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COMPARISON OF CHLOROPROCAINE AND LEVOBUPIVACAINE FOR SPINAL ANAESTHESIA IN PATIENTS UNDERGOING UNILATERAL KNEE ARTHROSCOPY

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ABSTRACT

Introduction: Spinal anaesthesia is a safe and reliable technique for surgery of the lower abdomen and lower limbs. Nevertheless, some of its characteristics may limit its use for ambulatory surgery, including delayed ambulation, risk of urinary retention, and pain after block regression. The choice of the correct local anaesthetic for spinal anaesthesia is therefore crucial in the ambulatory setting: the ideal anaesthetic should allow rapid onset and offset of its own effect for fast patient discharge with minimal side effects.

Aims: To compare the duration of sensory and motor blocks with use of chloroprocaine, and levobupivacaine as local anaesthetics in spinal anaesthesia.

Materials and method: The present study was a Prospective randomized open label double blind study. This Study was conducted From 18 months, from February 2018 to July 2019 at Department of Anaesthesia, Bankura Sammilani Medical College and Hospital. Total 72 patients were included in this study.

Result: We found that, In group-C, the mean duration of surgery (mean ±s.d.) of the patients was 43.7500 ± 5.6537 mins. In group-L, the mean duration of surgery (mean ±s.d.) of the patients was 44.5833 ± 4.3712 mins. There was no statistically significant difference in ASA gradings in between two groups (p=0.4865). There was no statistically significant difference in mean time to reach peak block height in between two groups (p=0.6142). In group-C, the mean two segment regression time (mean ±s.d.) of the patients was 57.0833 ± 8.5670. In group-L, the mean two segment regression time (mean ±s.d.) of the patients was 80.5833 ± 7.4234. There was statistically significant difference in mean two segment regression time in between two groups (p<0.001). There was statistically significant difference in mean time for regression to L1 in

between two groups (p<0.001). There was no statistically significant difference in PEAK BLOCK HEIGHT in between two groups. (p=0.4004).

Conclusion: we conclude that in patients undergoing unilateral knee arthroscopy, the use of chloroprocaine was associated with decreased time of duration of sensory and motor block and early recovery, early ambulation and early void. There were no statistically significant difference is noted in haemodynamic changes in between two groups. No adverse effects regarding allergic reactions, hypotension, shivering, bradycardia and nausea and vomiting were found during intraoperative and postoperative period.

Keywords: Spinal anaesthesia, Chloroprocaine, Levobupivacaine and Unilateral Knee Arthroscopy.

INTRODUCTION

In the last years, the number of surgical procedures performed on an ambulatory basis has increased worldwide.[1] Between 50% and 70% of all surgeries are currently performed as outpatient procedures in North America alone[2].

Spinal anaesthesia is a safe and reliable technique for surgery of the lower abdomen and lower limbs. Nevertheless, some of its characteristics may limit its use for ambulatory surgery, including delayed ambulation, risk of urinary retention, and pain after block regression.[3] The choice of the correct local anaesthetic for spinal anaesthesia is therefore crucial in the ambulatory setting: the ideal anaesthetic should allow rapid onset and offset of its own effect for fast patient discharge with minimal side effects.

To investigate the most suitable anaesthetic technique for day surgery, Liu et al published a meta-analysis in 2005 comparing regional and general anaesthesia, including more than 1,300 patients.[4] Regional anaesthesia reduced pain scores and pain medication request in the post-anaesthesia care unit.

Clinical research with spinal 2-Chloroprocaine has been limited mainly to dose comparisons and evaluation of block characteristics in patients undergoing short procedures.[5]

Knee arthroscopy is a short duration procedure which is frequently done under spinal anaesthesia. Levobupivacaine is a S-enantiomar of racaemic bupivacaine, because of its longer duration of action and less cardiotoxicity and less neurotoxicity. Levobupivacaine seems to be an attractive alternative to bupivacaine. Levobupivacaine and bupivacaine are equally effective and share many pharmacological properties. One exception is significantly longer duration of sensory

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blockade with levobupivacaine than with racaemic bupivacaine[6].

