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Comparison Of 2-Chloroprocaine Versus Lidocaine In Selective Spinal Anaesthesia In Patients Undergoing Transurethral Resection Of Prostate Surgeries: A Randomized Interventional Double Blinded Study

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Abstract
Background and aims*- TURP surgery is a short procedure so we need to find a local anaesthetic which acts for short duration and makes the patient to ambulate early. The aim of the study is to compare the two short acting local anaesthetics lidocaine and 2-chloroprocaine and fentanyl as adjuvant in both the groups in selective spinal anaesthesia in elderly patients undergoing transurethral prostate surgeries.*
Methods*- In this prospective, randomized, double blind, interventional study, selective spinal anaesthesia (SSA) was performed in 80 patients of American Society of Anaesthesiologists (ASA) grade I-III scheduled for TURP using 35 mg of lidocaine with 12.5 mcg fentanyl in group L and 40 mg of chloroprocaine with fentanyl 12.5 mcg in group CP. Primary outcome of this study was duration of sensory and motor recovery. Other objectives were onset of sensory block, time to reach maximum level, sensory regression to L1 and L3, hemodynamic variables and 24 hour analgesic consumption in both the groups.*
Results*- The results were comparable among the groups. The time to reach T10 sensory block level was 5.55±2.91minutes & 4.68±2.66 minutes for lignocaine and chloroprocaine respectively. The time to reach L3 level of sensory block level (2.90 ± 1.46min vs 2.55 ± 1.36min, p>0.05), The time to reach maximum Level of block (20.50 ± 3.89 min vs 18.88 ± 4.92 min, p>0.05), The duration of sensory block above T10 (62.63±18.57min vs 55.88±18.60 min, p>0.05), The time for sensory level to regress to S4 (161.3±10.3 min vs 158.2±9.56 min, p>0.05), Time to regress to L1 (72±10.3min vs 68±10.13, p>0.05), Duration of motor block (121.1±9.84 vs 117.4±8.91, p>0.05). There was no statistically significant difference between the two groups with respect to clinical end points (p>0.05).*
Conclusion*- Selective spinal anaesthesia with both chloroprocaine and lidocaine achieved by mixing them with small doses of fentanyl provided satisfactory anaesthesia for transurethral resection of prostate surgery. Both agents were comparable in terms of clinical end points of interest, recovery of sensory and motor block, as well as clinical anaesthesia conditions. In view of the incidence of TNS with lidocaine chloroprocaine can be a better alternative as it has no risk of TNS and provides comparable spinal block characteristics.*
Keywords*- Sensory, Motor, Lidocaine, Chloroprocaine.*

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I. Introduction

Spinal anaesthesia is the most frequently used anaesthetic technique for transurethral prostatectomy (TURP). Usually it requires a block up to T10 dermatome to obtund bladder distension sensation.To achieve spinal block up to T10,conventionally used dosage of local anaesthetics impose additional risk of hypotension, bradycardia, prolonged recovery and longer hospital stay in elderly patients with limited cardiopulmonary reserve.

In attempt to limit the distribution of spinal block to reduce adverse haemodynamic and pulmonary effects in such patients, by using very small doses of local anaesthetic, distribution of spinal block can be limited, but it often results to inadequate level of sensory block, Intrathecal opioids enhance analgesia from subtherapeutic dose of local anaesthetic and make it possible to achieve successful spinal block using otherwise inadequate doses of local anaesthetic.[1,2,3,4]

Longer acting LA,bupivacaine, ropivacaine require longer recovery time.Short acting LA like lidocaine may provide an acceptable alternative for outpatient spinal anaesthesia.Lidocaine, when used in conventional

dose (50 mg) raises concern about risk of transient neurological syndrome(TNS).In previous studies, incidence of TNS were not reported with low dose lidocaine.

Recently, 2-chloroprocaine has regained popularity with introduction of a new formulation without preservatives for intrathecal use.Reducing the dose of 2-chloroprocaine to 35 or 40 mg resulted in a faster ambulation and discharge.[5]

Till date ,very few studies has been conducted on clinical characteristics of lidocaine compared with chloroprocaine when administered in low intrathecal doses in patients undergoing TURP.

Therefore, we designed this study to compare the anaesthetic characteristics of lidocaine and 2-chloroprocaine and fentanyl as an adjuvant in both the groups in selective spinal anaesthesia (SSA) in patients undergoing TURP.

