Section: Anaesthesiology

Original Research Article

COMPARISON OF CHLOROPROCAINE AND LEVOBUPIVACINE FOR SPINAL ANAESTHESIA IN INFRAUMBILICAL DAY-CARE SURGERIES: A PROSPECTIVE, DOUBLE BLIND, RANDOMISED CONTROL STUDY

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ABSTRACT

Background: 2-Chloroprocaine may prove to be a good choice for short duration surgeries as it is rapidly metabolised via ester hydrolysis. Similarly, Levobupivacaine also has a comparatively shorter duration of action with fewer side effects as compared to racemic bupivacaine. This study was conducted with the aim of comparing the anaesthetic efficacy of Chloroprocaine and Levobupivacaine. **Materials and Methods:** After approval from institutions ethic committee and informed consent from the participant, this double blind, prospective randomised control study was conducted in 66 patients posted for inguinal herniorrhaphy under spinal anaesthesia. Patients were divided in two groups of 33 each, with group C receiving 4 ml of 1% Chloroprocaine and Group L receiving 3 ml of 0.5% Levobupivacaine. Inclusion criteria comprised of male patients between the age of 18-65 years of age with ASA physical status I-II, posted for unilateral inguinal hernia repair. JASP software was used for study analysis. P-value <0.05 wit 95% confidence interval was considered statistically significant. **Results:** Onset of sensory and motor blockade were significantly lower in Group C as compared to Group L [(2.3±1.6 vs 4.2±2.1, p<0.001) & (5.9±2.5 vs 8.6±3.0, p<0.001) respectively. But overall duration of sensori-motor blockade was comparable among both the groups. Similarly, requirement of rescue analgesic was also comparable between both groups. Duration of analgesia in Group C was almost 30 minutes lower than Group L(p<0.001). **Conclusion:** Chloroprocaine is an effective drug for day care surgery with minimum reduction observed in terms of analgesic efficacy as compared to Levobupivacaine. Comparability of VAS scores and similar requirement of rescue analgesic favours the use of Chloroprocaine use during day care surgery.

INTRODUCTION

Spinal anaesthesia is a commonly employed anaesthetic technique for performing infraumbilical surgeries such as inguinal herniorrhaphy, lower limb surgeries not excluding orthopaedic surgeries and lower segment caesarean section. It is safe, economical and easy to perform providing rapid and reliable anaesthesia. Though bupivacaine is most commonly used local anaesthetic, other alternatives are being explored for day cares surgeries to reduce the hospital admission time and early discharge. Chloroprocaine, Levobupivacaine and ropivacaine are such local anaesthetics under research due to their reduced duration of action and lesser incidence of complications.[1,2] 2-Chloroprocaine may prove to be a good choice for short duration surgeries as it is rapidly metabolised via ester hydrolysis.[3] Due to its rapid metabolism by ester hydrolysis, it is a favourable drug in short-duration surgeries. Similarly, Levobupivacaine also has a comparatively shorter duration of action with fewer side effects as compared to racemic bupivacaine.[4]

This study was conducted with the aim of comparing the anaesthetic efficacy of Chloroprocaine and Levobupivacaine. The primary objective of this study was to compare the efficacy in terms of duration of analgesia and sensorimotor blockade characteristics. The secondary objectives included comparison of haemodynamic parameters and side/adverse effects in both the groups.

MATERIALS AND METHODS

This study was conducted in a tertiary care institute over a duration of 1 year. After approval from

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institutions ethic committee and informed consent from the participant, this double blind, prospective randomised control study was conducted in 66 patients posted for inguinal herniorrhaphy under spinal anaesthesia. Inclusion criteria comprised of male patients between the age of 18-65 years of age with ASA physical status I-II, posted for unilateral inguinal hernia repair. All female patients, patient who refused to participate in the study, patient with any spine deformity, localised infection, raised intracranial pressure, coagulopathy, patient with impaired mentation and any other significant neurological, psychiatric, neuromuscular or cardiovascular disease were excluded from the study. Sample size was based on clinical trial with parallel design using superiority margin 25 minutes with the power of study being 80% and alpha error at 5%.[5] The sample size was calculated to be 30 patients in each group. Considering 10% drop out rate, 33 patients were included in each group.

