Comparison of percutaneous nephrolithotomy under epidural anesthesia versus general anesthesia: A randomized prospective study

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Original Article

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) has revolutionized the treatment of renal calculi putting almost an end to the era of open stone surgery. PCNL as a procedure for renal calculi has evolved significantly since its first description by Fernström and Johansson in 1976 and is currently

Aims and Objectives: We evaluated the surgical outcome after PCNL in two groups of patients randomly divided to undergo procedure under GA or EA.

Patients and Methods: Two hundred and thirty patients with American Society of Anesthesiologists (ASA) score <3 were randomly divided into two groups according to the type of anesthesia: i.e. GA (n=110) or EA (n=120). All patients underwent PCNL in prone position. Puncture was done using Bulls eye technique under fluoroscopic guidance and tract dilated using serial dilators up to 24Fr-28 Fr. Demographics, perioperative and postoperative parameters were noted and data analysed.

Results: The two groups were comparable in terms of mean age, distribution of stone location, and stone burden. The stone free rate was 90.9% in GA group and 89.2% in EA group and the difference was statistically insignificant (P= 0.659). The requirement for auxiliary procedures was similar between the two groups. A significant difference in pain score was seen in favor of EA group during early post-operative period (P< 0.05).

Conclusion: It seems that PCNL can be performed safely and effectively under regional epidural anesthesia with results comparable to general anesthesia with the added advantage of less immediate postoperative pain and analgesic requirement.

Keywords: Epidural anesthesia, general anesthesia, percutaneous nephrolithotomy

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the preferred modality for large and complex calculi at most institutions." Advances in surgical technique and technology have enabled urologists to further refine this procedure improving safety and efficacy and decreasing morbidity. The procedure can safely be carried out under general anesthesia (GA) or regional anesthesia namely spinal anesthesia (SA), epidural anesthesia (EA), or combined spinal and EA (CSEA) with each anesthesia technique having its advantages and disadvantages. The procedure has been carried out even under local anesthesia in combination with intravenous sedatives and analgesics. The advantages with GA include the ability to control breathing and respiratory movements which is essential especially when contemplating an upper pole puncture to avoid pulmonary complications. The complications associated with GA include drug reactions, atelectasis, postoperative nausea, vomiting, and tracheal tube displacement and neurologic events especially at the time of position change. A number of studies have demonstrated the success of regional anesthesia for PCNL with decreased overall analgesia requirement and complication rates similar to GA. Furthermore, GA may be unacceptable to patients with comorbidities and is less cost effective as compared to regional anesthesia.

Keeping in view that the patient can be maintained under EA for desirable duration of time as in GA, using epidural catheter and at the same time avoiding the inherent drawbacks of GA, we aimed to assess the surgical outcome after PCNL in two groups of patients randomly divided to undergo procedure under GA or EA.

PATIENTS AND METHODS

The study was carried out at Department of Urology, Sher-i-Kashmir Institute of Medical Sciences Srinagar, India between June 2016 and June 2019. A total of 230 patients were included in the study and randomly divided into two groups as per the anesthesia type, i.e., GA ($n=110$) or EA ($n=120$) using random number tables. The patients were evaluated with an ultrasound kidneys, ureter and bladder (KUB), X-ray KUB and computed tomography (CT) urogram. In patients with a deranged renal function, contrast was avoided and non-contrast CT scan (NCCT) was done with functional assessment obtained by a nuclear renogram. A written informed consent was obtained from all the patients. The study included patients older than 18 years, with renal stones larger than 2 cm. A negative urine culture was ensured prior to the procedure. Patients with skeletal deformity, renal anomaly, bleeding diathesis, anticoagulation use, the American Society of Anesthesiologists $>3$ were excluded from the study.

All patients received a $3^{rd}$ generation cephalosporin at induction.

