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STUDY TO COMPARE THE EFFECTIVENESS OF CHLORPROCAINE AND CHLORPROCAINE WITH NALBUPHINE IN SPINAL ANAESTHESIA FOR DAYCARE SURGERIES

Anaesthesiology

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ABSTRACT

Purpose: To study and compare the effectiveness of chlorprocaine and chlorprocaine with nalbuphine in spinal anaesthesia for day care surgeries.
Introduction: Recent advances in medical technology, anaesthesia and pain management have allowed a huge expansion of this modality of day-care with a consequent reduction in the need for hospitalization. In this study we compared postoperative analgesia and adverse effects of nalbuphine and fentanyl when used as an adjuvant to hyperbaric bupivacaine during spinal anesthesia.
Material & Methods: This comparative study was conducted with sample size 100. Patients were randomly divided into two groups (Group-C and Group-NC) of 50 patients. For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA). p-value ≤ 0.05 was considered statistically significant.
Results: Total 100 patients were included in this study, 50 patients in Group-C and 50 patients in Group-NC . Difference in mean duration of surgery in min (p-0.2834), motor block(p-0.9094) and mean duration of stay in PACU in min (p=0.8000)with both group was not statistically significant.
Conclusion: In this study we conclude that 1% chlorprocaine 40 mg intrathecally, is equally effective in terms of time for readiness to discharge from hospital;onset and duration of sensory and motor block as compared to combination of 1%chlorprocaine40 mg and nalbuphine 0.4mg intrathecally. We also conclude that they were comparable in safety profile as per hypotension, bradycardia, PONV, sedation and pruritus.

KEYWORDS

INTRODUCTION:

Recent advances in medical technology, anaesthesia and pain management have allowed a huge expansion of this modality of day-care with a consequent reduction in the need for hospitalization. The techniques of general anaesthesia, central neuraxial blocks, regional nerve blocks with indwelling catheters and monitoring techniques are deliberated upon. Finally the most important post-operative issues of discharge criteria, including recovery after spinal anaesthetic, oral fluid intake, voiding and travel after day surgery, are considered. Spinal anaesthesia is a reliable and safe technique for procedures of the lower extremities.

Our study compared postoperative analgesia and adverse effects of nalbuphine and fentanyl when used as an adjuvant to hyperbaric bupivacaine during spinal anesthesia.

Aim:

To study and compare the effectiveness of chlorprocaine and chlorprocaine with nalbuphine in spinal anaesthesia for day care surgeries.

OBJECTIVES:

- To study the onset, duration and time to complete regression of sensory blockade.
- To study the onset, duration and time to complete regression of motor blockade.
- To study the occurrence of complications like hypotension, bradycardia, respiratory depression, nausea, vomiting, pruritus, urinary retention.

MATERIAL & METHODS:

Study design:
This prospective, randomized, double blind, comparative study was conducted at Mahatma Gandhi Medical College and Hospital, Jaipur with sample size 100. Total of 100 patients were enrolled in our study. Patients were randomly divided into two groups of 50 each with the help of chit in box method. Both the patient and the observer were blinded to the study.

INCLUSION CRITERIA:

- Age of patient: 40-60 yrs.
- American society of anaesthesiologists (ASA) physical status I –II
- Patient undergoing elective day care surgeries under spinal anaesthesia, of duration 60 minutes or less.

EXCLUSION CRITERIA:

- Patient refusal for the procedure.
- Allergic to amide local anaesthetic agents.
- All general contraindications for spinal anaesthesia.

Methodology:
All patients who are in the inclusion criteria had assessed by a pre anaesthetic evaluation. Informed written consent was obtained from all patients. Those not consenting for the study shall be excluded from the study. Patients were randomly divided in two equal groups using chit in box method namely Group-C and Group-NC.

Group-C received only Chloroprocaine 40mg and Group-NC received injection Nabulphine 0.8mg with injection Chloroprocaine 40mg intrathecally. These drugs were provided in prefilled syringe labelled with C and NC having identical volumes.

Patients were monitored for oxygen saturation, electrocardiogram, heart rate (HR), blood pressure, and mean arterial pressure using multiparameter monitoring system and placed in sitting position and study drugs were injected in the sub arachnoid space at L3-L4 space, under aseptic precautions using 25-gauge Quincke needle, after confirming free & clear flow of CSF. Thereafter patients placed in supine position & oxygen administered at 5l/min with a face mask during the surgery.