II. Material And Methods

This prospective, randomized, double blinded, interventional study was conducted at a tertiary care center from April 2018 to march 2019 after obtaining approval of Instituitional Ethics Committee and written informed consent from all the patients. Patients of ASA grade I-III, aged 50-70yrs, weighing 50-70 kg undergoing TURP were included in this study. Patients having history of chronic diseases like hypertension, diabetes mellitus, cardio-respiratory disease, spinal disorders, allergic to study drugs, failure of spinal anaesthesia, cases in which general anaesthesia required were excluded from the study.

A total of 80 patients were randomized into two groups of 40 patients in each, using a computer generated randomization number table and all allocated groups were kept in sequentially numbered and sealed brown envelopes. Patients in Group L received lidocaine 35mg + 12.5mcg fentanyl and in Group CP received chloroprocaine 40mg +12.5mcg fentanyl. 1ml of 50mg lidocaine diluted to 5ml in 5cc syringe, 3.5ml taken from this solution to which 0.25ml (12.5mcg) fentanyl and 0.5ml normal saline added to make it to 4.25ml. In other group 4ml of 10mg/ml chloroprocaine and 0.25ml of fentanyl taken.Total drug volume was kept constant at 4.25 ml in both groups to achieve blinding.

The Anaesthesiologist involved in drug preparation was different from Anaesthesiologist performing spinal block. Both the patient and investigator involved in recording of data were also blinded to the study protocol.

Detailed pre anaesthetic check up was done a day prior to surgery.Concept of Visual analogue scale (VAS) was explained to the patient in preoperative room on the day of surgery. Patient was taken in operation theatre after checking fasting status and written informed consent, and intravenous access was established with 20G canula. NIBP, Spo2, ECG, were attached. All the baseline parameters of blood pressure, heart rate and Spo2 were recorded. Patients were pre-loaded with 10ml/kg of 0.9% normal saline prior to spinal anaesthesia.

Under all aseptic precautions subarachnoid block was performed using 25G Quincke needle in sitting position at L3-L4 space in midline approach. After ensuring free flow of CSF,4.25 ml drug was injected as per group assigned. Patient was placed in supine position immediately after spinal block in order to achieve desired level of block. When adequate level of spinal block was achieved, the patient positioned for planned surgery.

IV infusion was continued at a rate of 10ml/kg/hr throughout the surgery. Patients were given 4.0 L/min of oxygen by venturi-mask. Monitoring of electrocardiography (lead II & V), heart rate, non-invasive blood pressure and continuous pulse oximetry was carried out every 5 minute for first 30 minutes and thereafter every 15 min till complete motor and sensory recovery.

Hypotension defined as a fall in SBP more than 30% from baseline or a fall below 90 mm of Hg, was treated with IV fluid bolus or incremental doses of ephedrine 5 mg IV, if required. Bradycardia defined as HR < 55 bpm, was treated with IV atropine (0.3 – 0.6 mg)

The onset of sensory block was defined as the time from the intrathecal injection of the study drug to the time taken to achieve the T10 level of sensory block. This was assessed by pin prick test bilaterally in midclavicular line by using 25G hypodermic needle. The level of sensory block assessed every minute till the highest level of the block achieved and, the time to achieve the same was noted. Duration of sensory block was defined as the time of regression of sensory block to S4 level.

Onset of motor block was defined as the time from intrathecal injection of the study drug to the time taken to achieve complete motor block (grade-3) by using modified Bromage scale (0=no motor block, 1=hip blocked, 2=hip and knee blocked, 3=hip, knee and foot blocked). Duration of motor block assessed by recording the time elapsed from the maximum to the lowest Bromage score. (3-0)

Total duration of Analgesia was defined as time from intrathecal drug administration to patient's first demand of rescue analgesia (VAS 3). Post-operatively, the pain was assessed by using visual analog pain scale (VAS) between 0 and 10 (0 = no pain, 10 = most severe pain). It was assessed at every hour for first 8 hours,thereafter 4 hrly till 24 hrs. Patients were allowed to receive rescue analgesic on VAS score of 3. Inj. Tramadol IV (50 mg) was given as rescue analgesic. This was the end point of our study.

Post operative sedation level was measured using four point sedation scale.(1-spontaneous eye opening; 2-eye opening on verbal commands; 3-eye opening on shaking; 4-not arousable)

Patients were monitored for 24hrs for any adverse effects, such as nausea, vomiting, headache, bradycardia, respiratory depression, and hypotension, and treated accordingly.

