Original Research Article

Can mode of anaesthesia interfere with the discharge in patients undergoing day care ureteroscopic surgeries? A randomized control trial comparing general with spinal anaesthesia

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ABSTRACT

Background & Aim: Improvement in Surgical and Anaesthetic techniques allows even complex surgeries to be performed as day care cases. The objective of the study is to compare the recovery parameters of patients undergoing anaesthesia for ambulatory surgeries under General or Spinal Anaesthesia.

Materials and Methods: After approval by IEC, this study was performed in 60 patients undergoing elective ureteroscopic procedures. Patients were Randomized to receive either General anaesthesia (Group GA: n=30) or Spinal Anaesthesia (Group SA: n=30). GA was induced using standard protocols with airway maintained spontaneously using LMA. In group SA patients received 1.5 ml 0.75% Isobaric Ropivacaine for providing anaesthesia. Vitals were recorded in both the groups throughout the procedure. In addition to intra operative haemodynamics, the onset of duration and percentage of patients achieving complete sensory & motor block was also recorded in SA group.

Patients were kept in phase I recovery till score of Aldrete 9 was reached. In phase II recovery (PACU) the percentage of patients sitting at 180 min, standing at 300 min and walking at 360 min were recorded. The psychomotor skills of patients were assessed using digit symbol substitution test (DSST) before discharging from phase II recovery. The main criteria for discharging patients from phase II recovery was Post Anaesthesia Discharge scoring (PADSS). Patients were discharged from phase II recovery on reaching PADSS <10.

Results: Seventy three patients were enrolled and 60 patients completed the study. The onset of sensory and motor block in Group SA was 6.61±0.83 min and the onset of motor block was 9.48±0.91 min. Percentage of patients achieving complete sensory & motor block was 71%. The duration of sensory block was 208±17.95 min and the duration of motor block was 182.07±15.98. Patients in group GA took 221.07±4.97 and Group SA took 110.72±7.04 min to reach Aldrete score of 10 (p value <0.05). At 180 min only 22.33% patients in group GA were able to sit, while in Group SA it was 70 (p value <0.05). The comfort score assessed by surgeon was excellent in group GA (4/4) and was only satisfactory (2/4) in Group SA. There was no difference in pain perception or PADSS at 360 min or psychomotor skills tested by Digital symbol substitution test (DSST).

Conclusion: The technique of Anaesthesia doesn’t interfere with readiness of patients to discharge home in terms of maintain stable vitals, pain or side effects. Isobaric Ropivacaine was found to be a poor choice for providing spinal anaesthesia due to slow onset of sensory block, inability to achieve complete motor block thus providing difficulty to operating surgeon.

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1. Introduction

Day care surgery gives the freedom for the patient to be admitted on the day of planned surgical procedure and
return home on the same calendar day. Improvements in surgical and anaesthetic techniques has made more and more complex procedures like hip replacements, colorectal surgery, Robot assisted prostatectomy etc possible with ease. Hospitals have developed their own enhanced recovery after surgery (ERAS) protocols aiming to maximize recovery, minimize postoperative discomfort like pain, nausea, vomiting and promote early safe discharge. Considering the benefits of day care surgeries, the Royal College of Surgeons in their revised guidelines have suggested a day-case target for elective surgery of 50%. The most common procedure done as a day care case in our hospital is Uretero-lithotripsy and stenting. This study was done to evaluate the recovery parameters and readiness to discharge of patients undergoing either spinal or general anaesthesia for uretero-lithotripsy. GA was provided with airway secured using LMA while Isobaric Ropivacaine 12.5 mg (1.5 ml 0.75% Ropivacaine) was used for providing SA. Isobaric Ropivacaine was chosen because of its reduced toxic potential, better hemodynamic profile, and shorter duration of sensory and motor block allowing early mobilization.

