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Low dose spinal with chlorprocaine a prospective observational study

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Abstract

Low-dose spinal saddle anaesthesia is a safe and reliable anaesthesia technique in outpatient perianal surgery, which provides a reliable but restricted block with good surgical conditions. Chlorprocaine was re-introduced without antioxidant and preservatives, which can be used safely in spinal anaesthesia. Fentanyl is an opioid agonist, acts on mu receptor and of addition of fentanyl to chlorprocaine appears to lengthen the regression to L1 dermatome while minimally lengthening duration of block. This study was done to compare the effects of two different doses of fentanyl as an adjuvant to 1% Chlorprocaine under saddle block for perianal surgeries, and duration of stay in hospital.

Materials and Methods: The study was a randomized controlled double blinded trial conducted on 45 patients aged between 18 – 65 years (ASA 1 and 2) posted for perianal surgeries under spinal anaesthesia in private hospitals in and around Dakshina Kannada from January 2018 to June 2021. The groups are assigned as follows: Group A (n = 15) received 1% Chlorprocaine 20 mg plus 0.5 ml of normal saline intrathecally. Group B (n = 15) received 1% Chlorprocaine 20mg plus fentanyl 15 µg (0.3ml) + 0.2ml of normal saline intrathecally.

Group C (n = 15) received 1% Chlorprocaine 20 mg plus fentanyl 25 µg (0.5ml) intrathecally. The sensory block, modified Bromage scale, post operatively analgesia duration and the rescue analgesia patient's and surgeon's satisfaction score, side effects were noted.

Observations and Results: There was no significant difference in the maximum Bromage score for the motor block it was 11.57 seconds in Group A and Group B and 11. 11.6 in group C . NRS score that denotes the quality of analgesia was higher in group A indicating that the satisfaction was lesser .In the group A the time was the longest followed by group B and group C had the least two segment sensory regression time and was statistically significant with a p value < 0.05. In our study in the group A the time for motor regression to baseline was the highest followed by group C and group B had the least time for the motor regression to baseline and was statistically significant with a p value < 0.05. group A required the highest number of analgesia doses followed by group B and group C required equal number of analgesia and was statistically significant with a p value < 0.05. Group A had the least patient and surgeon satisfaction scores followed by group B and group C had the maximum time and was statistically significant with a p value < 0.05.

Conclusion: Group B had better hemodynamic parameters than group A and group C . Group C was associated with a lot of adverse event intra op like hypotension and group A had a higher need of analgesic and faster sensory loss Hence, considering the nature and duration of the procedure, low dose saddle block anaesthesia with 2-Chlorprocaine would be a suitable choice and we evaluated the drug in varying doses to study the clinical response of varying doses, for procedures lasting for small duration 20 mg is sufficient, the addition of fentanyl may be adjusted based on the expected time of surgery.

Keywords: Chlorprocaine, low-dose spinal, saddle, fentanyl.

Introduction

Low-dose spinal saddle anaesthesia is a safe and reliable anaesthesia technique in outpatient perianal surgery, which provides a reliable but restricted block with good surgical conditions. It is cost effective, easy to perform, less time consuming and patient is comfortable in the post-operative period as there is rapid onset and offset of the drug effect, with minimal side effects. It is effective in terms of analgesic consumption within 24 hours post-surgery and also satisfies all the essential discharge criteria for day care surgery ^[1]. In recent years, many local anesthetic agents have been used for spinal anaesthesia with benefits and adverse effects of its own. Chlorprocaine was re-introduced without antioxidant and preservatives, which can be used safely in spinal anaesthesia. It is a good alternative local anaesthetic to medium-acting (Lidocaine) and long-acting local anaesthetics (Bupivacaine) for outpatient spinal anaesthesia ^[2].