After subarachnoid block patients were placed supine position and then evaluated for sensory and motor block characteristics at frequent intervals as per proforma. Patients were evaluated for sensory and motor block, intra and postoperative hemodynamics, and side effects at frequent interval.

Sensory block was assessed using pinprick method using 25 g

hypodermic needle every 2 min until highest dermatomal level was reached and every 30 min till regression to S2 dermatome. Onset of sensory block, time to reach the highest dermatome, and time to regress to S2 level (duration of sensory block) was noted. Motor block was assessed using modified Bromage scale (0: no motor block, 1: inability to raise extended legs; able to move knees and feet, 2: inability to raise extended leg and move knee; able to move feet, and 3: complete block of motor limb) every 2 min and 30 min until regression of complete motor block. Onset of motor block (Bromage 2), time to reach maximum motor block (Bromage 2 or 3), and duration of motor block (Bromage 0) was noted. All the parameters were assessed from the time of intrathecal injection.

Pain was assessed using 10point visual analog scale (VAS) (0–10 where 0 = no pain and 10 = worst pain ever felt). Sedation was assessed using Ramsay sedation score. Side effects such as hypotension, bradycardia, shivering, respiratory depression, nausea and vomiting, and pruritus was noted during intraoperative and postoperative period. In postoperative period, VAS score was assessed every 30 min for 6 h, and if the score was found to be more than 3, all patients were treated with rescue analgesics, injection diclofenac sodium 75mg iv as infusion. This time was taken as the duration of effective analgesia and the number of patients receiving rescue analgesia was noted. Hypotension, defined as a decrease in systolic blood pressure by >20% from baseline or <90 mmHg, was treated with incremental IV doses of mephentermine 6 mg and further IV fluid as required. Bradycardia defined as HR <50 beats/min was treated with IV atropine 0.6 mg IV.

STATISTICALANALYSIS:

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. One-way analysis of variance (one-way ANOVA) was a technique used to compare means of three or more samples for numerical data (using the F distribution). A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate.p-value ≤ 0.05 was considered statistically significant.

RESULTS:

Total 100 patients were included in this study, 50 patients in Group-C and 50 patients in Group-NC. Majority of patients were 31-40 years old in both groups. Out of these 84% were male patients. In Group-C, the mean Height (mean± s.d.) of patients was 168.8800± 4.8458. In Group-NC, the mean Height (mean± s.d.) of patients was 169.0380± 4.9108. Difference of mean Height with both Group was not statistically significant (p=0.8717). In Group-C, the mean Weight (mean± s.d.) of patients was 65.5900± 7.8994. In Group-NC, the mean Weight (mean± s.d.) of patients was 65.0520± 7.5561.Difference of mean Weight with both Group was not statistically significant (p=0.7286).

In Group-C, 37(74.0%) patients had ASA grade I and 13(26.0%) patients had ASA grade II.

In Group-NC, 8(72.0%) patients had ASA grade I and 14(28.0%) patients had ASA grade II.

Association of ASA grade vs group was not statistically significant (p=.8217).

In Group-C, 8(16.0%) patients had brachytherapy , 16(32.0%) patients had haemorrhoidectomy, 16(32.0%) patients had fistulectomy , 4(8.0%) patients had Leg debridement and 6(12.0%) patients had Ligation of varicose vein.

In Group-NC, 9(18.0%) patients had brachytherapy, 14(28.0%) patients had haemorrhoidectomy, 16(32.0%) patients had fistulectomy, 5(10.0%) patients had Leg debridement and 6(12.0%) patients had Ligation of varicose vein.

Association of TYPE of surgery vs group was not statistically significant (p=0.9896).

Table-1: distribution of mean duration of surgery in min, duration of motor block in min duration of stay in PACU in min

		Number	Mean	SD	Minimu m	Maximu m	Media n	p- value
DURATIO N OF SURGER Y (min)	Group-C	50	35.9800	9.1729	18.0000	56.0000	35.5000	0.283 4
	Group- NC	50	38.0000	9.5512	18.0000	56.0000	38.0000	
DURATIO N OF MOTOR BLOCK (min)	Group- C	50	80.1833	10.8115	62.0000	101.0000	80.0000	0.909 4
	Group- NC	50	80.4872	11.0700	62.0000	101.0000	80.0000	
DURATIO N OF STAY IN PACU (min)	Group- C	50	46.9200	9.0955	31.0000	72.0000	47.0000	0.800 0
	Group- NC	50	47.4200	10.5349	31.0000	72.0000	45.5000	

Difference of mean DURATION OF SURGERY in min with both Group was not statistically significant (p=0.2834).
Difference of mean DURATION OF MOTOR BLOCK with both Group was not statistically significant (p=0.9094).
Difference of mean DURATION OF STAY IN PACU in min with both Group was not statistically significant (p=0.8000).

