

A Randomized Study Comparing Effectivity and Safety of Spinal Anesthesia Versus General Anesthesia in Patients Undergoing Percutaneous Nephrolithotomy (PCNL)

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Abstract: Context: Comparison of two anesthesia in Percutaneous Nephrolithotomy surgeries. Background and Aims: PCNL can be performed under general anesthesia, regional anesthesia or local anesthesia. Recently, PCNL under spinal anesthesia was reported as having some advantage over general anesthesia, such as lower post operative pain, lower dose requirement for analgesic drugs and avoidance of the side effects from multiple medication during general anesthesia. The aim of this study was to compare the efficacy and safety of regional spinal anesthesia (SA) and general anesthesia (GA) in patients who underwent PCNL. Methods: A hospital based, randomized and comparative study was performed in total 100 patients divided into 2 groups of 50 each. Group A received GA. Group B received spinal isobaric levobupivacaine (0.5%) 3.5ml. Sample size was calculated at 80% study power, a level 0.05 assuming difference in mean to be detected 12.9+ 21.1. Results: There was no significant difference in systolic blood pressure, diastolic blood pressure and mean blood pressure preoperatively and significant difference thereafter between the groups. Post operative average pain score at 2hr, 3hr and 6hr was showing highly significant difference between GA and SA groups (P value <0.001). There was highly significant difference in Mean tramadol requirement within 24 hours which was lower in spinal group (79.0± 28.7mg) than of general anesthesia group (125.0± 43.2 mg). There was statistically no significant difference in adverse effects like hypotension, bradycardia in both groups except nausea. Conclusion: The advantages of spinal anesthesia over general anesthesia are less postoperative pain, analgesic usage, nausea/vomiting and adverse effects from medication.

Keywords: Spinal anesthesia, general anesthesia, levobupivacaine, percutaneous nephrolithotomy

1. Introduction

Percutaneous nephrolithotomy (PCNL) is the treatment of choice for large renal calculi, staghorn calculi and calculi which fail treatment with extracorporeal shockwave lithotripsy and ureteral endoscopy. PCNL is usually performed under general anesthesia due to better control of breathing and more comfort for the patients. However, there are some occasional side effects from general anesthesia such as lung atelectasia, drug allergy and postoperative nausea and vomiting. Several attempts have taken place in last few years to reduce morbidity, analgesia requirements and duration of hospitalization after PCNL. One of these attempts is regional anesthesia instead of general anesthesia to avoid anaphylaxis due to use of multiple drugs and reduce complications of general anesthesia such as pulmonary (atelectasia), vascular, and neurologic disorders (brachial nerve injury); specially during change of the position [1].

However there are controversies among researchers regarding the use of SA in PCNL due to the most important issue which is acute hypotension, resulting from sympathetic block [2-5]. Therefore, BP and pulse rate (PR) can be helpful to monitor sympathetic drive in these patients. There are many studies comparing GA and SA in several surgeries [6-10], however, there is no definite comparison made by BP and PR in PCNL during surgery and in recovery room.

The present study was conducted to compare the effectivity and safety of spinal anesthesia versus general anesthesia in patients undergoing percutaneous nephrolithotomy (PCNL)

2. Material and Methods

The study included 100 patients of ASA grade I & II, between the age group 20- 60 yrs., undergoing PCNL surgery in Department of Anaesthesiology, S.M.S. Medical College and Attached Group of Hospitals, Jaipur with permission from Institutional ethical committee, Research Review Board & Informed consent was obtained for performance of spinal anesthesia or general anesthesia after complete explanation about the study protocol and the procedure.

Study design was hospital based, randomized, comparative and observational. Sample size was calculated at 80% study power, a level 0.05 assuming difference in mean to be detected 12.9 + 21.1 as per the seed article. For minimum detectable difference 50 patients were required in each Group as sample size.

