Comparison of spinal anaesthesia with isobaric chloroprocaine and general anaesthesia for short duration ambulatory urological procedures

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Abstract

Background and Aims: Chloroprocaine is a short-acting local anaesthetic agent for spinal anaesthesia (SA) that has been used in day care surgeries due to its faster recovery characteristics and faster discharge rates compared to other local anaesthetics. This study aimed at finding out its efficacy for the same as compared to general anaesthesia (GA).

Material and Methods: This observational study was conducted on 60 patients belonging to the American Society of Anaesthesiologists (ASA) physical status I and II who underwent short elective urological procedures (<60 min) under GA (group GA) as per standard of care in our hospital (n = 30) and SA (group SA) with 50 mg 1% isobaric 2-Chloroprocaine (n = 30). Time taken to meet the discharge criteria, modified Aldrete score and modified post anaesthesia discharge score in each group were noted. The cost of the anaesthetic procedure, anaesthetic procedural time, hemodynamics, supplemental analgesia, complications related to the procedure were noted and compared.

Results: Patient characteristics and duration of surgery were comparable. Time taken by group SA was significantly higher than group GA to meet the discharge criteria. Cost of GA [2624.76 (166.16) units] was significantly more than SA [1561.63 (81.32) units, \( P < 0.05 \)]. There was no requirement of supplemental analgesia in group SA and no hemodynamic instability or complications in either group.

Conclusion: GA is significantly better as compared to SA with 50 mg 1% isobaric 2-Chloroprocaine as an anesthetic technique in day care urology surgeries in terms of faster recovery and faster discharge rate but is costlier.

Keywords: Chloroprocaine, discharge criteria, general anesthesia, recovery, spinal anaesthesia, urology.

Introduction

Anaesthesia for day care or ambulatory surgeries requires fast recovery from the anaesthetic effects to enable early discharge. General anaesthesia (GA) has been a popular choice for this with the advent of supraglottic airway devices and short acting general anaesthetics. The number of urologic procedures/surgeries performed as day care procedures is increasing. Considering that most of these cases require infraumbilical anaesthesia, spinal anaesthesia (SA) can be another option for these group of patients. But the long duration of Bupivacaine anaesthesia has been the major deterrent to its use for spinal anaesthesia for day care urologic surgeries. Introduction of short acting 2-Chloroprocaine has rekindled the interest in spinal anaesthesia for these procedures. Since short duration (<60 min) urological day care procedures/surgeries can be performed under both general anaesthesia and spinal anaesthesia with...
2-Chloroprocaine, we sought to find out which one would be a better technique. We conducted this study to compare the techniques of spinal anaesthesia with 50 mg intrathecal 1% isobaric Chloroprocaine and general anaesthesia (Fentanyl/Propofol/Isoflurane with supraglottic airway device) for ambulatory surgeries/procedures in urology with respect to the fulfilment of the discharge criteria.

The primary objective was to compare the time taken to meet the discharge criteria in the post anaesthesia care unit (PACU) following surgery between the general anaesthesia group and the spinal anaesthesia group. The secondary objectives were to compare the incidence of significant increase or decrease in heart rate, blood pressure, assess the requirement for additional supplementation of anaesthesia/analgesia in the intraoperative period, compare the time taken to provide anaesthesia and cost comparison between the two techniques.

**Material and Methods**

This prospective observational study began after obtaining approval from the institutional ethics committee (Date and approval number – 13-12-2017; 700/2017) and was registered at the Clinical Trials Registry (CTRI/2018/03/012347). The study was conducted on patients undergoing short urological procedures lasting less than 60 min under GA (Fentanyl, Propofol And Isoflurane in air/oxygen mixture through a supraglottic airway device) or SA with 2-Chloroprocaine. Inclusion criteria were age 18 – 65 years, either gender, American society of anaesthesiologists physical status (ASAPS) I and II, undergoing elective ambulatory urological procedures expected to last not more than 60 min under GA or SA with 50 mg 1% Chloroprocaine. Exclusion criteria were any contraindication to spinal anaesthesia, known allergy to 2-Chloroprocaine or drugs used for general anaesthesia, patients with anticipated difficult airway or spinal anaesthesia as predicted by the concerned anaesthesiologist, procedures requiring postoperative irrigation or patient immobilization.

