conducting the case could not be blinded owing to different techniques of anaesthesia. The anaesthesiologists in the PACU and the ward were blinded to group allocation. Intramuscular atropine 0.6 mg was administered half hour prior to surgery in the preoperative holding area. In the operation theatre routine monitoring included electrocardiogram, oxygen saturation, non-invasive blood pressure and capnography. (PM-9000Express, Penlon, Abingdon, UK). Intravenous access was secured and pre-loading with crystalloid solution at 5 mL/kg was started. Intravenous (IV) pantoprazole 40 mg and ondansetron 0.08 mg/kg was given. Group GA patients received IV midazolam 0.02 mg/kg and fentanyl 2 µg/kg. Induction of anaesthesia was performed with IV thiopentone sodium up to 5 mg/kg, vecuronium 0.1 mg/kg and maintenance with 60% nitrous oxide in oxygen, intermittent vecuronium and propofol infusion 50–150 µg/kg/min titrated to

maintain heart rate (HR) and blood pressure $\pm 20\%$ of baseline. At the end of the surgery IV paracetamol 1 g and local infiltration with 0.25% bupivacaine was administered at the surgical site. After adequate antagonism of neuromuscular blockade and tracheal extubation, patients were shifted to PACU.

In group SEA, the epidural space was located with the patient in the sitting position at T₁₂-L₁ or T₁₁-T₁₂ space using the loss of resistance to saline technique. The epidural catheter (Epidural Minipack, System 1, Portex, Kent, UK) was inserted 5 cm cephalad in the epidural space (tip approximately at T8). Epidural catheter was fixed at the site of insertion using transparent medical dressing (3M™ Tegaderm™, USA), to maintain sterility. The remaining length of the catheter was fixed 5 cm parallel to the spine up to the shoulder, contralateral to the side of the surgery to ensure stability. Test dose of 3mL of lignocaine 2% with adrenaline 5 µg/mL was administered. Patients were then made supine and loading dose of 0.75% ropivacaine (Ropin, Neon, Mumbai, Maharashtra, India) 1–1.5 mL/segment depending on the height of the patient was injected to achieve an epidural block of T₆-T₁₂ segments. The sensory block level was checked, and if the desired level was not achieved then an additional dose of ropivacaine, 1 mL/spared segment was given. In spite of additional ropivacaine (maximum up to 16 mL), if the sensory block was still below T₆, then it was considered a block failure and GA was administered. Oxygen was supplemented through nasal prongs. A nasal capnograph was also placed. Once T₆ level was achieved, the surgical procedure was started.

The surgical procedure consisted of inserting a ureteric catheter in the lithotomy position for retrograde pyelography. This was followed by percutaneous renal access under fluoroscopic guidance in the prone position. Stones were disintegrated using pneumatic lithotripter.

In group SEA, ureteric catheterisation was accomplished using perurethral 2% water soluble lignocaine jelly, and if required IV propofol was administered. For patients who required propofol for ureteric catheterisation, prone position was given only when Ramsay Sedation Score of 2^[10] (cooperative, tranquil) was achieved. After ureteric catheterisation, all patients were given the prone position. The patients had their head and neck rotated to one side on a gel-based head ring. A breathing circuit with mask, oropharyngeal airway and a ProSeal

laryngeal mask airway (LMA) was kept ready as rescue airway devices. The segmental level of anaesthesia was checked after prone position was given. The total number of segments blocked and the volume of drug required was also noted. One hour after the initial epidural drug administration, sensory level was checked at T₆ level every 15 min using an ether swab. If the level was below T₆, epidural top-ups (3 mL 0.75% ropivacaine) were given till the completion of surgery. The protocol specified 3 mg/kg or 150 mg (20 mL), whichever was lesser as the maximum dose limit of ropivacaine for the entire surgery. In spite of an adequate level, if the patient complained of pain, then IV fentanyl 1µg/kg was given and if the patient was anxious, midazolam 0.02 mg/kg was given, up to a maximum of two rescue doses for each. Motor blockade of the lower limbs was also checked and noted at three-time intervals, i.e., before lithotomy, before prone and at the end of the surgery using Bromage scale (0- No loss of movement at hip, knee and ankle, 1 – loss of movement at the hip, 2 – loss of movement at hip and knee, 3 – loss of movement at the hip, knee and ankle). At the end of the surgery, 8 mL of 0.125% ropivacaine with 2µg/kg buprenorphine was administered for analgesia. The epidural catheter was removed before shifting the patient to PACU. If the irrigation and lithotripsy time exceeded two hours, or if more than three percutaneous renal access punctures were required to remove the stone load in either group, or if the upper limit of protocol specified dose of ropivacaine or rescue drugs was reached, then the surgery would have been completed in two sittings. The nephrostomy tube would be kept in situ and remaining stones would be removed in the next sitting.