Table-2: Distribution of mean time for first rescue analgesia, time until ambulation in min, time until first void, time until discharge from hospital (min):

	GROUP	Number	Mean	SD	Minimum	Maximum	Median	p- value
TIME FOR FIRST RESCUE ANALGESI A	Group-C	50	74.8400	23.6223	41.0000	132.0000	67.5000	0.7525
	Group- NC	50	76.3800	25.0476	41.0000	132.0000	68.5000	
TIME UNTIL AMBULATI ON in min	Group-C	50	153.1800	24.4830	115.0000	225.0000	152.0000	0.9095
	Group- NC	50	153.7800	28.0250	115.0000	225.0000	149.5000	
TIME UNTIL FIRST VOID	Group-C	50	177.4600	33.4110	124.0000	280.0000	169.0000	0.9646
	Group- NC	50	177.7800	38.4221	124.0000	280.0000	169.0000	
TIME UNTIL DISCHARG E FROM HOSPITAL (min)	Group-C	50	202.6400	32.5913	150.0000	290.0000	196.5000	0.8904
	Group- NC	50	201.6800	36.7498	150.0000	290.0000	196.0000	

Difference of mean TIME FOR FIRST RESCUE ANALGESIA with both Group was not statistically significant (p=0.7525).
Difference of mean TIME UNTIL AMBULATION in min with both Group was not statistically significant (p=0.9095).
Difference of mean TIME UNTIL FIRST VOID with both Group was not statistically significant (p=0.9646).
Difference of mean TIME UNTIL DISCHARGE FROM HOSPITAL (min) with both Group was not statistically significant (p=0.8904).

DISSCUSION:

Outpatient surgery is gaining popularity in the modern world due to its various advantages. In developing countries like India, where the health care cost and hospital bed occupancy are major concerns, same-day hospital discharge reduces the burden on the healthcare system; patient satisfaction is also higher due to early recovery and short hospital stays.

The increasing trend of using chloroprocaine in ambulatory surgery is due to its short duration of action. Smith KN et al performed a study in volunteers and compared different doses of chloroprocaine in spinal anaesthesia with or without epinephrine, and they observed that plain chloroprocaine 30 to 60 mg is the optimum dose for ambulatory

procedures, without TNS and addition of epinephrine is not recommended as its use is associated with side effect[1].

Teunkens A et al[2] (2016) found that Chloroprocaine was associated with a significantly faster recovery from motor block than lidocaine and bupivacaine. Times of first mobilization,urine voiding, and discharge were quite lower for chloroprocaine than bupivacaine, but not with lidocaine. In bupivacaine group, patients required significantly pared with lidocaine and chloroprocaine. Groups were differ with respect to patient satisfaction, incidence of bradycardia, hypotension and transient neurologic symptom rate. For spinal blockade patients undergoing ambulatory knee arthroscopy, chloroprocaine required the least amout of time to complete recovery of motor and sesory block compared with bupivacaine and lidocaine.

Regression of sensory block and Duration of motor block :
The time for two-segment regression and time for regression to S2 in our study was 51.12±9.849 min versus 51.7 ±9.3596 min (P =0.7634), and 147.64 ±14.15 min vs 148.060±13.7342 min (P =.8806) in group A and group B, respectively. Thus, the regression of sensory block was similar in both group of our study.

Thus Difference of mean TIME FOR REGRESSION OF TWO SEGMENTS (min) and Difference of mean TIME FOR REGRESSION TO S2 (min) with both Group was not statistically significant.

Regression of motor block was assessed using modified Bromage scale, the duration of motor block in our study is(80.1833±10.8115 min vs 80.4872±11.0700 was not statistically significant (p=0.9094).

