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COMPARISON OF 0.5% BUPIVACAINE AND 1% 2-CHLOROPROCAINE FOR SPINAL ANAESTHESIA FOR AMBULATORY SURGERIES: A PROSPECTIVE, OBSERVER-BLINDED, RANDOMIZED, CONTROLLED TRIAL

Anesthesiology

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ABSTRACT

Ambulatory surgeries are gaining popularity and they became the order of the day. Factors limiting the use of Spinal Anaesthesia in the ambulatory setting include delayed ambulation, risk of urinary retention and pain after block regression. Lignocaine has been associated with a high incidence of transient neurological symptoms, and bupivacaine produces sensory and motor blocks of long duration. Preservative free 2-chloroprocaine has re-emerged as an alternative to Bupivacaine for outpatient spinal anaesthesia. We have designed this trail to compare the efficacy of 40 mg of intrathecal preservative free 1% 2-chloroprocaine with 10mg of 0.5% Bupivacaine for Ambulatory surgeries like Hernioplasty/Herniorrhaphy, Hydrocele correction , Anal Fistulectomy, Fissurectomy and Haemorrhoidectomy etc.

Methods: After obtaining approval from the Institutional Ethical Committee and Informed Consent, 50 patients belonging to both sexes and aged between 18-55 years of ASA -1 & 2 Physical status were randomly taken for the study. They were divided into two groups, comprising of 25 patients each- C-Group (Chloroprocaine group) and B-Group (Bupivacaine Group). The primary outcome of the study was the time until reaching eligibility for discharge. Secondary outcomes included the duration of the sensory and motor blocks, the length of stay in the postanaesthesia care unit, the time until ambulation, and the time until micturition. They were compared and statistically analysed.

Results: The average time to discharge readiness was 277 min in the Group C and 353 min in Group B, a difference of 76 min (95% confidence interval [CI]: 40 to 112 min; P<0.001). The average time for complete regression of the sensory block was 146 min in Group C and 329 min in the group, a difference of 185 min (95% CI: 159 to 212 min; P<0.001). Times to ambulation and micturition were also significantly lower in the Group C. (P<0.001).

Conclusion: Spinal 2-chloroprocaine compared to bupivacaine provides adequate duration and depth of anaesthesia for short procedures with faster block resolution and earlier hospital discharge.

KEYWORDS

Ambulatory surgery, Bupivacaine, Chloroprocaine, Spinal anaesthesia

I. INTRODUCTION

Present days more procedures are performed in an outpatient setting, and many of them are conducted under spinal anesthesia. Spinal anaesthesia is a safe and reliable technique for surgery of the lower abdomen and lower limbs. No local anesthetic can provide a block with rapid onset, predictable duration, fast recovery, and lack of side effects[1,2]. For past many years, spinal lignocaine has been the local anesthetic of choice for outpatient surgery because of its fast onset and short duration. However, transient neurological symptoms have been reported[3-7] . As an alternative, hyperbaric bupivacaine, a long-acting local anesthetic has been used in the ambulatory setting by using smaller doses. However, the duration of the block remains prolonged, and they may provide insufficient anesthesia.[8,9]. An amino-ester local anesthetic, 2-chloroprocaine (2-CP), is of short duration of action. Initially used mostly for obstetrical epidurals. Concerns about its use were raised due to its neurotoxicity. Several studies have suggested that low pH and the presence of sodium bisulfite, an antioxidant, may have been responsible for the neurotoxicity. Subsequently, the pH of the 2- CP solution has been adjusted, and a preservative-free formulation has been released. This study was designed to compare 2-CP with bupivacaine for spinal anesthesia in elective ambulatory surgeries.

II. MATERIALS AND METHODS

Following ethical committee approval patients were thoroughly explained regarding the nature of the study. A written informed consent was obtained from all the patients.50 patients belonging to both sexes and aged between 18-55 years of ASA -1 & 2 Physical status were randomly taken for the study. They were divided into two groups, comprising of 25 patients each- C-Group (Chloroprocaine group) and B-Group (Bupivacaine Group). Group C patients were given 40mg of 1% 2- Chloroprocaine. Group B patients were given 10 mg of 0.5% Hyperbaric Bupivacaine. The following surgeries were included: Hernioplasty/ Herniorrhaphy, Hydrocele correction , Anal Fistulectomy, Fissurectomy and Haemorrhoidectomy etc.

Exclusion criteria:

- Patients with contraindications to spinal anesthesia
- international normalized ratio >1.3,
- platelets<75,000,
- use of anticoagulant drugs
- Neurologic disease
- multiple sclerosis,
- Symptomatic lumbar herniated disc,
- spinal stenosis,
- Fluid restriction (cardiac or renal insufficiency),
- Allergy or intolerance to local anesthetics and atypical plasma cholinesterase.