3. Selection of Patient

Inclusion Criteria

- ASA grade I, II
- Age 20- 60 years.
- Patient Ht.>145cm
- Patients undergoing PCNL (surgery for 1-2 hrs.)
- Patient wt 45 – 85 Kgs

Exclusion Criteria

- Patient refusal
- Patient having contraindications for spinal anesthesia (infection at the site of injection, spine deformity, patient receiving antiplatelet drugs such as aspirin, clopidogrel,

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patient receiving heparin, pre-existing neurological defects, bleeding disorders, coagulation diathesis), endocrinal disease.

- Patient with chronic history of headache & backache.
- Any contraindication to Levobupivacaine use.
- Known hepatic, renal, cardiac, neurological, psychiatric, metabolic or respiratory disease.
- Evidence of gross radiological and anatomical abnormality in lumbar region.

Pre-anesthetic Check Up

Thorough pre-anesthetic check up was done a day before surgery and it included:-

- Complete history of patient. (history of past and present illness, history of drug allergy and treatment)
- Local examination of lumbosacral region to look for presence of any deformity.
- General physical and systemic examination, any cardiac, pulmonary & neurological pathology of significant nature.
- Airway examination.
- Pulse rate, blood pressure, respiratory rate examination of the patient.
- Routine investigations: - Hb, TLC, DLC, BT, CT, Chest X-ray, ECG, FBS, B. Urea, Creatinine, Serum electrolytes, Urine examination.

Groups

Patients were randomly allocated into two groups of 50 patients each. Randomization was done by CHIT IN BOX method, a total of 100 chits (50 per group) were made, each chit mentioned a particular study group. Patients were asked to pick up a chit from the box. Patient were allocated to group mentioned on chit.

- 1) **Group A** - Received General Anesthesia
- 2) **Group B** - Received Spinal anesthesia with isobaric Levobupivacaine (0.5%) 3.5 ml

After taking informed consent & confirming overnight fasting, patient were taken in the operation theatre. Baseline vitals, BP, PR, RR, SpO₂ were recorded. i/v line secured with 18G canula.

Technique of General Anesthesia

- **Premedication** with Inj. Glycopyrrolate (0.005 mg/kg), injection Fentanyl(2µg/kg), inj. Midazolam (0.01mg/kg) and Inj. Ondansetron (0.1mg/kg)
- **Preoxygenation** with 100% oxygen for 3 minutes.
- **Induction** with inj. Thiopentone 5mg/kg followed by inj. Succinyl choline 1mg/kg after recording hemodynamic measurements.
- **Intubation** with ET tube of appropriate size after direct laryngoscopy. Hemodynamic measurements recorded just after intubation and 5min. interval.

- **Maintenance** with 40% O₂+ 60% N₂O+Isoflurane(0.6-1.5%) and inj. Atracurium (0.5 mg/kg) initially then 0.1 mg/kg supplemental dose as per requirement.
- **Intraoperative monitoring** continued and hemodynamic measurements recorded at 5 min interval for first 20 min, and every 10 min thereafter.
- **Reversal** with inj.neostigmine (0.05 mg/kg) and inj.glycopyrrolate (0.01 mg/kg). Hemodynamic measurements recorded after giving inj. neostigmine and inj. glycopyrrolate.
- **Extubation**- done and hemodynamic parameters recorded immediately after extubation and 5 min after extubation. Patients shifted to recovery room and any immediate post operative complication e.g. nausea, vomiting, shivering, respiratory depression, sedation, restlessness, hypotension, bradycardia etc were recorded and managed.

Technique of Spinal Block

Pre loading was done with 10-15 ml/kg Ringer lactate

Inj. Midazolam (0.01 mg/kg) and inj. Ondansetron (0.1 mg/kg) was given.

Patient was placed in sitting position on the operating table. Back of patient was painted & draped with sterilized hole towel. Under all aseptic precaution, a dural puncture was made at the L3-L4 interspaces with a 25 gauge spinal needle and isobaric levobupivacaine, (0.5%) 3.5 ml was administered in subarachnoid space.