Sixty patients were randomly divided into two groups of 33 each [Figure 1]. Group C received 40mg of 1% Chloroprocaine while group L received 15 mg of Levobupivacaine. After detailed pre-anaesthetic assessment, patients were kept nil per os prior to surgery, as per institutional guidelines. After transfer to operation theatre, wide bore cannula was secured on the non-surgical side. Perioperative monitoring was performed as per ASA monitoring guidelines i.e. continuously for heart rate, pulse oximetry, pulse rate and continually for non-invasive Blood pressure every 5 minutes. Under aseptic precautions, spinal anaesthesia was given in L3-L4 interspinous space, by an anaesthesiologist who was not part of the study., using 25G Quincke's spinal needle in sitting position after local skin infiltration with 2 mL of 2% lidocaine. Surgery was started after confirmation of a sensory level of T6. Injection midazolam 0.05 mg-0.075 mg/kg was given for anxiolysis. Oxygen was supplemented by nasal prong @ 2 L/min. If adequate sensory or motor blockade was not achieved even after 15 minutes, General Anaesthesia (GA) was administered and patients were excluded from the study. In case of early regression of more than two segments or prolonged surgeries more than two hours or the patient complaining of pain anytime during the course of surgery, GA was administered and patients were excluded from the study. Time of administration of spinal anaesthesia was taken as time zero. Time of onset of sensory and motor block was assessed using pin prick and modified Bromage scale of 3, respectively, at every minute. Duration of analgesia was considered from time of completion of block to first complain of pain. Inj Paracetamol 1000 mg intravenous was given for postoperative analgesia and Inj 100 mg Tramadol was given as rescue analgesic in case of breakthrough pain. Duration of sensory blockade and motor blockade were considered as complete, when effect has totally worn off. Block characteristics, haemodynamic parameters and side-effects were observed for 24 hrs.

Data were recorded in Microsoft Excel sheet and analysed using JASP software. Independent Student's T test was used for quantitative data which was expressed as Mean SD while Chi square test was used for categorical data and data was expressed as percentages or proportions. P-value <0.05 wit 95% confidence interval was considered statistically significant.

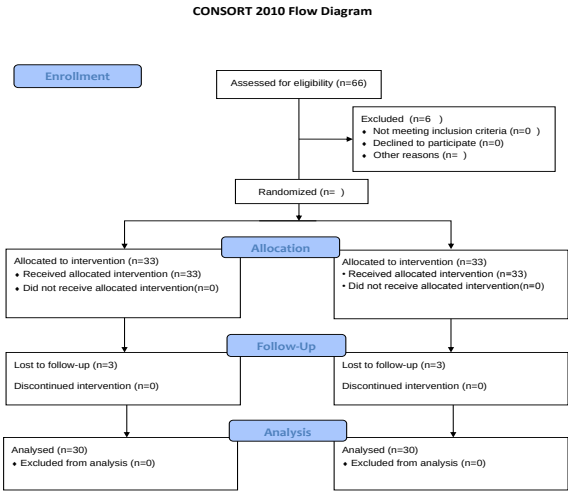

Figure 1: CONOSRT Diagram

RESULTS

Total 66 patients were recruited to the study and equally divided among two groups, Group C and Group L. Six patients were dropped out for requirement of GA and sixty patients were analysed. Demographic parameters were comparable in both the groups [Table 1]. Duration of analgesia was statistically significant higher in Group L as compared to Group C($p<0.001$). Time for onset of sensory blockade and motor blockade was quicker in group C as compared to group L($p<0.001$) [Table 2]. Duration of sensori-motor blockade was comparable in both the group [Table 2]. No statistically significant difference was observed in various haemodynamic parameters (heart rate, pulse oximetry and mean arterial pressure) during perioperative period, at various intervals. No difference in VAS score was observed between both the groups (Figure 2).

Three patients in group L had urinary retention requiring urinary catheterization which was resolved within 24 hours. One patient in Group C was observed to have hypotension. No other postoperative complications were reported in both the groups and no statistical difference was observed in overall rate of complications.

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Table 1: Demographic parameters of group C and group L

Variable	Group C(n=30)	Group L(n=30)	P value
Age (years)	45.4±6.6	46.1±5.9	0.357
ASA PS (I/II)	18/12	16/14	0.698
Height(cm)	160.7±12.6	162.8±10.9	0.654
Weight(Kg)	65.9±8.8	64.7±7.2	0.265
BMI(Kg/m^2)	24.7±3.9	23.9±4.5	0.951

Table 2: Comparison of sensori-motor blockade characteristics between group C and group L

Variable	Group C(n=30)	Group L(n=30)	P value
Duration of analgesia(minutes)	75.5±15.9	105.6±25.5	<0.001
Onset of sensory blockade(minutes)	2.3±1.6	4.2±2.1	<0.001
Time of sensory blockade(minutes)	78.9±10.5	87.1±15.5	0.268
Onset of motor blockade(minutes)	5.9±2.5	8.6±3.0	<0.001
Time of motor blockade(minutes)	72.3±10.9	90.2±14.6	0.456
Dose of rescue analgesic(gram)	168±65	149±53	0.846

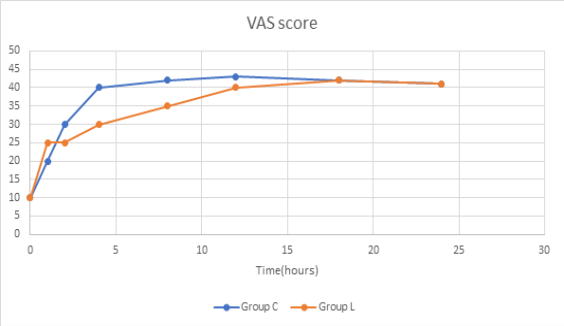

Figure 2: Comparison of Vas score between group C and group L

DISCUSSION

This study demonstrates that spinal anaesthesia performed with 40 mg Chloroprocaine provides adequate anaesthesia for short duration surgeries as compared to Levobupivacaine.