Briefly, for GA induction was done with xylocard $1$ mg/kg, propofol $2$ mg/kg, fentanyl $2$ $\mu$g/kg, and rocuronium $0.8$ mg/kg as muscle relaxant and maintained with a mixture of $O_2$ and $N_2O$, isoflurane and supplements of muscle relaxant and fentanyl. For EA, patient was made to sit on operating table, $T_2$, $T_{10}$ or $T_{10}$, $T_{11}$ thoracic intervertebral space identified and approached with 18G Touhy needle and confirmed by loss of resistance technique. An epidural catheter was placed for intermittent bolus technique. Epidural was activated by $8–10$ mL of $0.5\%$ ropivacaine with $10$ $\mu$g/mL of fentanyl. The extent of sensory block was assessed by blunt needle.

All patients underwent PCNL in prone position. Cystoscopic ureteric catheterization was done in lithotomy position after which the patient was shifted prone. Puncture was done using Bulls eye technique under fluoroscopic guidance and tract dilated using serial dilators up to $24$ Fr–$28$ Fr at which time the appropriately sized Amplatz sheath was deployed. A nephroscope was introduced into collecting system and stones were fragmented using pneumatic lithotripter or Ho:YAG laser and fragments extracted using grasper. A Double J (DJ) stent was inserted in all the patients at the completion of procedure and the nephrostomy tube insertion was optional depending on surgeon preference.

A KUB radiograph was obtained on the first postoperative day for all patients to assess the status of stone clearance. Stone free rate (SFR) was defined as residual fragments <4 mm. Patients with residual fragments <4 mm were reevaluated at 1 month with a fresh KUB radiograph and ultrasound/NCCT.

Statistical method

The recorded data were compiled and entered into a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, USA). The statistical analysis was performed using SPSS Version 20.0 (SPSS Inc., Chicago, USA) with 0.05 as level of significance.

Table 1: Demographic profile of patients

| Variable                  | GA (n=110) | EA (n=120) | $P$   |
|---------------------------|------------|------------|-------|
| Mean age±SD (years)       | 38.5±13.87 | 39.9±11.96 | 0.405 |
| Sex, n (%)                |            |            | 0.035 |
| Male                      | 62 (56.4)  | 66 (55)    |       |
| Female                    | 48 (43.6)  | 54 (45)    |       |
| Stone location            |            |            | 0.993 |
| Pelvis                    | 22         | 23         |       |
| Calyceal                  | 28         | 30         |       |
| Pelvic+calyceal           | 51         | 56         |       |
| Upper ureter              | 09         | 11         |       |
| Stone burden (cm²)        | 5.46±2.17  | 6.19±3.52  | 0.057 |

SD: Standard deviation
Illinois, USA). Continuous variables were expressed as mean ± standard deviation and categorical variables were summarized as frequencies and percentages. Graphically, the data were presented by bar diagrams. Student’s independent t-test was employed for comparing continuous variables. Chi-square test or Fisher’s exact test, whichever appropriate, was applied for comparing categorical variables. A *P < 0.05* was considered statistically significant. All *P* values were two-tailed.

RESULTS

The mean age of patients in the general group and spinal group was 35.5 ± 13.87 and 39.9 ± 11.96 years (*P* = 0.405), respectively. A total of 110 patients were included in GA group and 120 patients in EA group. Men constituted 56.36% in general group and 55% in epidural group and 43.63% and 45% were women in respective groups (*P* = 0.885). There was no significant difference between the two groups in terms of stone location and stone burden as summarized in Table 1.

Mean operative time calculated from calyceal puncture to nephrostomy tube insertion/puncture site closure was 36.52 ± 16.52 min and 38.49 ± 16.99 min for general group and epidural group respectively and was comparable between the two groups (*P* = 0.369). Mean hospital stay was 4.17 ± 1.92 and 3.79 ± 1.84 days respectively in general and epidural group (*P* = 0.127). Preoperative hemoglobin level was 13.64 ± 2.39 and 14.01 ± 1.98 in general group and epidural group respectively (*P* = 0.201) and the corresponding values at discharge were 11.68 ± 1.89 and 12.06 ± 2.16 and were comparable (*P* = 0.159). None of the patients in either group required blood transfusion.

