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Original Research Paper

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INTRATHECAL 0.5% BUPIVACAINE VS 2-CHLOROPROCAINE FOR SHORT GYNAECOLOGICAL PROCEDURES.

Dr Rashmi Bengali Asso. Professor, Department of Anaesthesia Govt. Medical college Aurangabad.

Dr Nidhi Chitravanshi* Chief Resident, Department of Anaesthesia Govt. Medical college Aurangabad. *Corresponding Author

ABSTRACT

A study was designed with intrathecal Bupivacaine to compare with 2-Chloroprocaine for short gynecological surgeries.

AIMS AND OBJECTIVES: To compare onset and duration of sensory and motor block and their effect on the hemodynamic status of the patients intraoperatively and to compare any post-operative complications

MATERIAL AND METHOD: Randomized, prospective single-blind clinical trial was undertaken with 60 ASA Grade I and II patients aged between 18 to 30 years, BMI < 22kg/m^2, posted for short gynaecological procedures were divided in two groups.

Group B – Patients received intrathecal 0.5% Bupivacaine 3ml.

Group C- Patients received intrathecal 1% preservative free 2-Chloroprocaine 3ml.

Patients were observed for onset, duration of sensory and motor block. Post-operative analgesia was measured.

Result: Onset of sensory block was similar with either drug but onset of motor block was faster with Bupivacaine. Duration of sensory and motor block was shorter in Chloroprocaine group. Post-operative analgesia was longer in the Bupivacaine group. Early ambulation was seen with Chloroprocaine.

Conclusion: Chloroprocaine is more hemodynamically stable than Bupivacaine to be used for short gynecological day care procedures.

KEYWORDS :

INTRODUCTION

The sole essence of anaesthesia is pain relief in peri and post-operative period. Regional anaesthesia has emerged as an important technique with simplicity, rapid onset of action, good muscle relaxation and safety so also excellent pain control, minimum side effects, decreased blood loss, improved cardiac and pulmonary function and shortened stay in the post anaesthesia care unit.

It is one of the most commonly used anaesthesia technique for gynaecological surgeries in day care practice. Spinal lignocaine has been a popular choice for ambulatory spinal anesthesia. Although, lignocaine has enjoyed a long history of safety and popularity, it has come under recent scrutiny because of transient neurologic symptoms (TNS)[1]. Bupivacaine is a highly protein bound amide local anaesthetic with a slow onset(5-8mins) because of its relatively high pka. It is important to select small doses of Bupivacaine (</= 10mg) to avoid prolonged detrusor block, inability to void and excessively prolonged time until discharge.

Modern preservative free preparations of Chloroprocaine an ultra-short acting ester local anaesthetic administered in small dose(30-60mg) produce reliable, short duration spinal anaesthesia, with faster recovery time.

A study was designed to compare the efficacy of intrathecal 1% 2-Chloroprocaine with Bupivacaine 0.5% for short Gynaecological procedures.

Aims and Objectives

The aim of this study was to compare the effect of intrathecal 2-Chloroprocaine 1% and 0.5% Heavy Bupivacaine on the onset and duration of sensory and motor block and their effect on intraoperative hemodynamic status of the patients.

OBJECTIVES

a) To compare the onset and duration of sensory block.
b) To compare the onset and duration of motor block.
c) To compare the hemodynamic stability with parameters like heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate and SpO2.
d) To compare any post-operative complications.

MATERIAL AND METHOD

After approval from ethical committee, a randomized, prospective single-blind clinical trial was carried out on 60 ASA Grade I and II patients aged between 18 to 30 years, BMI < 22kg/m^2, Height >150cm. posted for short gynaecological procedures like Polypectomy, Salphingectomy, Resuturing of wound gape, Bartholin cyst excision. Obese, ASA Grade III and IV, known allergic, elders with other systemic disorders were excluded. Patients were randomized into 2 groups with 30 each. Written valid informed consent was taken. A detailed history and thorough general and systemic examination was performed. All routine investigations like haemogram, urine routine and microscopic examination, LFT, KFT, ECG, RBSL were performed prior to surgery. After confirming the NBM status of patients, a 22G angiocath was secured and patients were preloaded with Ringer Lactate solution 10ml/kg. All patients were monitored with multipara monitor having NIBP, Pulse oximetry, Respiratory rate and ECG.