Intraoperative haemodynamic and respiratory parameters were noted every ten minutes till the end of surgery. Adverse events, if any were noted. Bradycardia (HR <45 bpm) was treated with IV atropine sulphate 0.01 mg/kg. Hypotension (drop in systolic blood pressure >20% of baseline) was treated with fluid replacement and if needed, IV ephedrine hydrochloride. At the end of the surgery, patients were auscultated to detect any pleural injury. Surgical characteristics pertaining to stones were noted.

In the PACU, patients were monitored for 2 h. Time to reach Aldrete's score of 9⁽¹¹⁾ was noted. Time of administration of the first rescue analgesic (IV tramadol 1 mg/kg given at VAS >3) was documented. VAS scores were noted at 1, 4, 6, 12, 24, 48 and 72 h. Along with tramadol, ondansetron 8 mg IV on day 1 and orally on day 2 and 3 was administered. Total analgesic requirement

was also noted. All the patients were discharged on post-operative day 3. Post-operative haemoglobin was done on day 2 and the difference from pre-operative level was noted. Surgeons were asked to opine regarding ease of patient positioning, locating pelvicalyceal system and overall comfort using a rating of good, fair or poor, immediately after surgery. Similarly, patients were asked to rate their overall satisfaction and overall comfort on a numerical scale (numeric rating scale 0–10) on post-operative day 3 in the surgical ward. Scores ranging from 0 to 2 were considered very poor, 3 to 5 poor, 6 to 8 fair and 9- to 10 were considered good. Reasons for fair, poor and very poor satisfaction were sought and noted.

Data analysis was done using SPSS version 16.0. (SPSS Inc., Chicago, Illinois, U.S. A.) Z-score normality tests were applied to assess whether variables were normally distributed. Normally, distributed continuous variables were evaluated using unpaired *t*-test for intergroup and paired *t*-test for intragroup comparisons. Data not normally distributed was evaluated by Mann–Whitney U-test. Categorical data were analysed using Chi-square test. *P* < 0.05 was considered as statistically significant.

Sample size calculation was based on the primary outcome parameter i.e. the overall patient satisfaction. Sample size was calculated based on the reported patient satisfaction in laparoscopic cholecystectomy under SA in comparison to GA⁽¹²⁾ where the population standard deviation was 1.1. To detect a difference of satisfaction score of 1 between the groups, with the power of the study at 80% and keeping alpha error at 5%, 43 patients were needed per group. To accommodate for dropouts ninety patients were recruited.

RESULTS

Ninety patients were recruited. All of them underwent their planned surgical procedure and received their allocated mode of anaesthesia. None of the assigned patients dropped out of the study. The patient's demographic characteristics were comparable between the two groups [Table 1]. The block characteristics are outlined in Table 2. The mean dose of ropivacaine required for the entire surgery was 70.27 ± 17.02 mg. One patient developed intraoperative discomfort in SEA group, and IV midazolam was supplemented. Three patients complained of pain mainly in the shoulder region, and after confirming adequate sensory level IV fentanyl was administered. None of the patients had Bromage score more than two at

any point of surgery, and most of the patients could position themselves in the prone position on their own, with minimal assistance.

Baseline haemodynamics were comparable in both groups. Intergroup comparison with respect to HR showed significant difference ($P=0.001$) between the two groups from 0 min upto 120th min; with mean HR in group GA (90.13 ± 2.19 beats/min) being higher than group SEA (78.62 ± 2.27 beats/min) [Figure 1]. After induction, group SEA had a fall in MAP (4-15%) from its baseline value which was statistically significant ($P=0.01$), but the patients were clinically stable [Figure 2]. Inter-group comparison of MAP at similar time intervals showed no significant difference ($P = 0.24$) between the two groups, except at 70–100 min, where group GA had higher MAP. One patient in group SEA developed bradycardia at the time of dilatation of puncture site which responded to IV atropine. Eight patients (18%) had hypertension in group GA in comparison to none in group SEA ($P = 0.0001$). The patients were treated with additional propofol boluses. There was no episode of desaturation in either group. EtCO_2 was in normal range and comparable in both groups.