The SFR was 90.9% in general group and 89.2% in epidural group with no statistically significant difference between the two groups (*P* = 0.659). The perioperative data are summarized in Table 2.

Pain score on visual analog pain scoring was significantly less in early postoperative period in EA group compared to GA group as detailed in Table 3, which translated into less postop analgesic requirement in EA group.

Auxiliary procedures included a repeat PCNL in three and two patients in general and epidural group respectively (*P* = 0.672). Ureteroscopy with/without DJ stenting and shock wave lithotripsy was required in seven and nine patients in general and 16 and 20 patients in epidural group respectively (*P* = 0.735) as detailed in Table 4.

The complications noted were graded as per Clavien–Dindo grading system and are presented in Table 5. No complications compatible with Clavien–Dindo Grade IIIb, IV, or V were noted in either group. Eight patients in general group and nine patients in epidural group had Clavien–Dindo Grade-I complication which included fever of <24 h duration, nausea, vomiting controlled by antipyretics and antiemetics. Clavien–Dindo Grade II complications were noted in 17 and 21 patients in general and epidural group, respectively, mostly in the form of fever >48 h duration managed by antibiotics. Seven cases in general and 6 cases in epidural group had Clavien–Dindo Grade IIIa complication which included clot retention in one patient from each group, stent related symptoms in 3 cases in general group and 4 cases from epidural group mandating stent removal, one patient in each group required chest tube placement for hydro-hemothorax and

| Variable                                      | GA       | EA       | *P*     |
|-----------------------------------------------|----------|----------|---------|
| Operative time (min)                          | 36.52±16.52 | 38.49±16.99 | 0.369   |
| Preoperative hemoglobin (g/dL)                | 13.64±2.39 | 14.01±1.98  | 0.201   |
| Hemoglobin at discharge (g/dL)                | 11.68±1.89 | 12.06±2.16  | 0.159   |
| Hospital stay (day)                           | 4.17±1.92  | 3.79±1.84   | 0.127   |
| Stone free rate (%)                           | 90.9      | 89.2      | 0.659   |

| Table 3: Perioperative data of patients who underwent percutaneous nephrolithotomy according to type of anesthesia (general vs. spinal) |
|------------------------------------------------------------------------------------------------|
| Assessment hour | GA (n=110) | EA (n=120) | *P*     |
|-----------------|------------|------------|---------|
| 1               | 6.41±3.09  | 2.98±2.92  | <0.001*|
| 3               | 5.36±2.72  | 3.07±2.41  | <0.001*|
| 12              | 3.92±1.98  | 3.45±2.03  | 0.078   |
| 24              | 3.43±2.14  | 3.26±1.85  | 0.519   |
| 48              | 2.37±1.79  | 2.03±1.86  | 0.159   |

*Statistically significant difference (*P*<0.05)

| Table 4: Requirement for auxiliary procedures after percutaneous nephrolithotomy in patients with different types of anesthesia |
|-------------------------------------------------------------------------------------------------------------------------------|
| Auxiliary procedure                                           | GA | EA | *P*   |
|---------------------------------------------------------------|----|----|-------|
| Re-PCNL                                                      | 3  | 2  | 0.672 |
| Ureteroscopy+Double J stenting                               | 7  | 9  | 0.735 |
| Shock wave lithotripsy                                     | 16 | 20 | 0.658 |

PCNL: Percutaneous nephrolithotomy

| Table 5: Perioperative complications as per Clavien-Dindo system grading |
|----------------------------------------------------------------------------|
| Complication             | GA | EA |
|--------------------------|----|----|
| Grade I                  | 8  | 9  |
| Grade II                 | 17 | 21 |
| Grade IIIa               | 7  | 6  |
| Grade IIIb               | 0  | 0  |
| Grade IV                 | 0  | 0  |
| Grade V                  | 0  | 0  |
two patients in general group had stent migration with urinary leakage after nephrostomy removal managed by DJ stent exchange.