Under all aseptic precautions lumbar puncture was performed with 23G spinal needle at L3-L4 intervertebral space. After ensuring free flow of clear CSF the desired drug was injected.

Group B – Patients received intrathecal 0.5% Bupivacaine 3ml.

Group C- Patients received intrathecal 1% preservative free 2-Chloroprocaine 3ml.

Patients were made to lie supine. All patients were given 4lit/min supplemental oxygen with face mask.

1) SENSORY BLOCK ASSESSMENT-

Onset of sensory level was defined as time interval from completion of subarachnoid injection to loss of pin prick sensation at the umbilicus (T10) tested in mid clavicular line every minute until the level was stabilized for two consecutive

tests. Afterwards sensory level was tested every 15 minutes until 2 segment regression to see the duration of anesthesia. Time taken to achieve maximum sensory level and 2 segment regression were noted. Time to regress the sensory level upto T12 from highest sensory blockade was taken as duration of sensory block.

2) MOTOR BLOCK ASSESSMENT-

It was assessed by straight leg raising while lying supine and was graded according to Modified Bromage Scale.

Grade 0- No motor block**, Grade 1**- inability to raise extended leg, **Grade 2**- inability to flex knee but able to flex ankle, **Grade 3**- inability to flex ankle

Onset of motor block was defined as time taken from injection of drug till the patient was unable to flex the ankles. Recovery was defined as the patient's ability to flex the hip and was recorded every 15 mins. Duration of motor block was calculated from time 0 to recovery of motor block.

3) HEMODYNAMIC STABILITY-

Pulse rate and blood pressure were monitored immediately after injection and then every 2 min till 10 min and every 5 min for 30 min and then every 15 min thereafter till the end of the surgery and till the recovery from the block. Hypotension was defined as fall in systolic BP more than 30% of baseline values. It was treated with, Leg elevation, Oxygen supplementation by mask, IV Fluids, Inj. Mephentermine 6mg IV repeated every 3min. Bradycardia was defined as fall in pulse rate below 60/ min. Inj atropine was kept ready as rescue drug. SpO2 monitoring was done. Inj Ondansetron 4mg IV was given for nausea and vomiting. Post-operative neurological symptoms and headache were enquired.

4) DURATION OF POST OPERATIVE ANALGESIA-

Duration of post-operative analgesia was measured from time of injection of spinal anaesthesia to the time when pain score becomes ≥3 according to VAS score measured as 0-No pain; 1, 2, 3- mild pain; 4, 5, 6 – moderate pain; 7, 8, 9 – severe pain;10- worst pain.

Rescue analgesic drug Inj Tramadol 50 mg IV in drip was given at the 1st complain of pain.

5) SIDE EFFECTS-

Intra-operative side effects like nausea, vomiting, shivering, bradycardia, urinary retention and hypotension requiring active treatment were also noted.

6) DATA ANALYSIS-

For analysis of this data SPSS (Statistical Software for social Sciences) software version 24th was used. To check significant difference between different parameters unpaired t-test was applied. Chi-square test was applied to check significant difference between two groups of attributes. P-value was calculated and level of $p < 0.05$ was taken as significant.

Observations

Comparative evaluation was done for age, weight and height. P value was calculated using t test and was statistically insignificant. ($p > 0.05$).

Table 1: Comparison according to time of onset of sensory and motor block in sec.

Groups	Mean(Sec)		SD		p value		R squared	
	Sensory	Motor	Sensory	Motor	0.1888	0.0001	0.029	0.2217
Group C	139.7	185.7	6.205	6.301				
Group B	129.0	151.3	5.028	5.627				

The mean sensory onset in Group C was (139.7 +/- 6.205 sec) and in Group B was (129.0 +/- 5.028 sec), P = 0.1888. The difference was statistically insignificant.

Whereas the mean time for onset of motor block in Grp C was (185.7 +/-6.301sec) and (151.3 +/- 5.627sec) in Group B which was significantly shorter (P = 0.0001).

Duration of post-operative analgesia was significantly longer in Group B than in Group C (168.66 +/-13.61 min vs. 76 +/- 9.70 min), P < 0.0001.