This study was designed to comparison of chloroprocaine and levobupivacaine for spinal anaesthesia in patients undergoing unilateral knee arthroscopy. Here I hypothesize that in patient undergoing unilateral knee arthroscopy, the use of chloroprocaine would be associated with decrease time of duration of sensory and motor block and early recovery and early ambulation and early discharge from hospitals.

MATERIALS AND METHODS

METHODOLOGY-

a) STUDY DESIGN- Prospective randomized open label double blind study.

b) STUDY SETTING AND TIMELINE- The study was conducted in rural based tertiary care hospital and medical college with a timeframe of about one and half years from acceptance of synopsis**.**

***c)* PLACE OF STUDY-** The proposed study was conducted under the aegis of Department of Anaesthesia, Bankura Sammilani Medical College and Hospital, Bankura in operation theatre, preoperative room and postoperative room of department of orthopaedics surgery.

***d)* PERIOD OF STUDY-** One and half year (18 month)

18 months, from February 2018 to July 2019.

a) Preparatory Phase-1 month

b) Data collection-12 months

c) Data Entry & Analysis-3 month

d) Report Writing-2 month

e) STUDY POPULATION- A total of 72 adult patients of either sex, between 18 to 60 years of age of ASA gradings I & II scheduled for elective unilateral knee arthroscopy under spinal anaesthesia was included in the study. Written Informed and valid consent was obtained from each patient prior to include him or her in the study.

f) SAMPLE SIZE/DESIGN-72 patients were selected randomly after taking informed written consent.

36 patients in each group of ASA-PS- I & II divided into 2 groups.

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Sample size was calculated from previous study by use of formula:

$$\text{Sample size (n)} = \frac{2\times SD^2\times(Z_\beta+Z_{\alpha/2})^2}{D^2}$$

(Sample size estimates were based on previous studies[23,24,25])

g) **CASE, CONTROL REQUIRED OR NOT-** not required

Inclusion criteria:

- Patients with ASA-PS I & II
- Patients of age group between 18 to 60 years
- Patients of either sex
- Patients scheduled for elective unilateral knee arthroscopy under spinal anaesthesia

Exclusion criteria:

- Patient refusal
- Known allergies to any of the drug
- Any co-morbid condition like neurological, neuromuscular, cardiovascular, pulmonary, renal and hepatic diseases
- Patient on antipsychotics and antidepressants drugs
- Pregnant and lactating mothers
- Spinal deformity, Local site skin infection

RESULT AND DISCUSSION

The present study was designed to compare the duration of sensory and motor blocks with use of chloroprocaine and levobupivacaine as local anaesthetics in spinal anaesthesia. A prospective randomized open label double blind study was done in which 72 patients, 18-60 yrs of age of ASA physical status I and II undergoing elective unilateral knee arthroscopy under spinal anaesthesia were allocated into two equal groups, group C, group L (n=36). Group C patients received spinal anaesthesia with 40 mg 1% chloroprocaine and Group L patients received spinal anaesthesia with 7.5 mg 0.5% levobupivacaine.

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The demographic data of the patients were as follows:

1) There was no statistically significant difference in mean age in between two groups (p=0.5880).

2) There was no statistically significant difference in mean weight in between two groups (p=0.7648).

3) There was no statistically significant difference in mean height in between two groups (p=0.6861).

4) There was no statistically significant difference in mean duration of surgery in between two groups (p=0.4865).

5) There was no statistically significant difference in ASA gradings in between two groups (p=0.8130).

6) There was no statistically significant difference in gender in between two groups (p=0.7813).

All two groups were comparable in terms of mean age, weight, height, mean duration of surgery, ASA gradings and sex.

In group-C, the mean SBP base line (mean ± s.d.) of the patients was 129.6111 ± 6.6688 mmHg.

In group-L, the mean SBP base line (mean ±s.d.) of the patients was 128.5278 ± 6.7379 mmHg.

There was no statistically significant difference in base line SBP in between two groups (p=0.4952).

In group-C, the mean DBP base line (mean± s.d.) of the patients was 82.1111 ± 5.3866 mmHg.

In group-L, the mean DBP base line (mean±s.d.) of the patients was 81.1111 ± 5.3333 mmHg.