Post-operative data are mentioned in Table 3. Time to reach Aldrete's score of 9 was significantly shorter in group SEA ($P = 0.0001$). Patient satisfaction score was higher in group SEA than GA ($P = 0.007$). More number of patients in SEA group reported satisfaction as good, as compared to GA group. Reasons for fair (15 patients) and poor (4 patients) satisfaction in group GA was mainly due to PONV and pain. On the other hand, five patients in group SEA reported fair satisfaction due to discomfort during epidural space location, and one patient with poor satisfaction had discomfort during surgery. Surgeon satisfaction was good for all cases except for one case in SEA group, where the patient had discomfort.

Table 1: Patient characteristics

Parameters	Group GA (n=45)	Group SEA (n=45)	P
Age (years)	44.13±11.52	44.17±14.98	
Sex (M/F)	28/17	25/20	
ASA Grade (I/II)	25/20	21/24	
Body mass index (kg/m ²)	22.26±1.91	21.72±3.18	
Duration of surgery in minutes median (IQR)	120 (100-130)	100 (90-130)	0.162

Data expressed as Mean±SD or median (IQR) or number (proportion). Group GA – General anaesthesia, Group SEA – Segmental epidural anaesthesia, ASA – American Society of Anaesthesiologists; SD – Standard deviation, IQR-Interquartile range

Pain scores were significantly lower in SEA group than in GA group at 1, 4, 6, 12, 24 and 48 h. Total tramadol requirements were significantly higher in GA group.

Patients in GA group had significantly higher incidence of nausea ($P = 0.02$). Although more number of patients in GA group experienced vomiting, the difference was not statistically significant. One patient in GA group had pleural injury which was managed with an intercostal drain and was discharged on day 5. Operative time, changes in haemoglobin and residual stones were comparable in both groups.

DISCUSSION

Based on the results, SEA appears to have few merits in terms of haemodynamic stability, faster recovery, better pain scores, lesser PONV, better patient satisfaction but also has notable demerits in terms of supplemental GA requirement, unprotected airway, intraoperative discomfort and possibility of patient movement.

GA carries its own risks in terms of stress response during induction, during lithotomy and prone position, intraoperative awareness, extubation response, post-operative restlessness and agitation.^[13] Moreover, the multiple changes of positions during PCNL are very cumbersome under GA. A previous

Table 2: Segmental epidural block characteristics

Block Characteristics	Data
Location of epidural space, n (%)	
T ₁₁ -T ₁₂	5 (12.5)
T ₁₂ -L ₁	40 (88.9)
Time taken for complete block (min; mean±SD)	10.62±2.25
Total segments blocked, n (%)	
T ₄ -T ₁₂	7 (15.5)
T ₆ -T ₁₂	27 (60)
T ₆ -L ₁	11 (24.4)
Patients requiring supplementary epidural doses, n (%)	12 (27)
Volume of ropivacaine (0.75%) for initial bolus	8.4±1.03
Total volume of ropivacaine for entire surgery including initial bolus (mL), mean±SD	9.37±2.21
Bromage score, median (IQR)	
Before lithotomy	0
Before prone	0 (0-1)
After surgery	1 (1-1)
Patients requiring rescue fentanyl top ups, n (%)	3 (1.35)
Number of patients requiring propofol for ureteric catheterisation, n (%)	5 (11)

Data expressed as mean±SD, number (proportion) or median (IQR). SD- Standard deviation; IQR- Interquartile range

Table 3: Post-operative recovery, analgesia and satisfaction scores

Parameters	Group GA (n=45)	Group SEA (n=45)	P
Time to reach Aldrete's score of 9 (min)	27.22±5.60	10.40±4.16	0.0001*
VAS score median (IQR), h			
1	2 (0.5-3)	0 (0-0.5)	0.0001*
4	3 (1-4)	1 (0-1)	0.0001*
6	3 (2-3)	2 (2-2)	0.0001*
12	4 (2.5-5)	2 (2-4)	0.001*
24	3 (3-4)	2 (0-2)	0.0001*
48	2 (2-3)	2 (1-2)	0.011*
72	2 (1-2)	1 (0.5-2)	0.018
Time to first rescue analgesic (min)	93.56±21.86	415.33±69.82	0.0001*
Total intravenous tramadol on day 1 (mg)	179.56±40.73	119.11±31.97	0.0001*
Total oral tramadol on day 2 and 3	295.45±21.07	391.11±95.99	0.0001*
Nausea, n (%)	17 (37.7)	4 (8.8)	0.001*
Vomiting, n (%)	2 (4.4)	0	0.15
Patient satisfaction score, median (IQR)	8 (6-9.5)	9 (9-10)	0.001*
Patient satisfaction, n (%)			
Good	26 (57.5)	39 (86.8)	0.005*
Fair	15 (33.3)	5 (11)	
Poor	4 (9.2)	1 (2.2)	
Very poor	0	0	
Surgeon satisfaction, n (%)			
Good	45 (100)	44 (98.8)	0.06
Fair	0	1 (2.2)	
Poor	0	0	