Patient was made in lying down position and level of sensory and motor block, quality of analgesia and vitals were recorded. After 5 minutes patient was changed to prone position.

Both the groups were compared in terms of

- Hemodynamic changes - systolic BP, diastolic BP, mean BP were recorded.
- Duration of analgesia – postoperative VAS score was noted at 2hrs. 3hrs and 6hrs. Postoperative analgesic use was recorded for 24 hrs.
- Side effects – hypotension, bradycardia, pruritis, nausea, respiratory depression were recorded.

4. Results

There was no statistically significant difference in the demographic profile and baseline of hemodynamic variables between the two groups.

Table 1: Demographic Distribution

Group	Minimum Age (in Years)	Maximum Age (in Years)	Mean Age ± S.D.	Minimum Weight (in Kgs)	Maximum Weight (in Kgs)	Mean Weight ± S.D.
Group A (GA)	20	60	40.6 ± 12.9	46	80	58.5 ± 11.3
Group B (SA)	20	60	37.5 ± 14.5	45	86	58.7 ± 8.2

On comparison, the p Value was found to be 0.2514(not significant) for age and 0.9025(not significant) for weight distribution.

Table 2: ASA Grade Distribution

	ASA Grade		Total
	I	II	
Group A(GA)	41	9	50
Group B(SA)	37	13	50
Total	78	22	100

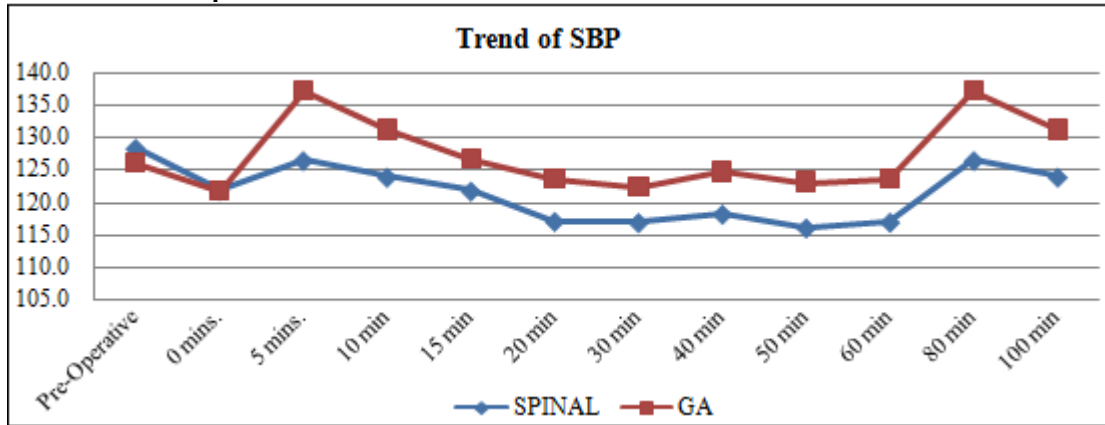
As shown in table 2, there was no significant difference in ASA grade between the groups. (p=0.3342)