There was no statistically significant difference in base line DBP in between two groups (p=0.4313).

All two groups were comparable in terms of base line mean SBP & base line mean DBP

Haemodynamic variables-

A) Heart Rate (HR): From table – 8 and graph – 8 it can be observed that the mean heart rate changes in Group C and Group L was insignificant in both intraoperative and postoperative period .

B) **Mean Arterial Pressure (MAP):** From table – 7and graph – 7 it can be observed that there was no statistically significant differences in the mean MAP in Group C & Group L during

intraoperative and postoperative period.

C) SPO_2- SPO_2 was recorded by pulse oximeter**.** From table –9 and graph – 9 it can be observed that there was no statistically significant differences in SPO_2 in Group C & Group L during intraoperative period.

Peak block height

Some other studies reported the similar results mentioned below-

1) **Yoos JR et al in 2005** designed a double-blind, randomized, crossover, volunteer study to compare 40 mg of 2-Chloroprocaine with small-dose (7.5 mg) bupivacaine with measures of pinprick anaesthesia, motor strength, tolerance to tourniquet and electrical stimulation, and simulated discharge criteria. However, bupivacaine often produces inadequate surgical anaesthesia and has an unpredictable duration. Preservative-free 2-Chloroprocaine has reemerged as an alternative for outpatient spinal anaesthesia. Peak block height (2-Chloroprocaine average T7 [range T3-10]; bupivacaine average T9 [range T4-L1]) did not differ between drugs (P = 0.15)[7].

Our results regarding Peak block height corroborate with the observation of **Yoos JR et al in 2005[7].**

Mean time to peak block height

Some other studies reported the similar results mentioned below-

Camponovo et al[8], 2014 This prospective, observer-blinded, randomised, multicentre study aimed at determining the non-inferiority of 50 mg of plain 1% 2-chloroprocaine vs. 10 mg of 0.5% plain bupivacaine in terms of sensory block onset time at T10 after spinal injection. The study hypothesis was that the difference in onset times of sensory block to T10 between the two drugs is ≤ 4 min. One hundred and thirty patients undergoing lower abdominal or lower limb procedures (≤ 40 min) were randomised to receive one of two treatments: 50 mg of plain 1% 2-chloroprocaine (Group C, n = 66) or 10 mg of plain 0.5% bupivacaine (Group B, n = 64). In their study time required to reach maximum sensory block level (8.5 vs. 14 min) ($P < 0.05$).

Our results regarding mean time to peak block height did not corroborate with the observation of **Camponovo et al[8], 2014** may be due to levobupivacaine was used in our study.

Mean two segment regression time of sensory blockade

Some other studies reported the similar results mentioned below

1) In the study done by **Yoos JR et al[7] in 2005** described previously, they found that mean two segment regression time in between chloroprocaine group and bupivacaine group were 45±20 min and 74±20 min(mean ± S.D) respectively.

Our results regarding mean two segment regression time corroborate with the results **Yoos jr et al in 2005[7].**

2) In the study done by **Kouri M et al[9] in 2004** described previously, they found that mean two segment regression time in between chloroprocaine group and lidocaine group were 57±14 min vs 73±23 min(mean ± S.D) respectively.
Our results regarding mean two segment regression time corroborate with the results **Kouri M et al[9] in 2004**

Mean time for regression of sensory blockade to L1

Some other studies reported the similar results mentioned below

1) **Vath JS et al[10] in 2004** reported the characteristics of 2-chloroprocaine spinal anaesthesia with or without fentanyl in 8 volunteers receiving 40 mg 2-chloroprocaine with saline or 20 micro g fentanyl in a double-blinded, randomized, crossover manner. Spinal anaesthesia was successful for all subjects with complete block regression, ambulation, and void by 110 min. Itching occurred in all subjects receiving fentanyl, though medication was not required Regression to L1 was 78 +/- 7 min with fentanyl and 53 +/- 19 min without fentanyl (P = 0.02).[24]

Our results regarding mean time for regression of sensory blockade to L1 corroborate with the results of **Vath JS et al[10] in 2004**

2) In the study done by **Yoos JR et al[7] in 2005** described previously, they found that in between two groups regression to L1 (2-Chloroprocaine 64 +/- 10 versus bupivacaine 87 +/- 41 min) did not differ between drugs (P = 0.12).