2. Materials and Methods

After approval by the Institutional Review Board, this study was registered with the Clinical trial registry of India (CTRI/2019/03/017979). This prospective, randomized study was done on 60 patients undergoing elective urological surgeries in a Tertiary Medical College Hospital between January to June 2019. Patients of the American Society of Anaesthesiologists (ASA) Physical status I or II; in the age group of 18–60 years were included in the study. Informed written consent was obtained from each patient for participating in the study, 60 patients (30 in each group) posted for day care urological procedures were enrolled for the study.

The patients were randomized to receive either general anaesthesia (Group GA: n =30) or spinal subarachnoid block (Group SA: n =30) by computer generated random numbers and closed envelope method. The commonly used doses of drugs as per literature evidence were selected. All the patients received Tablet Alprazolam 0.5 mg, Ranitidine 150 mg and Metoclopramide 10 mg premedication overnight and two hours before surgery. A randomization envelope was opened at this stage and the patient was allocated to Group SA or GA. All the patients were monitored continuously with an electrocardiogram, non-invasive blood pressure (NIBP) and pulse oximetry intra-operatively and post-operatively for 24 hours.

Patients received spinal anaesthesia in sitting position using 27 G Quincke Babcock spinal needle with 0.75% isobaric Ropivacaine as anaesthetic agent. Dose for spinal was standardized as 12.5 mg (1.5ml) of 0.75% isobaric Ropivacaine with 0.5ml (25mcg) of Fentanyl. The onset of sensory (Time to reach T 10 level) and motor block (Bromage 3) was recorded. Percentage of patients achieving adequate sensory block (T10) and motor block (Bromage 3) at 10 minutes after injecting the study drug spinal was also assessed.

Group GA received premedication with intravenous Ondansetran 4mg. Anaesthesia was induced with Fentanyl 2mcg/kg, Propofol 2mg/kg. Proseal LMA of suitable size was inserted. Anaesthesia was maintained with Oxygen, Nitrous oxide at 1:2 ratio, with inhalational anaesthetic Sevoflurane 0-2%. Sevoflurane was discontinued after DJ stent placement at the end of surgery. LMA was removed when the patient responded to oral commands. Patients were shifted to Phase I recovery for further monitoring.

In SA Group Inj. Midazolam 1mg was given to patients to reduce anxiety if required. Any complaints of pain or discomfort during procedure were treated with Inj. Fentanyl 1mcg/kg IV bolus. If still pain or discomfort persisted the attending anaesthetist was allowed to convert the case to GA at his discretion. Patients in both the groups received Paracetamol 20mg/kg intravenously at the end of surgery. Surgeon was asked to grade their comfort during surgery which was recorded in four grades from 4-excellent to 1-poor.

Patients in both groups were shifted to phase 1 recovery area and monitored till Modified Aldrete score of 9 was achieved. HR, MAP, Oxygen saturation and VAS score were recorded in phase I recovery. Once Aldrete score of 10 was achieved they were shifted to phase II recovery. In phase II recovery patients were monitored for HR, NIBP and Saturation. In addition; in patients who received SA total duration of sensory block and total duration of complete motor block were also recorded. At 3.00 hours (180 min), Ramsay sedation score was checked if the score was ≥2, and if vitals were stable patients were encouraged to sit in the bed with support. If the patients had no complaints of nausea and vomiting, they were encouraged to drink water. At 5 hours (300 min) they were encouraged to stand with support (Staffs holding on either side). In spinal group standing was encouraged only after confirming return of Bromage to 1 (No detectable weakness in lower limbs). If the patient had no complaint of giddiness, they were encouraged to walk from 6th hour (360 min). PADSS score of 9 (Post anaesthesia discharge scoring system) which includes vital signs, ambulation, gait, pain, nausea vomiting, surgical bleeding were recorded every half an hour in all patients from 6th hour (360 min) till score of 9 was achieved. Patients were discharged from phase 2 recovery on reaching PADSS score of ≥9.