All patients were seen on the day of surgery, assessed for suitability of inclusion in the study. Written informed consent was obtained preoperatively. The patient was assessed by the consultant anaesthesiologist and the plan of anaesthesia was decided by the consultant in-charge (not an investigator of the study) based on the medical condition of the patient and patient’s preference for GA or SA. Accordingly, patients received GA (induction with Propofol, Fentanyl and maintenance with oxygen in air and Isoflurane through a laryngeal mask airway or i-gel) or SA under aseptic precautions using 50 mg 1% Chloroprocaine administered through a 25 G spinal needle.

At the end of the study, patients were grouped into two groups group GA, who received general anaesthesia and group SA who received spinal anaesthesia. There was one observer in the study who did the preoperative evaluation, checked the suitability for inclusion in the study and took informed consent. He monitored the patients during the procedure and in the postoperative period and collected the data required for the study.

The primary outcome measure, readiness to discharge from PACU and then from the hospital were assessed using modified Aldrete score (mAS) and modified post anaesthesia discharge score (mPADS) respectively [Tables 1 and 2]. A score >9 was considered as fit for discharge in both the scoring systems. Time taken to achieve the modified Aldrete score of 9 was calculated as the time interval from the patient reaching PACU from operating room to the time point when the modified Aldrete score was 9 in the PACU. Group SA patients were considered fit to be discharged from PACU only after regaining motor function in the lower limb even though they met the Modified Aldrete Score of 9 with complete motor blockade of lower limbs. Hence readiness for discharge from PACU was considered not only when the modified Aldrete score was 9 but also the score for activity had to be 2 which meant that the patient’s motor function in the lower limb had recovered. This would ensure safe ambulation. Modified Aldrete score assessment was done every 5 min up to half an hour and every 10 min after that. Time taken to achieve modified post anaesthesia discharge score (mPADS) of 9 was defined as the time from regaining motor function in the PACU to the time point when mPADS was 9. This was evaluated every 5 min for half an hour and every 10 min after that. Time taken to provide anaesthesia was defined as the time from which patients were shifted into the operating room to completion of the anaesthetic procedure and handover to the surgeon.

Blood pressure and heart rate were recorded at 1, 3, 5 min after induction of anaesthesia in group GA and after intrathecal injection in group SA, and every 5 min thereafter till the end of the procedure. Increase or decrease in mean arterial pressure or heart rate by 20% or more from the baseline was considered significant and was recorded. The concerned anaesthesiologist managed these at his/her discretion, and such interventions were recorded. Incidence of postoperative nausea, vomiting, hoarseness of voice and any other complication before meeting the discharge criteria was noted.

In group SA, sensory block was assessed using an alcohol swab (cold sensation) every 1 min till 5 min and every 5 min if need be till the maximum level of sensory blockade was attained. Level of blockade present and its regression was
noted every 5 min starting from the time of attainment of the highest level of sensory blockade. Motor blockade was assessed every minute till 5 min and every 5 min after that till the end of the procedure. The Bromage scale was used to determine the extent of the motor blockade (Grade 0 – able to move legs and feet, Grade 1 – partially able to move knees and feet, with about 33% block, Grade 2 – able to move only feet, suggesting about 66% of block and Grade 3 – unable to move feet also, which is complete block).\(^{[4,5]}\) Any requirement to supplement anaesthesia/analgesia intraoperatively was noted.

For comparing means with standard deviations of the time taken to achieve mPADS score of 9 between the two groups from our pilot study (conducted at our institution following ethics committee approval), assuming a power of 95% and a level of significance of 5% a two-tailed t-test was used to attain a total sample size of 42. Accounting the possible drop-outs and prevalence of 50% for either technique of anaesthesia, it was decided that 60 patients would be enrolled in the study. The software G-Power ver. 3.1.4 was used to calculate the sample size.

Data obtained from the study were analysed using SPSS version 16 for Windows in consultation with the Department of Medical Statistics. Numerical data expressed as mean (standard deviation) were analysed using two-tailed t-test. Categorical data were analysed using the Chi-square test. \(P\) value less than 0.05 was considered significant.