Total duration of analgesia was significantly shorter in Chloroprocaine group as compared to Levobupivacaine group($p<0.001$). Similar observations have been made by Teunken at el and Lacasse et al who observed the readiness of discharge depending on the duration of sensory blockade and analgesia.[6,7] Also, requirement of rescue analgesic was comparable among both the groups despite difference in duration of analgesia signifying that overall patient outcome is variable and not just dependent on one factor.

The mean time of onset of the sensory and motor block was faster in group C as compared to group L. Camponovo et al. made similar observations with the use of Chloroprocaine, with faster onset in Chloroprocaine group.[5] Similar study by Tiwari et al. also made the similar observations with faster onset in Chloroprocaine group.[8] Onset of a local anaesthetic is determined by its pKa, as non-protonated form easily crosses the membrane at physiological ph. Faster onset of action of Chloroprocaine can be attributed to effect of pKa and higher concentration available for transfer across cell membrane.

The total duration of the sensory block in group C was almost 15 minutes less than Group L and no statistical difference was observed in this study. Camponovo et al. observed almost 2 hrs more in bupivacaine group as compared to Chloroprocaine group.[5] Teunkens A et al. compared similar local anaesthetics i.e. lidocaine, Chloroprocaine and bupivacaine for spinal anaesthesia for outpatient surgeries and observed that the time of sensory block was the least in Chloroprocaine group and longest in bupivacaine group.[6] Lacasse et al made the similar observations with similar difference between bupivacaine group and Chloroprocaine group.[7] All studies were in concordance of present study. Chloroprocaine is rapidly metabolised as compared to bupivacaine. Furthermore, protein binding of a drug also affects the elimination half-life of a drug, hence affecting the duration of the block drug of the block. As compared to bupivacaine, Chloroprocaine has lower protein binding, resulting in the shorter duration of sensory blockade.

Campanovo et al. observed difference between 1% Chloroprocaine 50 mg and 10 mg bupivacaine. The mean duration of complete motor block was twice in the bupivcaine group.[5] Lacasse et al. They observed that the total duration of motor block was 76 minutes in the Chloroprocaine group and 119 minutes in the bupivacaine group.[7] Casati et al., conducted a double blind randomised controlled trial to compare Chloroprocaine and Lidocaine for spinal anaesthesia in patients undergoing knee arthroscopy in an outpatient setting. They concluded that among the three groups Chloroprocaine group had the fastest offset time.[6]

In the Group L, three patients had urinary retention whereas none was reported in Group C. Urinary relotention was relieved with the help of urinary catheterisation and it was not needed after 24 hrs. Only one patient receiving Chloroprocaine developed hypotension which improved with bolus of 250 ml crystalloid. This may be attributed to slightly frail condition of the patient despite belonging to ASA physical status II category. Gys et al. evaluated effect of prilocaine, Chloroprocaine and bupivacaine for similar surgeries and concluded that bupivacaine was associated with difficulty in micturition for prolonged periods as compared to other drugs especially Chloroprocaine.[10] Urinary

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retention following spinal anaesthesia is a well observed side effect of subarachnoid block with local anaesthetic and its incidence in the overall surgical population undergoing spinal anaesthesia was found to be around 3.8% in a research done by Baldini et al.[11,12] Though it is treatable with urinary catheterisation, but that is an invasive procedure associated with its own long term consequences.[13] No other side effects were observed in both the groups and overall incidence was comparable in the groups.

Study was limited by comparatively small sample size. Other factors affecting the blockade characteristics of spinal anaesthesia, such as obesity, height etc were not covered by this study. Identification of such risk factors for difference in duration of the blockade may have warranted a larger sample size. It was conducted in a small rural population and may not represent population of different geographic location.

CONCLUSION

Chloroprocaine provides comparable sensorimotor blockade to Levobupivacaine, though duration of analgesia seems to be lacking. Use of Chloroprocaine in spinal anaesthesia provides rapid onset of sensory and motor blockade with comparable duration of action to Levobupivacaine. Furthermore, use of Chloroprocaine is associated with fewer post-operative side-effects like urinary retention in comparison to Levobupivacaine. Hence, Chloroprocaine may be safely used for short duration of surgery such as inguinal herniorrhaphy.

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