The Practice Guidelines for Post anaesthetic Care recommends that the routine requirement for urination before discharge should not be part of a discharge protocol and may only be necessary for selected patients. In our study data on voiding was not collected as all patients
were catheterized, and it was systematically removed on 3rd postoperative day during outpatient consultation. At the end of 300 min psychomotor skills of patients was assessed using digit symbol substitution test method.\textsuperscript{10,13} DSST (Digit symbol substitution test) measured recoding skills and recognition of sensory (visual) information, mental concentration, fine muscular coordination and ability to alter eye fixation. In DSST patients were given 90 seconds to replace 30 randomly arranged digits with appropriate symbols located in a legend at the top of the page.

Pain at rest was assessed using VAS score at 1, 4, and 6 hour post operatively. Pain on ambulation was checked at 6th hour using VAS score before discharging patient from PACU. Anytime VAS was above 4, rescue analgesic Inj. Tramadol 100mg IV was given. During recovery stay presence of complications like nausea, vomiting and shivering were also recorded.

Sample size calculation was based on an initial pilot study with time to sit up as the primary endpoint of the study. The incidence of patients who were able to sit up in GA group was 22.33\% at 180 min and was 70\% in SA group. With \( \alpha \) error of 0.05 and power of the study \( (1- \beta) \) at 95\%, the sample size required is calculated as 54. Allowing 10\% attrition, we needed 59 patients to complete the study. We enrolled 73 patients and completed the study with 60 patients. The patients, who were part of the pilot study, were not included in the study. Descriptive statistics including proportions and measures of central tendency and measures of dispersion were used to describe the data. Students unpaired t test was used to compare means & standard deviation. Further, The Fishers’ exact test was utilized to analyse categorical data. A \( P < 0.05 \) was considered to be statistically significant and a \( P < 0.001 \) as statistically highly significant

3. Results

73 patients were recruited into the study. A consolidated Standards of Reporting Trials (CONSORT) flow diagram depicting the passage of participants’ through the study has been provided in Figure 1. There were three cases of an incomplete block in SA group after 20 minutes and all were converted to general anaesthesia. The data from these three patients were excluded from the study. There were no variations in demographic characteristics like age, sex, weight and ASA physical status between the three groups. The demographic profile of patients was comparable between the groups. Type of surgery and duration of surgery were also found to be similar [Figure 1].

Patients in group SA received Isobaric Ropivacaine. The onset of sensory block was 6.61± 0.83 min and the onset of motor block was 9.48± 0.91 min. Percentage of patients achieving complete sensory & motor block was 71\%. The duration of sensory block was 208± 17.95 min and the duration of motor block was 182.07±15.98. On comparing the hemodynamic parameters, no significant difference in vitals were found between the groups during surgery, phase 1 recovery or during stay in PACU. Patients in both the groups maintained saturation throughout the procedure. Patients in both the groups had score VAS <4 (Group GA 2.04 ± 1.147 and SA1.62 ± 0.77) during stay in phase 1 recovery.

The time taken to achieve mean Aldrete score of 9 was comparable with 8.5 ± 4.3 min in group GA and 8.9 ± 5.73 min in group SA. There was significant difference in the time taken to achieve Aldrete score of 10. (GA 221.07 ± 4.97 and SA 110.72 ± 7.04)

Percentage of patients sitting with support at 180 min was 22.33\% in GA and 70\% in SA group. All the patients in SA and GA group were able to stand with support at 300 min and walk with support at 360 min. Post Anaesthesia Discharge Score (PADSS) of 9 was achieved by all the patients in both the groups at 360 min. Quality of anaesthesia assessed by surgeon at the end of procedure was 2/4 for group SA while it was 4/4 for group GA (p value 0.66).

Pain perception by VAS score was assessed at 1, 4, and 6 hours post operatively. Pain on ambulation was also checked at 6th hour before discharging patient from PACU. None of the patients had VAS>4 indicating absence of pain.

The Psychomotor skills of patients were tested in the post-operative period at 300 min in both the groups using digit symbol substitution test. Group GA completed the digit symbol substitution test (DSST) in 58.67 ±0.41 seconds and group SA completed in 60.52±0.37 seconds. Test for statistical significance using unpaired t test showed p value of 0.131 indicating no significant difference between the groups.