Sample size was calculated to be 40 subjects in each of two groups at 95% confidence & 80% power to verify the comparable intra-operative and post-operative profile and acceptable anaesthesia in both groups for TURP surgery based on a previous study.[6] Statistical analysis was done using SPSS version 20.0.(SPSS Inc.,Chicago, Illinois, USA). Adverse events were documented during surgery and recovery. Continuous variables (quantitative data) were presented as mean and standard deviation and analysed by applying one way-ANOVA test. Categorical variables (Qualitative data) were presented in frequency and percentage and analysed using chi-square test. P value < 0.05 was considered as statistically significant.

III. Results

A total of 80 consented patients scheduled for TURP were randomized into two groups of 40 each.Both groups were comparable for their demographic data of age,weight, ASA physical status (Table 1). Both groups were comparable in the maximal dermatome height achieved. Characteristics of sensory and motor block were comparable in both groups (Table 2). Incidence of adverse effects was not statistically significant in both groups (p value > 0.05) (Table 3). 24 hr analgesic consumption, sedation score & VAS score were given comparable results among the groups.

TABLE 1 : Demographic Variables

Variable	Group L (Mean±SD)	Group CP (Mean±SD)	P value	Significance
Age (Yrs)	65.35±7.16	65.10±6.61	0.871	NS
Weight (kg)	62.58±5.34	65.20±3.86	0.282	NS
ASA status (I/II)	25/15	26/14	1.000	NS

TABLE 2. Block Characteristics

Characteristics	Group L (Mean±SD)	Group CP (Mean±SD)	P value	Significance
Time to reach T10 (Onset in min)	5.55±2.91	4.68±2.66	0.164	NS
Duration of sensory block above T10 (min.)	62.63±18.57	55.88±18.60	0.108	NS
Time to reach L3(min)	2.90±1.46	2.55±1.36	0.271	NS
Duration of sensory block above L3(min.)	93.38±27.49	103.50±38.40	0.179	NS
Time to reach maximum level (min.)	20.50±3.89	18.88±4.92	0.141	NS
Highest level of block (median)	T8	T9		
Time to regress to L1(min.)	72±10.3	68.62±10.13	0.144	NS
Duration of sensory block (min.)	161.3±10.3	158.2±9.56	0.067	NS
24 hr analgesic consumption (mg)	136.87±60.97	144.38±78.55	0.634	NS
Time to full motor recovery (min.)	121.1±9.84	117.4±8.91	0.078	NS

TABLE 3: Adverse Effects

Adverse effects	Number (%)	Number (%)	P value	Significance
Bradycardia	4 (10)	3 (7.5)	0.757	NS
Hypotension	6 (15)	4 (10)	0.512	NS
Nausea	3 (7.5)	2 (5)	0.346	NS
Vomiting	0 (0)	0 (0)	0.00	NS
Shivering	4 (10)	5 (12.5)	0.875	NS