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Chloroprocaine is an amino-ester local anaesthetic, and its advantageous pharmacological properties leads to faster onset, shorter half-life (45 to 53 min) and few incidences of adverse effects like transient neurologic syndrome (TNS), urinary retention, delayed ambulation and spinal hypotension. But it lacks immediate postoperative analgesia.^[3]

Intrathecal opioids are synergistic with local anesthetics and intensify the sensory block, to improve the quality of analgesia and minimise the requirement of postoperative analgesics^[4].

Fentanyl is an opioid agonist, acts on mu receptor and are principally responsible for analgesia along with sedation, nausea, vomiting, pruritis and respiratory depression^[5]. The addition of fentanyl to chlorprocaine appears to lengthen the regression to L1 dermatome while minimally lengthening duration of block^[6].

The requirement of this study is to compare the effects of two different doses of fentanyl as an adjuvant to 1% Chloroprocaine under saddle block for perianal surgeries, and duration of stay in hospital. The objective is to evaluate the quality of analgesia, onset of sensory and motor block and duration of analgesia.

The mean age in Group C, Group A and Group B was 48.6 years, 46.6 years and 44.6 years respectively. We had 20 (44.44%) males and 25 (55.56%) females. 15 cases that underwent lateral sphincterotomy 6 cases who underwent fistulotomy and 24 cases who underwent hemorrhoidectomy. In our study in the group B the time was the shortest followed by group A and group C had the maximum time for the onset of the sensation in the saddle area insensitivity for pain. There was no significant difference in the maximum Bromage score for the motor block it was 11.57 seconds in Group A and Group B and 11.11.6 in group C.

Even though the difference was not significant the onset was faster in group C as compared to group A and group B. The maximum Bromage scale achieved was significantly more in the group C than the Group A and Group B. NRS score that denotes the quality of analgesia was higher in group A indicating that the satisfaction was lesser. In the group A the time was the longest followed by group B and group C had the least two segment sensory regression time and was statistically significant with a p value < 0.05. In our study in the group A the time for motor regression to BS was the highest followed by group C and group B had the least time for the motor regression to BS and was statistically significant with a p value < 0.05. Group A required the highest number of analgesia doses followed by group B and group C required equal number of analgesia and was statistically significant with a p value < 0.05. Group A had the least patient and surgeon satisfaction scores followed by group B and group C had the maximum time and was statistically significant with a p value < 0.05.

Materials and Methods

Source of data

The study was a Randomized controlled double blinded trial. Conducted on 45 patients aged between 18 – 65 years (ASA 1 and 2) posted for perianal surgeries under spinal anaesthesia in private hospitals in and around Dakshina Kannada from January 2018 to June 2021.

Method of Study

A Prospective, Randomised Double Blinded Study was

under taken on 45 patients aged between 18 - 65 (ASA 1 and 2) posted for perianal surgeries like haemorrhoids, fistula in ano, fissure in ano etc, under spinal saddle anaesthesia, was assigned to three groups as per computer generated random numbers. Each group will contain 15 participants.

The groups are assigned as follows:

- Group A (n = 15) received 1% Chloroprocaine 20 mg plus 0.5 ml of normal saline intrathecally.
- Group B (n = 15) received 1% Chloroprocaine 20mg plus fentanyl 15 µg (0.3ml) + 0.2ml of normal saline intrathecally.
- Group C (n = 15) received 1% Chloroprocaine 20 mg plus fentanyl 25 µg (0.5ml) intrathecally.

With aseptic precaution Fentanyl is taken in insulin syringe, 25 mcg equal to 20 units (insulin syringe) and 15 mcg equals to 12 units. Each group shall receive a total volume of 2.5 ml intrathecally.

Preanaesthetic evaluation was done for patient scheduled for perianal surgeries under spinal saddle anaesthesia. Written informed consent was obtained from all study patients. They were asked to remain nil per oral for 8 hours prior to surgery and were explained about 11-point numerical pain rating scale for pain during preanesthetic evaluation to be assessed intra and post operatively. Patients were premedicated with Tab. Rantidine 150 mg HS and Tab Alprazolam 0.5 mg HS night before surgery.