4. Discussion

The International Association for Ambulatory Surgery defines true ambulatory surgery as a discharge during the time frame of one working day (6-8 hours) with no overnight stay and ambulatory surgery with extended recovery with a stay for 1 night postoperatively in a hospital facility (overall stay up to 23 hours).\textsuperscript{14} Anaesthesiologists have now evolved to become Perioperative physicians playing a key role in fast-tracking patients for ambulatory surgeries.\textsuperscript{15}

Urosurgical procedures account for a large proportion of elective ambulatory surgical cases in our centre. In our study we compared the readiness to discharge provided by two techniques: SA using Isobaric Ropivacaine and GA with airway maintained spontaneously using LMA. Ropivacaine was chosen as it provides good sensory block, predictive levels which lack ascending to higher segments, good differential block and shorter duration compared to Bupivacaine.\textsuperscript{16}
Table 1: Demographic characteristics

|                  | Group GA       | Group SA       | P value |
|------------------|---------------|---------------|---------|
| Age distribution | 38.89±8.5     | 37.22±10.69   | 0.505   |
| Sex distribution |               |               |         |
| Male             | 62.22%        | 68.9%         | 0.588   |
| Female           | 37.8%         | 31.11%        |         |
| ASA              |               |               |         |
| I                | 60.00%        | 73.3%         | 0.276   |
| II               | 40%           | 26.7%         |         |
| Duration of surgery | 41.04±8.9 | 44.48±10.8    | 0.1834  |

Table 2: Modified Aldrete score

|                  | Group GA       | Group SA       | P value (student t test) | Standard error of difference |
|------------------|---------------|---------------|-------------------------|-----------------------------|
| Time to achieve Mean Aldrete score of 9(in min) | 8.5±4.3 | 8.9±5.73 | 1.00 | 1.308 |
| Time to achieve Mean Aldrete score of 10(in min) | 221.11±5.063 | 117.76±4.973 | 0.0001 | 1.573 |

Table 3: Details of sensory & motor block(in min)

|                              | Group GA | Group SA       |
|------------------------------|---------|---------------|
| Onset of sensory block       | 6.61±0.83 | 9.48±0.91     |
| Onset of motor block         | 208±1.75 | 182.07±15.89  |
| %of patients achieving complete sensory and motor block at 10 min | 71%     |               |
| Duration of sensory block    | 208±1.75 |               |
| Duration of motor block      | 182.07±15.89 |            |

Fig. 1: CONSORT diagram
Suresh KS\textsuperscript{17} compared Isobaric Ropivacaine and Bupivacaine for subarachnoid block in knee arthroscopies. The onset of sensory block with Ropivacaine was 6.14±5.09 min which was significantly slower in comparison with Bupivacaine. The duration of sensory block was 257.57±39.12 min which was significantly less than that of Bupivacaine, indicating rapid recovery from the effects of Ropivacaine. This rapid recovery according to him was not an advantage; as more number of patients had experienced pain requiring rescue analgesic. In our study the mean onset of sensory block was 6.66±0.83; and the duration of sensory block was 208.14±17.95 which was comparable with the study of Suresh KS et al. Kulkarni\textsuperscript{18} et al compared the effect of hyperbaric Ropivacaine and Bupivacaine in subarachnoid block. The onset of sensory block in hyperbaric Ropivacaine group was 4.3 min and duration of sensory block was 155 min. In this study we find that although the onset of sensory block was rapid with hyperbaric Ropivacaine compared to isobaric Ropivacaine; the duration of sensory block remained still remained low.