The mean duration of sensory block in Bupivacaine was 164.5+/-12.99 min and motor block was 148+/-14.52 min, compared to 73.16+/-11.36 min duration of sensory block and 69.83+/-10.49 min duration of motor block in Chloroprocaine group with p < 0.0001.

The ambulation time was calculated and was found to be significantly shorter statistically in Group C than in Group B, (122 +/- 9.00 min vs. 192.33 +/-12.16min), P =0.0001.

The incidence of Hypotension (fall in SBP >30% of baseline) was in 6 out of 30 patients in Grp B and in 2 out of 30 patients in Grp C.The incidence of bradycardia was in 2 patients in Bupivacaine group while no patient had any episode of bradycardia in Chloroprocaine group.There was no incidence of nausea reported in Grp C, while 2 patients had nausea in Grp B.

Table No.2: Showing comparison between both groups according to pulse rate.

Time of Assessment (min)	Group C Beats per min	Group B Beats per min	P value
Basal	79.73 ± 6.69	76.43 ± 7.01	0.0692
2	79.66 ± 5.16	76.4± 7.83	0.0660
5	81.1± 8.26	80.73 ± 11.78	0.8913
10	80.8 ± 9.54	81.73 ± 12.23	0.7472
20	82 ± 11.13	83.07 ± 13.47	0.7436
40	81.87 ± 10.21	82.73 ± 14.09	0.7896
60	81.03 ± 9.10	82 ± 13.08	0.7451

No significant change in pulse rate was found throughout and the groups were comparable.($p > 0.05$)

Table No.3: Showing comparison between the two groups according to MAP.

Time of assessment (min)	Group C (mm of Hg)	Group B (mm of Hg)	P Value
Basal	81 ± 8.56	92.13 ± 4.99	0.0001
2	83.1 ± 4.64	84.83 ± 4.27	0.1445
5	77.1 ± 5.38	81.17 ± 7.63	0.0225
10	76.3±4.9	79.6 ± 7.83	0.0594
20	78.97±3.68	79.5 ± 6.04	0.6864
40	81.13±3.42	80.17 ± 3.96	0.3246
60	83.4 ± 2.70	82.47 ± 4.12	0.3127

The MAP was 77mmHg in Grp C and 81mmHg in Grp B at 5th min, which was statistically significant. ($p < 0.05$) While it was comparable and statistically insignificant at rest of the intervals in either group. Mean respiratory rate at all intervals was comparable with no significant difference between the two groups. So also mean SpO_2at all intervals were comparable and statistically insignificant in either groups.

DISCUSSION:

Newer spinal anesthetic techniques for common ambulatory procedures highlight the success of combining subclinical doses of local anesthetics and intrathecal opioid adjuncts[2]. The neuraxial block with shorter acting local anesthetic agents, specific to the expected duration of surgery, may provide superior recovery profiles in the ambulatory setting[3].

As an alternative, attempts have been made to adapt hyperbaric Bupivacaine, to the ambulatory setting by using smaller doses. However, the duration of block may remain prolonged or may provide insufficient anaesthesia[4,5].Urinary retention is frequently encountered with Bupivacaine, delaying the time of discharge[6].

With newer molecule of 2-Chloroprocaine having adjusted pH, the intrathecal use is found to be safe.[7].

Yoos et al[8](2005)carried out a double-blind, randomized crossover, study in 8 volunteers comparing 40mg of 2-Chloroprocaine (2 CP) with small dose (7.5mg) of Bupivacaine. The peak block height, regression to L1 and tourniquet tolerance did not differ (P>0.05). However, discharge time was significantly longer with Bupivacaine 191 +/-30 min, than 2-Chloroprocaine 113 +/- 14min, (P = 0.0009).

M A Lacasse[9] (2011)concluded that 2-Chloroprocaine and Bupivacaine showed no difference in the onset of sensory and motor block similar to our study.(p>.05).

In our study the mean time for the onset of motor block was significantly longer in the Chloroprocaine group than the Bupivacaine group, while there were no significant differences in the time for the onset of motor block in the study done by **M Tandan et al**[10] . **Kannan et al**[11]in 2017 found that, onset of motor block with 40mg of 1% 2-Chloroprocaine was (4-8min), while with 10mg of 0.5% Bupivacaine was (5-9min) and was statistically significant (p = 0.04).