*P<0.05. Data expressed as mean±SD or median (IQR) or number (proportion). GA – General anaesthesia; SEA – Segmental epidural anaesthesia; SD – Standard deviation; VAS- Visual analogue scale; IQR- Interquartile range

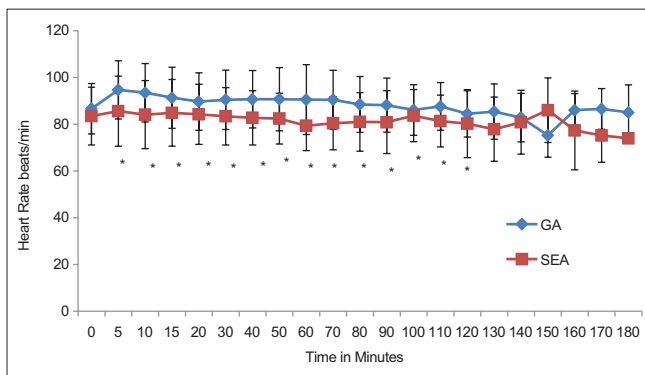


Figure 1: Changes in heart rate intraoperatively and in PACU. Time '0' intubation/ epidural drug injection. Data expressed as mean (Standard deviation). *P<0.05.

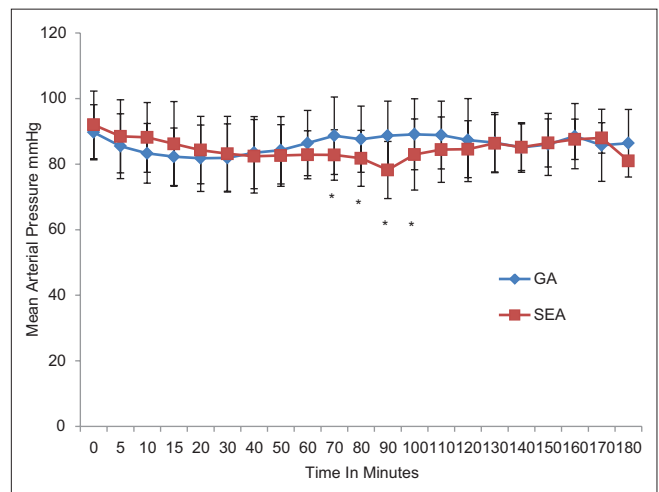


Figure 2: Changes in mean arterial pressure intraoperatively and in PACU. Time '0' intubation/ epidural drug injection. Data expressed as mean (Standard deviation)*P<0.05

study also observed that EA is better than GA for open renal surgeries in the lateral position.^[13]

We chose SEA for PCNL, as SA or CSE has its own limitations. Hypotension has been reported when SA is administered for PCNL.^[14,15] Moreover, SA does not give the margin for prolonged surgery if required. CSE may also lead to haemodynamic instability, as peripheral pooling of blood does occur. Authors comparing GA with CSE for PCNL^[5] reported that 21% of patients in CSE group required phenylephrine. Patient positioning would also be a concern in SA

and CSE, like in GA cases. In the current study, eight patients had hypertension in group GA, mainly at the time of serial dilatation of the percutaneous renal access site. This was observed inspite of titration of propofol infusion to protocol specified upper limit. In the absence of depth of anaesthesia monitors in our set up, it was treated with additional propofol boluses. The SEA technique aimed to block only

the T₆-T₁₂ segments; thereby eliminating lower limb motor blockade (median Bromage 0) and hypotension, ease of surgical positioning, having the advantage of prolonging the block through epidural catheter and avoiding the potential problem of headache caused by dural puncture.^[14,15] However it can be argued that with the SEA technique, there is always a risk of patient movement during surgery. We did not experience such a situation, probably because the patients were adequately counseled and experienced surgeons were performing the surgery. Bleeding is an important risk during PCNL and injury to renal calyces is possible with patient movement. So the advantage of easy positioning is offset with the possibility of patient movement during surgery. Moreover, patients with good motor blockade are likely to be more comfortable as compared to those with no blockade.