Kallio et al\textsuperscript{19} compared the efficacy of Plain versus hyperbaric Ropivacaine for subarachnoid block for lower limb surgeries. They found that only 64\% patients in isobaric Ropivacaine achieved motor block at T10. In our study also we found that complete sensory block at T10 and motor block of Bromage 1 were achieved only in 71\% of patients. We had noticed placing patients in lithotomy position difficult in SA group. In addition patients were constantly moving the limbs which caused much inconvenience to the surgeon (Quality of Anaesthesia 3/5). Mc Namee et al. studied the effect of Isobaric Ropivacaine 17.5 mg with Bupivacaine 17.5 mg in spinal anaesthesia for orthopedic surgeries. He observed that the onset of motor block with Isobaric Ropivacaine was delayed and he noticed a few of his patients totally failed to get any motor block during surgery.\textsuperscript{20}

Claudio\textsuperscript{21} did a retrospective analysis on the clinical impact of SA with 1\% 2-Chlorproacine compared to GA in patients who underwent knee arthroscopy. They evaluated 61 charts and found that all the patients (100\%) who received SA were able to bypass PACU while only 72\% patients needed ICU stay in GA group. They also noted patients in SA group experienced less pain, less PONV and were discharged faster. We could not draw any comparison with the study of Claudio et al. They concluded that spinal anaesthesia could be competitive and economically viable option when compared to GA. In our study we did not notice any difference in the incidence of Pain or PONV in both the groups.

Suresh KS\textsuperscript{17} compared the time to achieve PADSS score and found that patient’s who received Isobaric Ropivacaine achieved PADSS >9 faster than Bupivacaine. In our study we didn’t check the time to achieve PADSS >9, but compared percentage of patients achieving PADSS >9. We found that all the patients (100\%) in both GA and SA groups could achieve PADSS>9 at the end of 360 min. Doraic et al\textsuperscript{22} evaluated the feasibility of discharging patients on the same day after Robot Assisted radical prostatectomy (RAPC) under GA. 97 patients were enrolled in the study and the readiness to discharge was assessed using PADSS. In his study only one patient had PADSS score>9 on day zero. 74\% patients achieved discharge criteria only on the next day (day 1). The mean duration of RAPC was 2.5 h. This probably was because RAPC was done in patients with ASA 3, having prostatic malignancy and in addition the procedure was more invasive and time consuming, when compared to ours.

Scott et al\textsuperscript{23} had measured the postoperative psychomotor performance by choice reaction time (CRT) in patients undergoing surgery under GA. He used an electronic apparatus to measure CRT. His apparatus found that it took six hours for patients to completely recover from psychomotor effects of anaesthesia and surgery. In our study we measured the psychomotor performance of patients at the end of 6\textsuperscript{th} hour using digit symbol substitution test. We found that patients were able to complete the test on time and there was no difference in psychomotor recovery among patients who have undergone GA or SA. Although deaths related to ambulatory anesthesia is extremely rare, patients who undergo surgery are recommended to refrain from automobile driving for 24 hours post operatively.\textsuperscript{24} Despite the large number of tests available, no single psychomotor test can correlate well with recovery from anaesthesia and fitness for discharge. This may be the reason why psychomotor tests have not made their way into routine clinical practice.

### 5. Conclusion

In this study comparing Spinal Anaesthesia with Isobaric Ropivacaine versus GA for in patients undergoing ureteroscopic surgeries, we found that the technique of anaesthesia does not interfere with readiness to discharge from Phase II recovery in terms of vitals, incidence

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**Table 4:**

| Time (min) | SA | GA |
|-----------|----|----|
| 180 Sitting | 70 | 22.8 |
| 300 Standing | 100 | 100 |
| 360 Walking | 100 | 100 |
of nausea and vomiting, pain or psychomotor skills. Isobaric Ropivacaine is a poor choice for providing spinal anaesthesia due to slow sensory onset and poor motor block.

We could have assessed the incidence of Post spinal headache in patients who have undergone SA. We find it as limitation in our study. Further study to evaluate for better agents like 1-2% Chlorprocaine with fast onset and predictable recovery are recommended.

6. Source of Funding
None.

7. Conflict of Interest
The authors declare that there is no conflict of interest regarding the publication of this paper.

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