Our results regarding mean time for regression of sensory blockade to L1 did not corroborate with the results of **Yoos JR et al[7] in 2005** may be due to they use bupivacaine in their study.

Mean time for complete regression of sensory blockade to s2

Some other studies reported the similar results mentioned below

1) **An Teunkens et al[11] in 2016** showed that for spinal anaesthesia in patients undergoing ambulatory knee arthroscopy, chloroprocaine has the shortest time to complete recovery of sensory and motor block compared with bupivacaine and lidocaine. The primary endpoint was the time until complete recovery of sensory block. Patients in the chloroprocaine group had a significantly shorter time until recovery from sensory block (median, 2.6 hours; interquartile range [IQR], 2.2–2.9 hours) than patients in the lidocaine group (3.1 hours; IQR, 2.7–3.6 hours; $P < 0.006$) and in the bupivacaine group (6.1 hours; IQR, 5.5 hours to undefined hours; $P < 0.0001$).[70]

Our results regarding mean time for complete regression to s2 corroborate with the results of **An Teunkens et al[11] in 2016.**

2) In the study done by **Lacasse MA et al in 2011** described previously, they found that the average time for complete regression of the sensory block was 146 min in the 2-Chloroprocaine group and 329 min in the bupivacaine group, a difference of 185 min (95% CI: 159 to 212 min; P < 0.001)[12].

Our results regarding mean time for complete regression to s2 corroborate with the results of **Lacasse MA et al in 2011[12].**

3) In the study done by **Kouri M et al[9] in 2004** described previously, they found that chloroprocaine anaesthesia resulted in faster resolution of sensory (103 +/- 13 min versus 126 +/- 16 min, P = 0.0045).

Our results regarding mean time for complete regression to s2 corroborate with the results of **Kouri M et al[9] in 2004.**

Mean time for complete recovery from motor block

1) In the study done by **An Teunkens et al in 2016** described previously, they found that chloroprocaine was associated with a significantly faster recovery from motor block than lidocaine and bupivacaine[11].

2) In the study done by **Camponovo et al[8] in 2014** described previously, they found that mean time for complete recovery from motor block of 2-chloroprocaine group and bupivacaine group were 100 min and 210 min respectively. ($P < 0.05$)

3) In the study done by **Casati A et al[13] in 2007** described previously, they found that median (range) times for recovery of motor function, was faster with 2-Chloroprocaine [60 (45-120) min] than lidocaine [100 (60-140) min] ($P = 0.0005$).

Our results regarding Mean time for complete recovery from motor block corroborate with the results of **An Teunkens et al in 2016[11], Camponovo et al in 2014[8] , Casati A et al in 2007[13].**

Mean time to first ambulation

Some other studies reported the similar results mentioned below

1) In the study done by **An Teunkens et al[11] in 2016** described previously, they found that times to first mobilization were significantly shorter for Chloroprocaine when compared with bupivacaine.

2) In the study done by **Yoos JR et[7] al in 2005,** described previously, they found that mean time to first ambulation of chloroprocaine group and bupivacaine group were 113±14 min and 191±30 min respectively.

3) In the study done by **Camponovo et al[8] in 2014,** described previously, they found that 2-chloroprocaine group showed faster unassisted ambulation (142.5 vs. 290.5 min) ($P < 0.05$) than bupivacaine group.

Our results regarding Mean time to first ambulation corroborate with the results of **An Teunkens et al in 2016[11], Yoos JR et al[7] in 2005,** and **Camponovo et al[8] in 2014.**

Mean time to void

Some other studies reported the similar results mentioned below

1) In the study done by **Kouri M et al[9] in 2004** described previously, they found that mean time Mean time to void of chloroprocaine group and lidocaine group were 104±12 min and 134±14 min respectively.

3) In the study done by **Lacasse MA et al[12] in 2011,** described previously, they found that mean time to void of chloroprocaine group and bupivacaine group were 271±96 min and 338±99 min respectively. Times to micturition were significantly lower in the 2-chloroprocaine group.