The reason for the observed differences between our results and those seen in the other studies mentioned above could be attributed to the methodological differences such as - difference in the drug dosage or total volume of the drug used.

The mean time taken to reach maximum sensory level in Group C was (8.2 +/-1.37 min) and in Group B was (6.13+/-1.08min) in our study. The difference was found to be statistically significant, P = 0.0001.

Arvind et al[12](2019) showed that the time taken to reach maximum sensory level was 3.4 +/- 0.5 min in Chloroprocaine group and 4.9+/-0.5 min in Bupivacaine group . (p <0.001).

M A Lacasse et al[9](2011), concluded that regression of block to L1 was almost 50% faster in the 2-Chloroprocaine group than in the Bupivacaine group (82 min versus 160 min, respectively, p <0.001) . The time for complete regression to S2 in the 2-Chloroprocaine was less than half that of the Bupivacaine group (146 min v/s 329 min, respectively (p < 0.001).

In our study, mean time for two segment regression was significantly higher in Group B than in Group C (mean 87.83 +/- 12.22 min vs. 51.66 +/-6.36 min), P =0.0001.

Whereas mean duration of sensory block in Chloroprocaine group was 73.16 +/- 11.36 mins and motor block was 68.93 +/-10.49 mins. While in Bupivacaine group it was 164.5 +/- 12.99 mins for sensory and motor block was 148 +/- 14.52 mins, which was significantly longer in Bupivacaine group (p < 0.0001.)

As per **Kannan B et al**[11] (2017) the duration of sensory block was significantly shorter with Chloroprocaine [60-90min], than Bupivacaine [180-225min],(P=0.001).Duration of motor block was significantly shorter in Chloroprocaine (50-75min), than in Bupivacaine (135-180min), p=0.005, which was statistically significant, which was similar with our study.

Duration of post-operative analgesia was significantly longer in Group B than in Group C (168.66 +/-13.61min vs. 76 +/-9.70min), P < 0.0001, in our study as 2-Chloroprocaine group, demanded rescue analgesia earlier.

Arvind et al[12](2019),observed the duration of analgesia 127.6 +/-9.81min in Chloroprocaine group and 286.9 +/- 32.01min in Bupivacaine group (p< 0.001). Rescue analgesia was given when the VAS score > 3 or when patients demand for IM/IV analgesia. In our study, the ambulation time is significantly shorter in Group C than in Group B , (122 +/- 9.00 vs. 192.33 +/-12.16), P =0.0001

The incidence of hypotension in our study, in Group C was 6.6% while in Group B was 20% suggesting the fall more in Bupivacaine group. **Arvind et al**[12] also observed statistically significant similar results .Bradycardia was observed in 2 patients in Bupivacaine group while none in Chloroprocaine group. No incidence of nausea or vomiting was observed in either group.

Mean pulse rate changes at all the intervals were found to be statistically insignificant and comparable (p>0.05) between the two groups. The MAP was 83mmHg in Grp C and 84mmHg in Grp B at 2nd min and 77mmHg in Grp C and 81mmHg in Grp B at 5th min, which was statistically significant. No significant change was observed in respiratory rate and SpO2 in either group.

According to **Arvind et al**[12](2019), significant hypotension was noted in the Bupivacaine group with incidence of 20% while there was not a single incidence of hypotension noted in the Chloroprocaine group. (P =0.002)

Thus in our study, intrathecal 1% Chloroprocaine provided earlier ambulation and more hemodynamic stability with minimum intra-operative and post-operative side effects but with lesser duration of post-operative analgesia as compared to Bupivacaine.

CONCLUSION

It can be concluded that the onset of sensory block is similar with Bupivacaine and Chloroprocaine but onset of motor block was faster with Bupivacaine group. Two segment regression was earlier with the Chloroprocaine than with the Bupivacaine. Duration of sensory and motor block was shorter in the Chloroprocaine group than in the Bupivacaine group. Post-operative analgesia was longer in the Bupivacaine group. Early ambulation was seen with the Chloroprocaine and was hemodynamically stable than the Bupivacaine. Hence Chloroprocaine can be a better choice for short gynaecological procedures in day care surgeries.

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