## Results

Patient characteristics were comparable between the two groups [Table 3]. The duration of surgery was 39.16 (9.31) min in group GA and 41 (10.37) min.
in group SA ($p = 0.478$). Group SA took a longer time to reach the discharge criteria as compared to group GA [Table 4]. This was because of residual motor blockade and weakness in the lower limbs even after regaining movements. Time to ambulate was delayed because of these factors as compared to group GA who did not have any motor blockade. The total time taken from the start of the surgery until the point of time when the patient was ready for discharge from the hospital was also calculated. This was also found to be longer in the SA group [Table 4]. The difference in time taken to provide anaesthesia was not significant clinically, though general anaesthesia could be provided marginally faster [13.16 (2.40)] min than spinal anaesthesia [17.66 (3.09)] min, $P < 0.05$. Cost of spinal anaesthesia [1561.63 (81.32) units] was significantly lower than general anaesthesia [2624.76 (66.16) units], $P < 0.05$. The actual amount billed to the patient was recorded for comparison and excluded the anaesthesiologist’s fees which remains the same for GA and SA in the institution.

There were no significant hemodynamic fluctuations in either groups. There were no technical difficulties in performing either GA or SA in any of the patients. There were no complications, postoperative nausea vomiting, sore throat and hoarseness of voice associated with either of the techniques. There was no requirement for supplemental analgesia/anaesthesia for the patients in group SA.

**Discussion**

In the present study, we compared spinal anaesthesia with 50 mg 1% isobaric 2-chloroprocaine and general anaesthesia (Fentanyl/Propofol/Isoflurane/supraglottic airway device-based technique) with respect to the time taken to meet the discharge criteria from PACU and hospital. We found that despite the short duration of action of 2-Chloroprocaine, discharge criteria are met sooner in patients receiving general anaesthesia.

Spinal anaesthesia is a good choice for day care urological surgeries/procedures since they are mostly infraumbilical. However, it is not widely practised due to the long duration of action with bupivacaine which delays the patient discharge after day care procedures. 2-Chloroprocaine seemed to solve this problem on account of its shorter duration of action and quicker recovery. Hence, we wanted to find out which of the techniques, spinal anaesthesia with Chloroprocaine or general anaesthesia (the commonly used combination of fentanyl/Propofol/Isoflurane/supraglottic device at our institution), is better for day care urologic procedures.

Camponovo compared general anaesthesia and spinal anaesthesia with Chloroprocaine with respect to the recovery profile and cost of both the techniques in outpatient knee arthroscopies. The time taken to discharge the patients receiving SA with Chloroprocaine was found to be lesser compared to the patients receiving GA as all the patients receiving SA were able to bypass the PACU compared to only 18% in group GA. This was attributed to a lesser incidence of postoperative nausea and vomiting and pain in group SA compared to GA, which made the patients meet the discharge criteria faster. Our findings contradict these results. This could be because of all the patients in GA group receiving ondansetron as prophylaxis against postoperative nausea vomiting and better management of pain in the GA group as well. Moreover, the type of surgery was different and there was no provision of bypassing the PACU at our institution.

**Table 3: Patient Characteristics**

| Table 3: Patient Characteristics          | Group GA (n=30) | Group SA (n=30) | $P$  |
|-------------------------------------------|----------------|----------------|-----|
| Age (years)                               | 46 (13.70)     | 46.4 (13.89)   | 0.91|
| Gender (Males/Female)                     | 22/8           | 21/9           | 0.77|
| Body Mass Index (Kg/m²)                   | 25.63 (2.0)    | 25.4 (2.4)     | 0.69|
| ASAPS (1/2)                               | 14/16          | 16/14          | 0.61|

Data are mean (standard deviation) for age, body mass index and absolute number of patients for gender and American Society of Anaesthesiologists physical status (ASAPS)