FIGURE 1
SENSORY DISTRIBUTION AMONG THE GROUPS

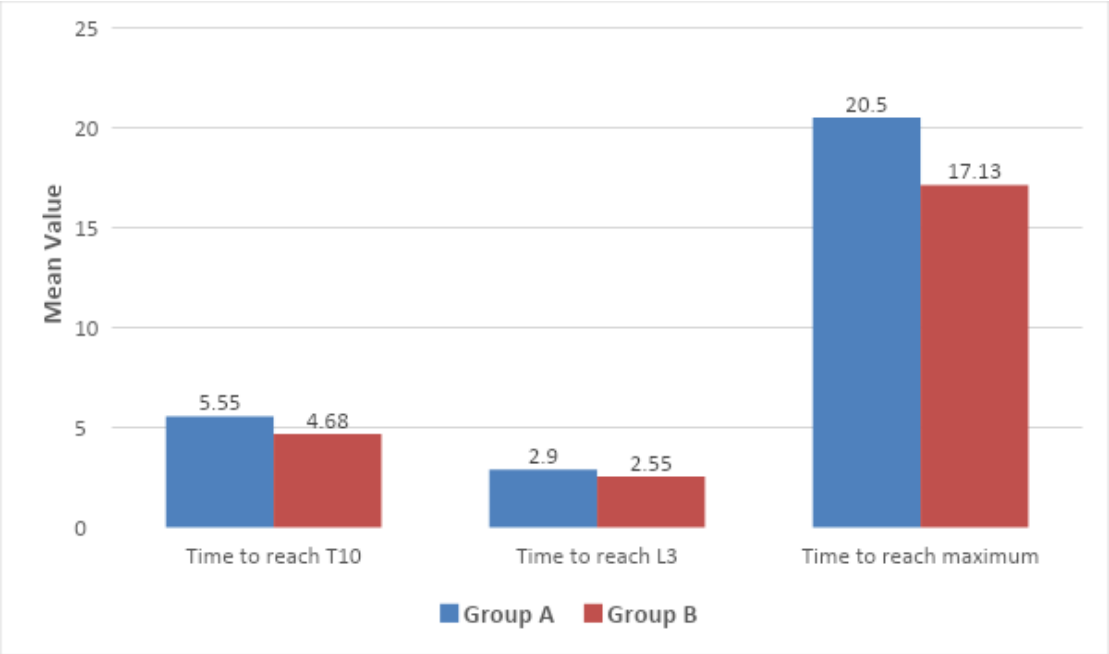


FIGURE 2: DURATION OF BLOCK ABOVE T10

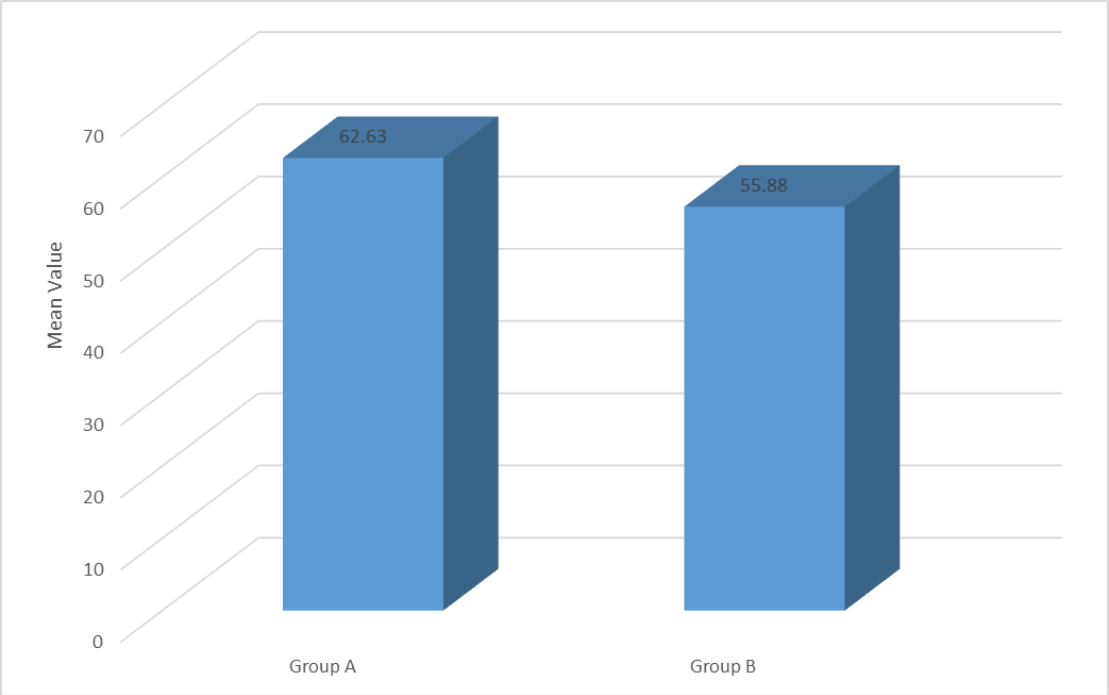
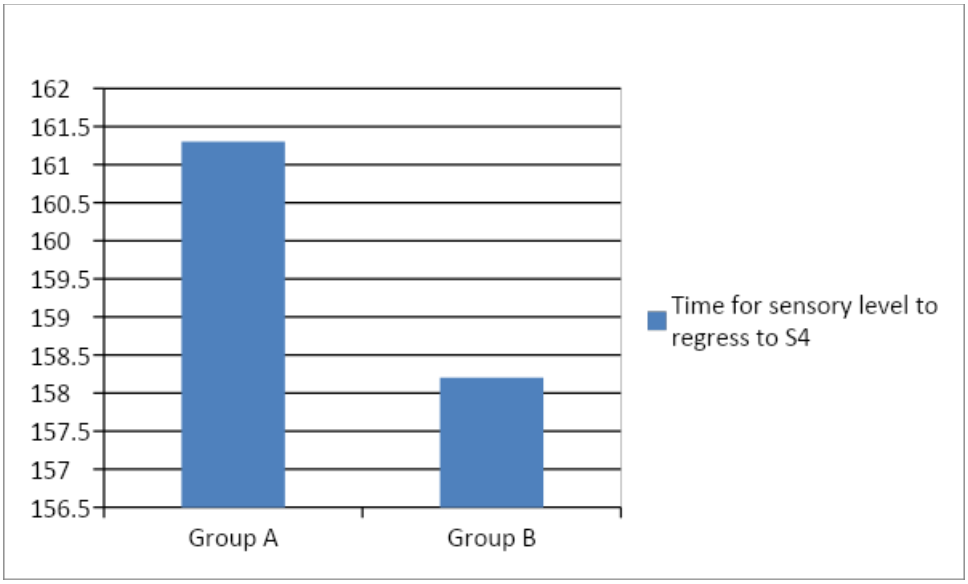