Table 3: Duration of Surgery

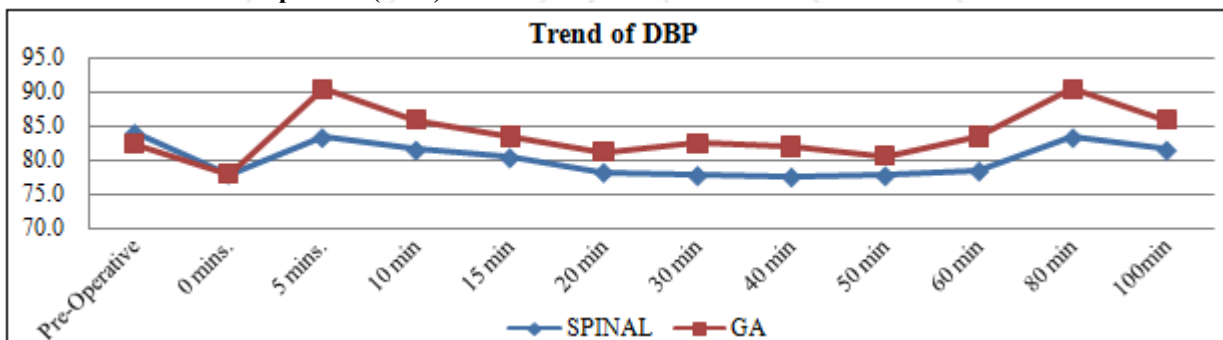
Group	Minimum duration (in minutes)	Maximum duration (in minutes)	Mean duration ± S.D.
Group A (GA)	60	90	74.6 ± 10.7
Group B (SA)	60	100	69.8 ± 10.5

As shown in table 3, there was significant difference in duration of surgery between the groups. (p=0.0015)

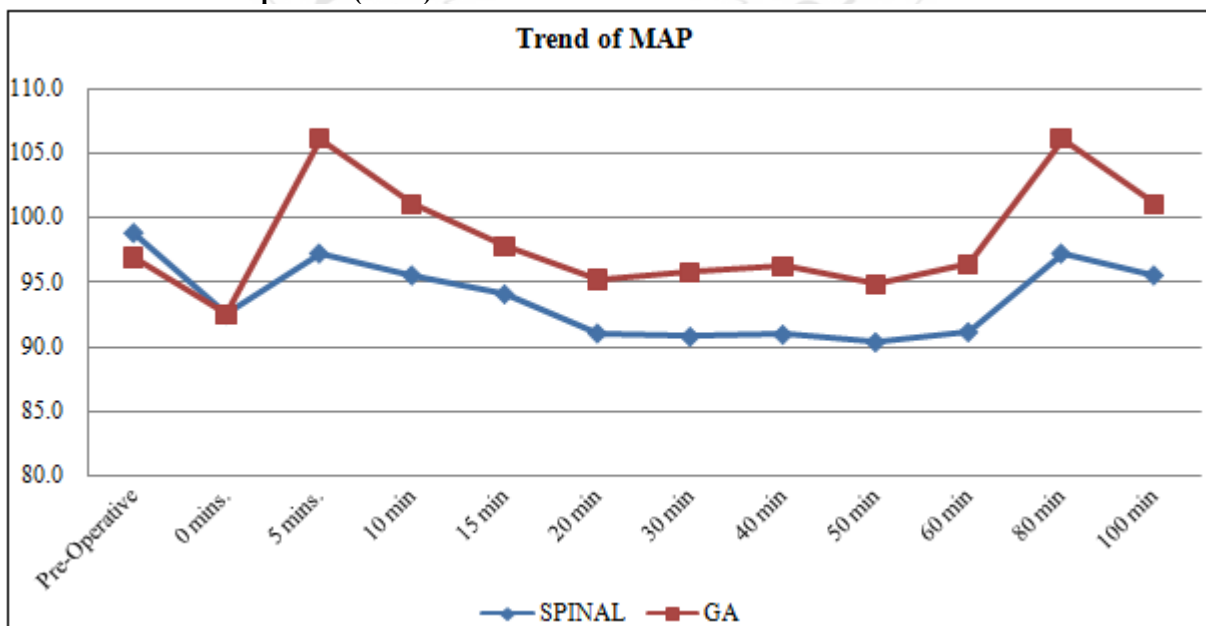
Systolic Blood Pressure Comparison



Diastolic Blood Pressure Comparison (DBP).