**DISCUSSION**

PCNL as a minimally invasive procedure has become the preferred modality for treating large and complex renal calculi as well as upper ureteric stones at most institutions.[2,3,13]

The procedure has undergone several modifications such as mini-PCNL, ultra mini PCNL, micro-PCNL, Super mini-PCNL, tubeless PCNL, totally tubeless PCNL all aiming at reducing morbidity yet maintaining a high efficiency in terms of stone clearance.[14‑17] On the other hand there have been efforts to minimize the anesthesia related morbidity during PCNL and in the postoperative period without compromising the efficacy of the procedure. This has translated into more and more use of regional rather than GA during PCNL. GA has its inherent risks such as increased incidence of anaphylaxis due to multiple drugs used, more pulmonary complications such as atelectasis, nausea, vomiting, vascular, and neurologic complications as well as problems associated with endotracheal tube during change of position from lithotomy to prone.[7‑10] In a study by Basiri et al., 11 patients had developed devastating neurologic events after PCNL under GA in prone position and no such neurologic events were noted in patients under SA.[18] This difference in neurologic complications may be attributed to unawareness during GA during position change. For the first time, PCNL was performed under regional anesthesia (epidural) in 1988 by Ballestrazzi et al. and revealed acceptable findings in patient satisfaction and hemodynamic status, although the effect on surgical parameters was not reported.[19] Saied et al. in 1991 and later Atallah et al. in 2006 revealed that SA is a reliable option for PCNL and that the procedure is pain free and the postoperative requirement for opioids also was significantly less.[20,21] The SA is safe, feasible and well tolerated method particularly for elderly patients with cardiac and pulmonary comorbidities.[22] During SA, however, if the surgery gets prolonged or the anesthesia wears off intraoperatively, it is difficult to convert to GA due to prone position and oftentimes leads to abandonment of the procedure. This difficulty can be overcome by using EA via epidural catheter and in case the procedure gets prolonged or the anesthesia wears off intraoperatively the same epidural catheter in place can be used for top up anesthesia. The EA was reported to be safe and effective for renal surgery by Bajwa et al. in their study comparing GA with EA in patients undergoing renal surgeries.[23] Kuzgunbay et al. in their comparison of CSEA with GA for PCNL reported that CSEA was a feasible option for PCNL especially in patients with high risk for GA and difficult intubation with comparable results.[7] Mean age, stone size, hemoglobin drop, SFR, and hospital stay were comparable between the two groups.

In a randomized study comparing the surgical outcomes in 64 patients who had undergone PCNL with different types of anesthesia (CSEA vs. general), Singh et al. reported a significantly lower analgesic requirement in 24 h after PCNL. ($P < 0.003$).[24] Mean operative time, hospitalization period, fluoroscopic time, SFR, and blood transfusion rate were reported to be comparable between the two groups. The meta-analysis by Liu et al. showed that the frequency of nausea and vomiting in the RA group were lower than that in the GA group. Moreover, PCNL under RA was associated with decreased postoperative pain with lower analgesia requirement.[25]

This study was performed to assess and compare various surgical parameters and the analgesia requirement in patients randomly assigned to undergo PCNL in GA or regional EA. Operative time, hospital stay, hemoglobin drop, SFR, requirement for auxiliary procedures and complication rates were comparable between the two patient groups and pain score on VAS was significantly better in early postoperative period in EA group. Similar results were reported by Tangpaitoon et al. in their comparison of the efficacy and safety of EA with GA in patients undergoing PCNL.[26] Further, we maintain the epidural catheter in place routinely till 1st postoperative day and use it for epidural analgesia as and when required. With this early ambulation is possible and patients are started on light orals the same evening which has the potential to cut down the hospital stay as shown by other studies also.[24-26]

**CONCLUSION**

PCNL can be performed safely and effectively under regional EA with results comparable to GA with the added advantage of less immediate postoperative pain and analgesic requirement. Patients can be maintained under EA for desirable duration to allow PCNL for even larger and complex stones. We consider that EA may be a safe and effective alternative to GA for PCNL especially in patients unfit for GA or difficult to intubate.

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Conflicts of interest
There are no conflicts of interest.

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