FIGURE 3: TIME FOR SENSORY LEVEL TO REGRESS TO S4



IV. Discusion

In this prospective, randomized, double blind study, we found that selective spinal anaesthesia (SSA) with lidocaine 35 mg with fentanyl 12.5 mcg as well as with chloroprocaine 40 mg with fentanyl 12.5 mcg provided acceptable level of anaesthesia for TURP with a comparable intraoperative and post operative profile.

A decade ago, reports of neurologic deficits associated with spinally administered lidocaine generated concern. So started searching for alternative local anaesthetics for spinal anaesthesia. Most clinicians have substituted bupivacaine, a rational decision based on its infrequent incidence of TNS.[7] Although there were reports describing the use of small-dose bupivacaine combined with fentanyl, many practitioners report frequent failure with this technique, and complete recovery may still be delayed.

Introduced into clinical practice more than 50 years ago, chloroprocaine quickly gained widespread popularity as an epidural drug, particularly in obstetrics, where its rapid hydrolysis by pseudocholinesterase virtually eliminated concern for systemic toxicity and fetal exposure.[8,9] Despite this data and the lack of apparent adverse effects, chloroprocaine was never evolved as a spinal anaesthetic, because of the development and marketing of the lidocaine. We used lower dose of ligocaine to minimize the adverse effect of TNS.

Even though the prostate is innervated by a dual sympathetic output (T11-L2 and S2-S5) and a parasympathetic output from S2-S4, conventional-dose spinal anaesthesia has been traditionally employed for TURP to ensure a spinal block as high as T10 in order to obtund bladder pain due to distension.[10] Selective spinal anaesthesia techniques have been shown to allow considerable dose reduction of the spinal local anaesthetic without compromising quality of spinal block because the addition of adjuvant opioid agents enhances analgesia via the Aδ and C-fiber nociceptive pathways.

This study was designed to examine and compare the lidocaine and chloroprocaine with fentanyl as additive in terms of following variables; onset of sensory block, time to reach L3 and maximum level, time to regress to L1, L3 and S4 level of block. In this randomized double-blind study, we found that selective spinal anaesthesia (SSA) with either 35 mg Lidocaine mixed with 12.5 mg fentanyl or 40 mg chloroprocaine mixed with 12.5 mg fentanyl provided acceptable anaesthesia for TURP with a comparable intraoperative and post-operative profile.

Clinical end points of interest were comparable between the two groups. These results were comparable with study by Kouri M et al[11] in volunteers receiving a low dose (40 mg) of either lidocaine or chloroprocaine for spinal anaesthesia, sensory recovery occurred earlier in the CP group. In our study, we used a lower dose of lidocaine not only because of previous study with low dosage for short-duration laparoscopy by vaghadia H et al[12] advocated it, but also to minimize the potential for TNS development. Chloroprocaine has also been used in a wide variety of cases in varying doses of 20–60 mg with no reported cases of TNS. We could not use less than 40 mg of chloroprocaine, because of lack of published experience with this dose for TURP and out of concerns for block failure if an inadequate block height were achieved. The lack of faster recovery in our CP group may be due to the added dose of fentanyl, which is known to enhance the action of intrathecal local anaesthetics as previous study by Liu S et al[13]. In our study we have not come across the symptoms of TNS. It is comparable to earlier studies done by Vaghadia H et al[12] where the incidence was zero.

VAS scores were monitored hourly upto 8 hour postoperative then 4 hourly for 24 hours. Analysis with Kruskal-wallis H test and Mann-whitney U test revealed that VAS scores were comparable in Group A and group B ($p>0.05$).

V. Conclusion

Selective spinal anaesthesia with both chloroprocaine and lidocaine achieved by mixing them with small doses of fentanyl provided satisfactory anaesthesia for transurethral resection of prostate surgery. Only modalities we desired for the surgery are blocked as we used selective spinal anaesthesia with very low doses of drugs. Both agents were comparable in terms of clinical end points of interest, recovery of sensory and motor block, as well as clinical anaesthesia conditions. In view of the incidence of TNS with lidocaine chloroprocaine can be a better alternative as it has no risk of TNS and provides comparable spinal block characteristics.

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