In the operating room electrocardiography, non-invasive blood pressure and oxygen saturation, heart rate was monitored. 18 G IV cannula used for intravenous cannulation. They were started on Compound Ringer lactate solution and were briefed about the method.

The study drug was prepared and administered by anaesthesiologist who is not a part of the study and the parameters were assessed by another anaesthesiologist who is blinded to the study drugs that were injected intrathecally.

Inj. Rantidine 50 mg was given slow IV 15 minutes before spinal anaesthesia. With the patient positioned in sitting position under aseptic precautions 25G Quincke's Spinal needle was introduced into L3 – L4 Subarachnoid space by confirming clear Cerebro spinal fluid free flow, then the drug preparation was injected at the rate of 0.2 ml / sec. Patient was in sitting position for 10 mins. Surgery was commenced after establishment of adequate block (sensory block coccygeal and S5 dermatome). Patient's cardio pulmonary parameters shall be monitored throughout the time of surgery.

- Time of intrathecal injection was noted.
- Loss of sensation, and level of sensory block assessed with pin prick.
- Degree of motor block assessed by modified Bromage scale.
- Blood pressure (BP) is monitored every 5 mins for 1st 15 mins and fall of Systolic BP > 20% of baseline was treated with Inj. Ephedrine 6mg I.V
- If heart rate < 45/ min is treated with Inj. Atropine 0.6 mg I.V.
- Other side effects of chlorprocaine and fentanyl were monitored throughout the procedure and postoperatively for 24 hours.

Parameters Observed

Criteria for discharge

The following criterias are considered for patients to be discharged from the hospital.

- Able to walk steadily
- Able to void.
- Stable vital signs.
- Under sufficient pain control

The Analgesic efficacy (Quality of analgesia)

Assessed by 11- point numerical pain rating scale. Intra-operatively for pain at the surgical site, pain score was assessed using an 11-point numeric rating scale (NRS; 0: no pain; 10: worst pain imaginable).

Sensory parameter

Assessment of extension of the sensory block after the patients was positioned directly before and immediately after surgery. Pricks with a pin pick was set in the perianal dermatomes moving outwards until the prick felt spiky. The last anaesthetized dermatome was documented. If the sensory block had covered at least the coccygeal and the S5 dermatome (outer margin of S5 at 3 cm lateral to the mucocutaneous junction of anal opening), patients are eligible for surgery

Motor parameter

In the operating room, before the patient brought into lithotomy position and after returned to supine position post-operatively, the motor block was assessed using the modified Bromage scale.

Modified Bromage scale

Grade 0 Patient is able to move the hip, knee and ankle and able to lift his leg against gravity

Grade 1 Patient is unable to move his leg against gravity but is able to flex his knee and ankle

Grade 2 Patient is unable to flex the hip and knee but is able to flex ankle

Grade 3 Patient is unable to flex his hip, knee and ankle but is able to move his toes

Grade 4 Complete paralysis

Onset of motor block, time to achieve maximum motor block (time interval from intrathecal injection to achievement of maximum motor block), duration of motor block (time interval from onset of motor block to regression of motor block to modified BROMAGE Grade 0) was recorded.

Rescue analgesia

Post operatively patients was examined at regular intervals to note the duration of effective analgesia (it is the time from onset of sensory block to when VAS score of ≥ 4). Rescue analgesia Inj Diclofenac sodium 1.5 mg/kg IV was given, when VAS score $\geq 4/10$.

Patient's and Surgeon's Satisfaction score [Time Frame: 24 hours after surgery]

Patient's and Surgeon's satisfaction, was evaluated with a 4-point score.

0 = Poor, 1= Good ,2 = Very Good,3 = Excellent

Side effects

Incidence of nausea, vomiting and pruritus was noted and treated with appropriate medication.

Statistical Tests

Chi square test was used to analyse the categorical (qualitative) data and one way ANOVA t for pair wise comparison was used for analysing the continuous data among three groups. P value less < 0.05 was considered significant.