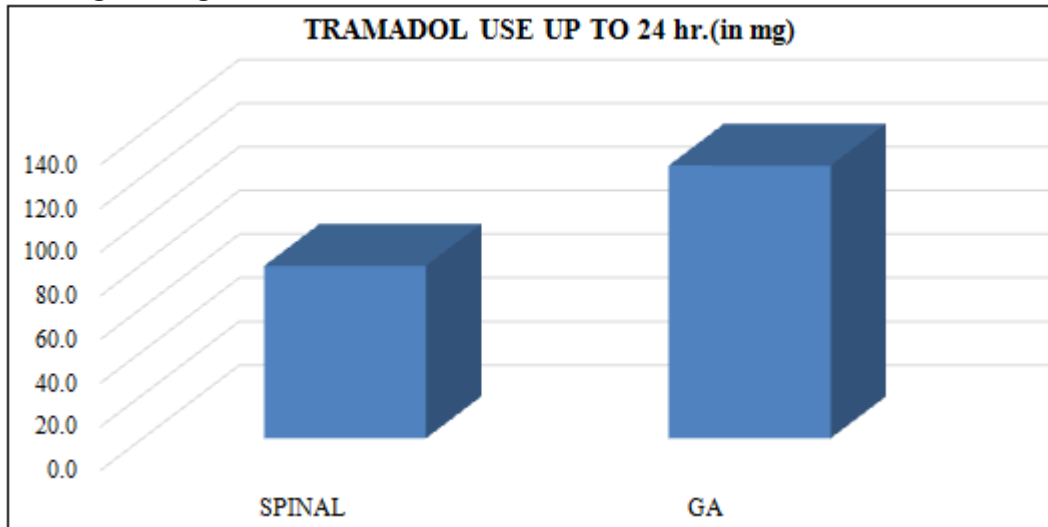
Mean Arterial Pressure Comparison (MAP)



Post Operative VAS score

	Anaesthesia	N	Mean	SD	P value
2hr	Spinal	50	1.0	0.0	< 0.001
	General	50	1.9	0.5	
3hr	Spinal	50	2.2	0.6	< 0.001
	General	50	3.7	0.8	
6hr	Spinal	50	3.8	0.8	< 0.001
	General	50	5.3	0.8	
12hr	Spinal	50	3.6	0.9	< 0.001
	General	50	5.1	0.8	
18hr	Spinal	50	2.7	0.7	< 0.001
	General	50	3.4	0.6	
24hr	Spinal	50	1.5	0.6	< 0.001
	General	50	2.3	0.5	

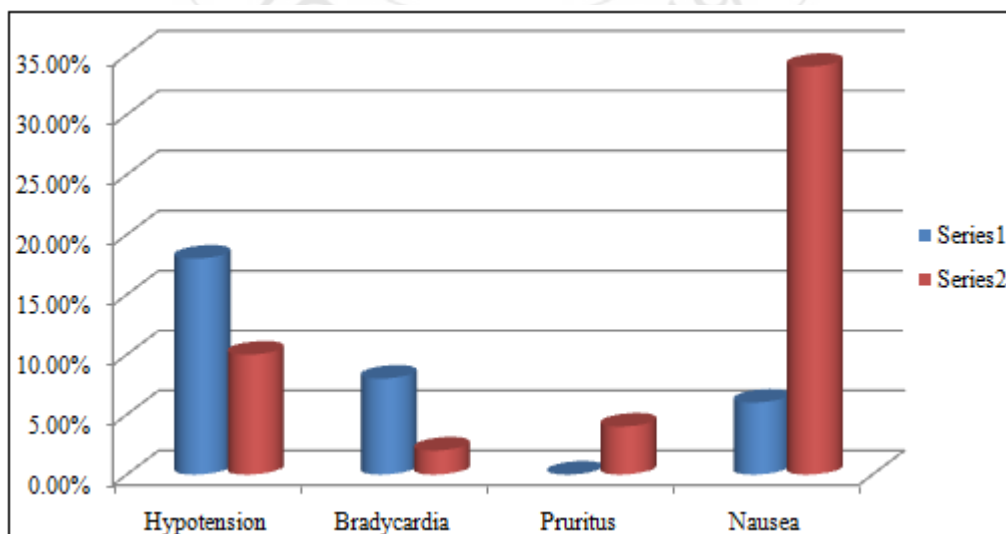
Post Operative Analgesic Usage



P value 0.0000 Highly significant

There was highly significant difference in Mean tramadol requirement within 24 hours was lower in spinal group (79.0± 28.7mg) than of general anesthesia group (125.0± 43.2 mg).