**Table 4: Time Taken to Reach A Modified Aldrete Score of 9 and Modified Post-Anaesthesia Discharge Score of 9**

| Table 4: Time Taken to Reach A Modified Aldrete Score of 9 and Modified Post-Anaesthesia Discharge Score of 9 | Group GA (n=30) | Group SA (n=30) | $P$  |
|-----------------------------------------------------------------------------------------------------------|----------------|----------------|-----|
| Time to achieve mAS of 9 (min)                                                                          | 10.66 (3.59)   | 23 (8.524)*    | <0.05|
| Time to achieve mPADS of 9 (min)                                                                         | 19.5 (3.73)    | 38.33 (11.27)  |     |
| Total time from start of surgery till readiness for discharge from the hospital (min)                    | 69.33 (9.80)   | 99.4 (17.30)   |     |

mAS - modified Aldrete Score, mPADS - modified Post Anesthesia Discharge Score. *Group SA patients were considered fit to be discharged from PACU only after regaining motor function in the lower limb (grade 0 in the Bromage scale) even though they met the mAS of 9 with complete motor blockade of lower limbs.
score of 2 in modified Aldrete Score (grade 0 in the Bromage scale). This may be considered as a bias against group SA. But we felt it to be an essential criterion for safe ambulation.

We have considered the time taken to meet the discharge score and not the actual time of stay of the patient in the hospital or the surgical duration. Discharge readiness is influenced by anaesthetic technique but the actual discharge time is influenced by many non-anaesthetic factors as well.

Liu and colleagues did a meta-analysis comparing GA with Regional anaesthesia (SA and peripheral nerve block) to see the recovery time from each technique for discharge from the hospital.[7] They found that even though the recovery from anaesthesia was faster with regional anaesthesia due to lesser usage of drugs, lesser consumption of opioids, lesser incidence of postoperative pain and lesser incidence of postoperative nausea and vomiting, the discharge time from hospital was not faster as compared to GA as they didn’t meet some of the common discharge criteria like, ability to ambulate without assistance. The ambulatory surgical unit stay was prolonged by 35 min in patients who received SA. Our findings corroborate with theirs because patients who received SA did not meet the discharge criteria mainly because they were not able to ambulate.[7]

Postoperative urinary retention is another factor delaying the discharge from the hospital in patients receiving SA. Studies conducted earlier showed that patients receiving SA had postoperative urinary retention causing delay in discharge from the hospital.[8,9] The patients in their study underwent surgeries which had a high risk for postoperative urinary retention like transurethral resection of prostate, cystoscopy, hernia and peri-rectal surgeries. Spinal anaesthesia with 2-Chloroprocaine was not associated with any postoperative urinary retention in another study.[10] Studies have shown that if there are no surgery-related or underlying risk factors for urinary retention then the incidence of urinary retention is low with short acting SA. Mulroy and colleagues suggested that discharge criteria might be relaxed in terms of postoperative urinary retention when low-risk surgeries are done under short-acting local anaesthetics used in SA and may be discharged without using urinary retention as a discharge criterion.[11] In our study, we did not encounter urinary retention in any of the patients delaying the discharge.

The cost of GA was more compared to SA. This is evident from the polypharmacy and use of more consumables associated with GA. This increase in cost has to be weighed against additional operating room time made available by use of GA due to marginally faster turn over. Since what is billed to the patient was compared, SA is more economical to the patient compared to GA.

Chloroprocaine has also been compared with the other drugs that are used for providing spinal anaesthesia, i.e., 1% Lidocaine and 0.5% Bupivacaine with respect to recovery of sensory and motor blockade, postoperative analgesia, postoperative urinary retention, time to mobilize, and time to discharge.[8,9,11‑16]

Some of the limitations of our study were:
(a) Cost estimation was done analysing what was billed to the patient for the particular anaesthetic and operating room turnover was not considered in the economics.
(b) The discharge time of the patient was considered as the time required to meet the required discharge score and not the actual discharge time of the patient from the hospital.
(c) Sevoflurane or desflurane would have been better agents to study for day care anesthesia. Isoflurane is widely used due to cost constraints.

Nevertheless, our study has shown that the choice of anaesthetic technique does influence the readiness for discharge and the cost incurred by the patient, both of which are important in day care surgeries. To conclude, general anaesthesia (Fentanyl/Propofol/Isoflurane/supraglottic device based) is significantly better compared to spinal anaesthesia with 50 mg 1% isobaric 2-Chloroprocaine as an anaesthetic technique in day care surgeries/procedures in urology in terms of faster recovery and discharge readiness but is costlier.

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Conflicts of interest
There are no conflicts of interest.

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