Our results regarding Mean time to void corroborate with the results of **Kouri M et al[9] in 2004 and Lacasse MA et al in 2011[12].**

4) In the study done by **Casati A et al in 2007,** described previously, they found no differences in first voiding were reported between chloroprocaine [180 (100-354) min] and lidocaine patients [190 (148-340) min] (P = 0.191)[13].

So our results regarding Mean time to void did not corroborate with the results of **Casati A et al[13] in 2007** may be due to we took levobupivacaine in place of lidocaine.

No adverse effects regarding allergic reactions, hypotension, shivering, bradycardia and nausea and vomiting were found during intraoperative and postoperative period.

We found that in patients undergoing unilateral knee arthroscopy, the use of chloroprocaine was associated with decreased time of duration of sensory and motor block and early recovery, early ambulation and early void. There was no statistically significant difference is noted in haemodynamic changes in between two groups.

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CONCLUSION

From this prospective randomized open label double blind study, we conclude that in patients undergoing unilateral knee arthroscopy, the use of chloroprocaine was associated with decreased time of duration of sensory and motor block and early recovery, early ambulation and early void. There were no statistically significant difference is noted in haemodynamic changes in between two groups. No adverse effects regarding allergic reactions, hypotension, shivering, bradycardia and nausea and vomiting were found during intraoperative and postoperative period.

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Table 1: Distribution of mean Duration of Surgery in Groups

		Mean± SD	**p-value**
Duration of Surgery(minutes)	Group-C (n=36)	43.7500±5.6537	0.4865
	Group-L (n=36)	44.5833±4.3712	

Table 2: Distribution of mean TIME TO REACH PEAK BLOCK HEIGHT, TWO SEGMENT REGRESSION TIME, TIME FOR REGRESSION TO L1, TIME FOR COMPLETE REGRESSION TO S2, COMPLETE RECOVERY FROM MOTOR BLOCK, TIME TO FIRST AMBULATION and TIME TO VOID (minutes) in Groups

		Mean± SD	**p-value**
TIME TO REACH PEAK BLOCK HEIGHT(minutes)	Group-C (n=36)	15.5833±3.2634	0.6142
	Group-L (n=36)	15.2222±2.7683	
TWO SEGMENT REGRESSION TIME(minutes)	Group-C(n=36)	57.0833±8.5670	<0.001
	Group-L (n=36)	80.5833±7.4234	

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TIME FOR REGRESSION TO L1(minutes)	Group-C (n=36)	91.8056±10.4302	<0.001
	Group-L (n=36)	126.6667±13.4164	
TIME FOR COMPLETE REGRESSION TO S2(minutes)	Group-C (n=36)	151.0000±13.0931	<0.001
	Group-L (n=36)	244.8611±22.2802	
COMPLETE RECOVERY FROM MOTOR BLOCK(minutes)	Group-C (n=36)	103.3333±12.3056	<0.001
	Group-L (n=36)	153.8889±12.1368	
TIME TO FIRST AMBULATION(in minutes)	Group-C (n=36)	108.0278±13.2697	<0.001
	Group-L (n=36)	236.8056±16.1313	
TIME TO VOID(minutes)	Group-C (n=36)	168.1944±11.9015	<0.001
	Group-L (n=36)	257.0833±19.4340	

Table 3: Association between PEAK BLOCK HEIGHT in. Group

GROUP					
PEAK BLOCK HEIGHT	**Group-C**	**Group-L**	**TOTAL**	**Chi-square value**	**p-value**
T10	11 30.6%	17 47.2%	28 38.9%	6.2073	0.4004
T12	3 8.3%	1 2.8%	4 5.6%		
T4	1 2.8%	2 5.6%	3 4.2%		
T6	8	9	17		

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	22.2%	25.0%	23.6%		
T7	1 2.8%	0 0.0%	1 1.4		
T8	10 27.8%	7 19.4%	17 23.6%		
T9	2 5.6%	0 0.0%	2 2.8%		
TOTAL	36 100.0%	36 100.0%	72 100.0%		