All patients were pre medicated with 0.05mg/kg of Midazolam 45 min before surgery. In the operating room in intravenous cannula [18g] was inserted & IV hydration with Ringer lactate solution was started. Pulse Rate , BP, RR & SpO2 were recorded [baseline measurements]. Under all strict aseptic conditions lumbar puncture was performed with 25 gauge Quinckes needle in L3 – L4 space in sitting position & study drugs were injected as per group of the patient according to random assignment. No adjuvant medication (fentanyl, epinephrine, etc.) was added to either local anaesthetic.

The evolution of both sensory and motor blocks was evaluated by a blinded observer, every minute until readiness to surgery, every 5 min after the maximum level of sensory block was reached (three consecutive observations with the same maximum level of sensory block), and then every 30 min until complete regression of sensory block to S2 and readiness for home discharge. Levels of motor and sensory block were measured every 30 min until the end of anaesthesia. Sensory block was verified by bilateral pinprick test using a 20-Ghypodermic needle. Motor block was verified using a modified Bromage's scale as follows: no motor block = 0; hip blocked = 1; hip and knee blocked = 2; hip, knee and ankle blocked = 3. Readiness to surgery was defined according to the presence of an adequate motor block (Bromage's score ≥ 2,) and loss of Pinprick sensation at T10. Small boluses of Mephenteramine [3 – 6mg] were given as per need to treat hypo tension [MAP < 7O mm Hg] & IV Atropine [O.6mg] if Heart rate < 55 bpm. Postoperative analgesia consisted of [non-steroidal antiinflammatory agents (NSAIDs) or opioids]. Ondansetron 4 mg iv was offered for nauseous patients.

Patients were discharged from the Postanaesthesia care unit (PACU)

according to White et al scoring system. Maximum score is 14. A score of 12 (with no less than 1 in any category) provides criteria for discharging PACU.

- Level of consciousness
- Physical activity
- Circulation
- Respiratory stability
- O2 Saturation status
- Postoperative pain assessment
- Post operative emetic symptoms

Patients were discharged from the postanesthesia care unit (PACU) when they had attained all of the following criteria:

- a minimum of 60-min stay,
- stable vital parameters,
- regression of the motor block (Bromage 0 to 2),
- no requirement of analgesia within the previous 20 min, and
- Normal level of consciousness.

The Modified Postanaesthesia discharge scoring system (PADS) was used to determine home readiness.
Includes-

- Vital signs
- Activity level
- Nausea and/or vomiting
- Pain
- Surgical bleeding

Score >9 required for discharge.
Discharge from hospital was possible when the patients reached all of the following criteria:

- complete regression of the block to light touch,
- ability to void,
- ability to walk,
- stable vital signs,
- no nausea,
- Pain controlled with oral medication (last dose given at least one hour before discharge), and
- ability to tolerate liquids by mouth.

The primary outcome of this study, i.e., the time to eligibility for discharge from hospital, was measured from the time spinal anaesthesia was performed to the time the patient attained all of the discharge criteria.

secondary outcomes are time for complete regression of the sensory and motor blocks, length of stay in the PACU, and time to ambulation and micturition.

Patients were followedup for 7 days following surgery to assess potential complications related to the spinal anesthesia.

- the presence of headache,
- paresthesia or dysesthesia in the lower limbs,
- lower back pain,
- nausea or vomiting, and
- difficulty in voiding.

the patient's satisfaction with the anaesthesia provided was assessed using a scale from 0 to 10 (0 = total dissatisfaction; 10 = total satisfaction).

III. OBSERVATIONS AND RESULTS

Our study was Randomised observer blind controlled study. Parametric data were reported as Arithmetic mean +/- standard deviation and analysed using Student's t test. Nominal data [characteristics of hemodynamics& postoperative complications] were analysed using Chi square test or Fisher's exact test.

50 Patients were enrolled in the study. The groups were demographically similar in all respects [Table 1].

The study results regarding characteristics of block are summarised in [Table 2].

Table:1 Dermographics

	2 Chloroprocaine	Bupivacaine	P value
Age	49 (5)	49 (5)	0.95
Weight	72 (6)	70 (8)	0.378
Height	167 (7)	166 (7)	0.76
Duration of surgery(min)	35 (7)	32 (7)	0.136
ASA I/II	10/15	14/11	
Sex (M/F)	14/11	12/13	