As SEA blocked only T₆-T₁₂ segments, the protocol included propofol for ureteric catheterisation. Out of the 34 patients who had level up to T₁₂, only 5 patients required propofol for catheterisation. This could be explained because of perurethral application of lignocaine jelly. It could also be because of blockade of thinly myelinated fibres, which carry afferents from bladder and ureter.^[16] However, the fact that propofol was necessary for these 5 patients during ureteric catheterisation, means that standalone SEA is not useful and supplemental GA is required. Even though prone position was given in these patients only when Ramsay Sedation Score of 2 was achieved, there is a chance of change in sedation levels which could jeopardise positioning, haemodynamics and airway. EA does not block proprioception which may cause discomfort to patients in spite of an adequate sensory blockade. Propofol infusion has been used for sedation for PCNL performed under EA in a recent study.^[6] In the current study, most of the patients were comfortable in prone position without any sedation, probably because they were adequately counselled. Monitoring of adequacy of respiration in prone position was done clinically as well by nasal capnography. Breathing circuit with mask, oropharyngeal airway and ProSeal LMA were kept ready as rescue airway devices, and as the patient's head was turned to one side, there was easy access to airway. ProSeal LMA is a suitable alternative rescue airway and can be inserted easily in prone position by experienced users.^[17,18]

A previous study^[7] which compared GA, EA and paravertebral block for PCNL inserted the epidural

catheter at L₃-L₄ level and injected 25 mL of 0.5% bupivacaine. Authors reported lower MAP in lumbar epidural group requiring vasopressors. A recent study^[6] evaluating EA for PCNL, used continuous epidural infusion (at L₁-L₂ level) with levobupivacaine at 5 mL/h. The study has compared surgical outcomes. Block characteristics and haemodynamics have not been mentioned. A meta-analysis^[19] in 2015 confirmed the potential advantages of RA over GA in terms of efficacy and safety in PCNL. A recent study comparing SEA and SA for PCNL^[9] concluded SEA technique is better in terms of haemodynamics, positioning, postoperative analgesia, patient satisfaction and PONV. However, the authors found the SEA technique difficult to execute in terms of epidural space location.

Patient satisfaction scores were significantly better in SEA group. This is consistent with studies where RA was used for PCNL.^[5,9,18] The reasons for fair and poor satisfaction in GA group were due to pain and PONV. The fair satisfaction in SEA group was due to discomfort in epidural space location and highlights the importance of anaesthesiologists experience in thoracic epidural for this technique. One patient with poor satisfaction complained of intraoperative discomfort, which highlights the limitation of SEA technique. The epidural catheter was removed at the end of surgery, as surgeons in our set up are not comfortable with epidural catheters in the busy surgical ward. Group SEA had lower VAS scores post-operatively on day 1. This could mainly be due to the pre-emptive analgesic effect of neuraxial anaesthesia.^[19] In spite of removal of epidural catheter, VAS scores were lower in group SEA on 2nd post-operative day. This could be explained because neuronal hypersensitivity and nociception after incision are maintained primarily by sensitised nociceptors during the perioperative period.^[20] Higher incidence of nausea in GA group was probably due to nitrous oxide, opioids and higher tramadol consumption. Higher patient satisfaction in SEA group was mainly due to lesser postoperative pain and PONV. This advantage may be negated by other concerns related to SEA technique. There is a possibility of patient movement during surgery with need of supplemental GA. Lack of access to airway halfway into the procedure, with critical surgical situation is a limitation of RA, even though rescue airway devices are kept ready. Hypothermia is a risk in PCNL and there is a greater risk with central neuraxial blockade. We used irrigation solutions at 37°C and forced air warmer to keep the patients warm. However

a long duration surgery under SEA may render the patient hypothermic as well as uncomfortable. These shortcomings may limit the use of SEA routinely, and can be only be used for short duration cases with prior discussion with the surgeons.

The main limitation of the study was that it included a selected group of patients and experienced surgeons only. We excluded patients with undilated PCS because surgeons in our setup find it difficult to locate the PCS in these cases, as a precise puncture is required. We did not have depth of anaesthesia monitoring. Hence, there could have been an error in evaluating the incidence of hypertension in the GA group that had been encountered. This could be a confounder for analysing results pertaining to haemodynamic comparisons between the two groups. Future research options could include use of additives to SEA to obtain better patient comfort^[13] and planned studies recruiting high risk patients where a combination of SEA and GA could be evaluated.

CONCLUSION

SEA is possible for percutaneous nephrolithotomy in selected patients, for short duration surgery, with experienced surgeons and anaesthesiologists working in coordination. Choice of patients and pre-operative counselling is very important.

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Conflicts of interest

There are no conflicts of interest.

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