Lavanya c et al[3] (2019) administered 4 cc of 1% chloroprocaine intrathecally; and intravenous nalbuphine 0.4 mg/Kg to patients undergoing Diagnostic Hysterolaparoscopy (DHLS) as day care procedure.They found that the onset time was rapid (sensory block 5.8±2.2 min). The mean time of 2-segment recession of spinal block, taken as duration of anaesthesia, was 38.3±6.195 min which was sufficient as the duration of surgery was 31.36±5.46 min. The intraoperative conditions were excellent with minimal & treatable intraoperative side effects. Mild chest heaviness was seen in all patients due to pneumoperitoneum in head low position. The time of PADS of 12 (252±36 min) showed that patients were ready for discharge in 5 hrs. PDPH was seen in 16 patients on 1st day & 4 patients on 2nd day. Patient satisfaction was good (t = 4.09).

Gurunath BB et al[4] (2018) administered intrathecally: hyperbaric bupivacaine with nalbuphine (300 µg) (Group N); hyperbaric bupivacaine with fentanyl (25 µg) (Group C). They observed that nalbuphine group (Group N) showed delayed onset of sensory blockade (3.9 ± 0.35) min compared to fentanyl group (Group C) (3.1 ± 0.18 min), two- segment sensory regression time was prolonged in Group N (193.16 ± 39.55) as compared to Group C (167.41 ± 30.17 min) and minimal bradycardia which could be easily managed.

Kumaresan S et al[5] (2017) studied four groups (n = 30). They administered nalbuphine0.4 mg (Group A), nalbuphine 0.6 mg (Group B), and nalbuphine 0.8 mg (Group C) (total volume 3 ml) and normal saline (Group D) along with 0.5% hyperbaric bupivacaine. There was statistically insignificant difference (P > 0.005) in all four groups in the onset of sensory and onset of motor block; however the duration of sensory block and duration of motor blockade were significantly prolonged in Groups B (0.6 mg) and Group C (0.8 mg). The incidence of adverse effects was frequently higher in Group C (P < 0.005) compared to other groups. They concluded that nalbuphine is effective adjuvant in spinal anesthesia, in a dose of 0.6 mg to prolong the duration of analgesia without increased adverse effects.

Time for first rescue analgesia:
n our study, the requirement of rescue analgesics was similar in both group (74.84±23.6223 min in group C, vs 76.25.0476 min in group NC(p=0.7525).

Similar observations were found by Campnovo C et al[6] in a comparative study of Chloroprocaine 40 mg to chlorprocaine40 mg with 20 mcg fentanyl in spinal anaesthesia, they also observed that the similar time (77.84±21.6223 min) requirement of rescue analgesics in both group.

Time for first void:
Urinary retention is a major concern in ambulatory surgery under spinal anaesthesia, further urological procedures increase the risk of urinary retention. In our study, we observed that the time for. The first void was 177.4600±33.411 min in group C and 177.780±38.4221 was in group NC . The data showed that the time to first void was significantly similar in both group (p=0.9646).

A recent study in 2019 conducted by Palamara C et al compared chloroprocaine and Chlorprocaine with fentanyl in spinal anaesthesia for ambulatory urology surgery and observed similar time (177. 4600 ±33.411 min) of first void Results.

Time for readiness to discharge from hospital:
Our primary outcome was time for ready to discharge from hospital, we observed that this time was 202.64±32.59 min in group C and 201.68±36.74 min in group NC and P value was 0.8904, indicating no significantly difference.

Early ambulation, void, and minimum side effects, all contribute to short hospital stay after day care surgery.

Teunkens et al compared three local anaesthetic agents; chloroprocaine, bupivacaine, and lidocaine in spinal anaesthesia and observed that the time to discharge from hospital was significantly shorter in chloroprocaine group in contrast to bupivacaine, but no significant difference found between chloroprocaine and lidocaine group[7].

Our observations coincide with studies of Yoos et al[8],Wesselink E et al[9] as all the authors found earlier unassisted ambulation and void, leads to early home readiness with chloroprocaine spinal anaesthesia.

CONCLUSION:
In this study we conclude that 1% chlorprocaine 40 mg intrathecally, is equally effective in terms of onset and duration of sensory and motor block as compared to combination of 1%chlorprocaine40 mg and nalbuphine 0.4mg intrathecally. We also conclude that they were comparable in safety profile as per hypotension, bradycardia, PONV, sedation and pruritus.

Limitations:
In spite of every sincere effort my study has some lacunae.The notable short comings of this study are as follows:-

1. The sample size was very small. Only 100 cases are not sufficient for this kind of study.
2. The study has been done in a single centre.
3. The study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out.

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