Table 2: characteristics of block

	2 CP	BUPIVACAINE	P value	Difference btwn 2 groups
Primary outcome				
Time to eligibility for discharge from hospital (min)	260 (6.25)	367 (82)	< .0001	106.56 [56.12 to 116.6]
Secondary outcome				
Time to readiness for surgery (min)	5.5 (0.6)	5.6 (0.7)	0.7	- 0.068 [-0.46 to 0.32]
Peak block height	T7 (T1-T10)	T7 (T1-T11)	1	T7 (T6 to T8)
Time to peak block height (min)	16 (4)	17 (5)	0.55	-0.76 [-3.33 to 1.81]
Time for 2 segment regression (min)	48 (8)	73 (20)	< 0.001	25.32 [33.96 to 16.88]
Time for regression to L1 (min)	67 (11)	164 (32)	< 0.001	-96.72 [110.33 to 83.11]
Time for complete regression to	134 (23)	317 (46)	<0.001	-182.56 [-203.19 to -161.9]
S2 (min)				
Motor	72 (12.48)	99 (40.4)	0.003	-27 .15 [-43.85 to -9.83]
Duration of motor block (min)				
Discharge				
Time to ambulation (min)	216 (28)	276 (33)	<0.001	-60.44 [-78.1 to -42.78]
Time to micturition (min)	247 (56)	340 (57)	<0.001	-93.2 [-125.51 to -60.89]
Length of stay in PACU (min)	67 (7)	67 (6)	0.95	-0.13 [- 4.03 to 3.78]

The onset characteristics of the block were similar. However, regression characteristics did show a different profile between the two groups. Regression of the block to L1 was faster in the 2-CP group than in the bupivacaine group. The time for complete regression to S2 in the 2-CP group was less than half that of the bupivacaine group. Similarly, the duration of the motor block was significantly shorter in the 2-CP group (Table 2). Successful spinal anesthesia was attained in all patients.

Table 3: Hemodynamic parameters

	2- CP	Bupivacaine	P value
During surgery			
hypotension (≥ 25 % baseline)	2 (8 %)	1 (4 %)	0.55
bradycardia (< 50 beats /min)	2 (8 %)	3 (12 %)	0.64
pain requiring analgesia	5 (20 %)	3 (12%)	0.7
In the PACU			
hypotension (≥ 25 % baseline)	2 (8 %)	1 (4 %)	0.55
bradycardia (< 50 beats /min)	0 (0 %)	1 (4 %)	0.31
PONV	1 (4 %)	1 (4 %)	1
Pain requiring analgesia	10(25 %)	1 (4 %)	0.006

Length of stay in the PACU was similar in both groups. However, in terms of discharge criteria, the time to ambulation, micturition, and eligibility for discharge were all significantly shorter in the 2-CP group (Table 2).

During surgery & in the PACU the incidence of hypotension, bradycardia, pain requiring analgesia were similar between groups (Table 3).

However, some patients in the 2-CP group experienced pain in the PACU, with a 28% difference in the incidence of pain between groups (P = 0.02).

The incidences of complications recorded during the follow-up phone calls were all similar between groups (Table 4).

Table 4: side effects

	2-CP	Bupivacaine	P value	Difference between groups (95% CI)
Postdural puncture headache	1(4%)	1(4%)	1	
Transient neurologic symptoms	0	0		
Back pain	12(48%)	10(40%)	0.77	
Satisfaction (/10)	9.04	9	0.86	0.04 (-0.42 to 0.50)

IV. DISCUSSION

The principal finding of this study is spinal anesthesia with 2-CP can provide a satisfactory surgical block while permitting an earlier discharge from hospital than spinal bupivacaine. This advantage is due to a more rapid regression of the sensory and motor block, which helps patients ambulate and void faster. In eight healthy volunteers, Yoos et al. compared 2-CP 40 mg with bupivacaine 7.5 mg. They concluded that spinal 2-CP provides adequate duration and density of block for ambulatory surgical procedures, and it has a significantly faster resolution of block and return to ambulation compared with bupivacaine[10].

The finding that shows the most significant advantage is the time for regression of the sensory block to S2, as 2-CP was 2 times faster than bupivacaine. patients in the 2-CP group experienced pain in the PACU because their spinal anesthesia regressed more rapidly. The primary outcome of this study i.e., the time to eligibility for discharge from hospital, a significant difference of 107 min was observed in favour of the 2-CP group due to faster regression of the block, resulting in earlier ambulation and earlier voiding. Delayed discharge due to urinary retention was particularly problematic in the bupivacaine group. Breebaart et al. also demonstrated a longer interval to first voiding in patients having spinal anesthesia with long acting local anesthetics (levobupivacaine and ropivacaine) compared with those with shorter-acting agents[11].

Marie-Andre´e Lacasse et al demonstrated that intrathecal 2-CP 40 mg produces a satisfactory surgical block for procedures lasting <60 min. When compared with hyperbaric spinal bupivacaine 7.5 mg, it resulted in a significantly faster regression of the block, shorter time to ambulation and micturition, and earlier discharge from hospital[12]. Camponovo et al demonstrated that 50 mg of plain 1% 2-chloroprocaine proved to be comparable with 10 mg of 0.5% plain bupivacaine in terms of onset of sensory block at T10 in patients undergoing spinal anaesthesia for short procedures. Furthermore, 1% 2-chloroprocaine showed faster recovery from anaesthesia and thus prompter eligibility for home discharge than the control, suggesting its suitability for the ambulatory setting[13].

V. CONCLUSION

Spinal 2-chloroprocaine compared to bupivacaine provides adequate duration and depth of anaesthesia for short procedures with faster block resolution and earlier hospital discharge.

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