Intraoperative Side Effects



There was no significant ($p > 0.05$) difference in adverse effects like hypotension, bradycardia in both groups except nausea. There was no sedation, pruritis, respiratory depression and vomiting in any case.

5. Discussion

The present study was done to compare spinal anesthesia and general anesthesia in patients undergoing PCNL in terms of hemodynamic stability, postoperative analgesia and side effects. The disadvantages of general anesthesia compared to spinal anesthesia are increased incidence of anaphylaxis due to multiple medications usage and more pulmonary, vascular, neurologic complications and problems associated with the endotracheal tube during the change of position from supine to prone Mehrabi et al. [11]. Recently PCNL under spinal anesthesia was reported to gain benefits because of better postoperative quality of life due to early postoperative recovery.

In our study there was highly significant difference in post operative average pain score at 2hr (SA-1.0 , GA-1.9) 3hr (SA-2.2,GA-3.7) 6hr (SA-3.8, GA-5.3), 12hr(SA-3.6, GA-5.1), 18 hr (SA-2.7, GA-3.4), 24 hr (SA-1.5, GA-2.3) Mean tramadol requirement within 24 hours was lower in spinal anesthesia group (79.0± 28.7mg) than of general anesthesia group (125.0± 43.2 mg).p < 0.001. Result of our study is similar to Movasseghi et al. [12], Mehrabi et al. [11], Karacalar et al. [14] and Kuzgunbay et al. [15].

Pulse rate

There was no significant difference in pulse rate preoperatively between the groups (P value >0.05) but there was increase in pulse rate at 5 min and 10 min in GA group which was significant (p<0.05). These hemodynamic changes may be because of stress response at the time of intubation and increase in pulse rate at 60 min, 80 min, 100 min in GA group was also significant (p<0.05). It may be due to extubation response in GA group.

Blood pressure

There was no significant difference in systolic blood pressure, diastolic blood pressure, mean arterial pressure (p-value >0.05), preoperatively but significant difference thereafter between the groups (p-value <0.05). There was increase in SBP, DBP and PR at the time of intubation and extubation in GA group and hemodynamic changes at the time of positioning of the patient in both the groups.

Lowering blood pressure is due to peripheral pooling the blood in lower extremities in SA group in comparison to GA group. But fall in blood pressure not so significant that cause hypotension when we use drug Levobupivacaine in SA group. Result of our study is similar to Hazem El Sayed Moawad and Ahmed S.El Hefnawy [17], Cacciapaglia et al. [16] in which they found significant difference in blood pressure intraoperatively in GA group and to Movasseghi et al. [12] in which they concluded that heart rate was not significantly different at designated time points between two groups (P > 0.05).

Our study showed similar results like vomiting, pruritis, hypotension, bradycardia, were not different between the groups but higher rate of nausea in general anesthesia group and also less postoperative pain ,less analgesic medication requirement in SA group. The results of our study were similar to study done by Mehrabi et al. [11], Andreoni et al.

[18], Karacalar et al. [14], Hazem El Sayed Moawad and Ahmed S.El Hefnawy [17] and Movasseghi et al. [12].

6. Conclusion

Regional spinal anesthesia is an alternative technique to General anesthesia in PCNL with reduced morbidity. The advantages of spinal anesthesia over general anesthesia are early postoperative recovery, less postoperative pain, analgesic usage, nausea/vomiting and adverse effects from medication with the same efficacy and safety.

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