Results and Observations

The mean age in Group C, Group A and Group B was 48.6 years, 46.6 years and 44.6 years respectively. We had 20 (44.44%) males and 25 (55.56%) females. 15 cases that underwent

lateral sphincterotomy 6 cases who underwent fistulectomy and 24 cases who underwent hemorrhoidectomy. In our study in the group B the time was the shortest followed by group A and group C had the maximum time for the onset of the sensation in the saddle area. Insensitivity for pain. There was no significant difference in the maximum Bromage score for the motor block it was 11.57 seconds in Group and Group B and 11. 11.6 in group C.

Even though the difference was not significant the onset was faster in group c as compared to group A and group B. The maximum Bromage scale achieved was significantly more in the group C than the Group A and Group B. NRS score that denotes the quality of analgesia was higher in group A indicating that the satisfaction was lesser. In the group A the time was the longest followed by group B and group C had the least two segment sensory regression time and was statistically significant with a p value < 0.05 . In our study in the group A the time for motor regression to baseline was the highest followed by group C and group B had the least time for the motor regression to baseline and was statistically significant with a p value < 0.05 . group A required the highest number of analgesia doses followed by group B and group C required equal number of analgesia and was statistically significant with a p value < 0.05 . group A had the least patient < 39 ; satisfaction scores followed by group B and group C had the maximum time and was statistically significant with a p value < 0.05 .

Discussion

Sentiment, awareness and previous experience every single thing can have an influence on the person's reaction to noxious stimulus. The person's anxiousness with respect to the pain that one has to bear in the immediate postoperative period changes the attitude towards surgery, also if the pain relief is done adequately in the form of early intervention to control pain, it can go a long way to affect the long-term outcome in the patients undergoing surgery⁽²⁾.

The pain related to surgery in the immediate postoperative period is a result of various mechanisms that act in conjunction multiplicity, hence to control them a multimodality management involving with an amalgamation of opioid and non-opioid analgesic medications is often used to improve the analgesic efficiency and to decrease the need for opioid and their associated side effects⁽³⁾.

In our study in the group B the time was the shortest followed by group A and group C had the maximum time for the onset of the sensation in the saddle area insensitivity for pain. Sugandarajappa et al noted that there were statistically significant differences in time for onset of sensory block.

There was no significant difference in the maximum Bromage score for the motor block it was 11.57 seconds in Group A and Group B and 11. 11.6 in group C. Even though the difference was not significant the onset was faster in group c as compared to group A and group B. The maximum Bromage scale achieved was significantly more in the group C than the Group A and Group B. Sugandarajappa et al.^[7] noted that there were statistically significant differences in time for onset of motor block.

NRS score that denotes the quality of analgesia was higher in group A indicating that the satisfaction was lesser. In our study in the group A the time was the longest followed by group B and group C had the least two segment sensory regression time and was statistically significant with a p value < 0.05 . Sugandarajappa et al noted that there were statistically significant differences in

time for duration of analgesia.

Dan J. Kopacz *et al.* (2005)^[8] observed that the degree of motor blockade generally increased with increasing dosage from 10 to 60 mg.

We also noted that the degree of the motor block was highest with 50 mg dose, with p value <0.001 which is statistically significant.

The onset of sensory and motor block was faster in the group that received plain 2-Chlorprocaine followed by the those who received fentanyl.

The regression of sensory and motor block was slowest in the group that received 50 mg 2-Chlorprocaine followed by the 40 mg 2-Chlorprocaine group and 30 mg 2-Chlorprocaine group.

Sell *et al* (2008)^[1] noted that the time to complete the sensory block regression was faster than in the 50 mg group (136 min, P 0.005).

Sugandarajappa *et al* noted that there were statistically significant differences in time for two segment regression which were shorter in chlorprocaine 20 mg (group A) compared to chlorprocaine 30 mg (group B).

In our study the time to complete the motor block regression was longer in the group that received 50 mg 2-Chlorprocaine followed by the 40 mg 2-Chlorprocaine group and 30 mg 2-Chlorprocaine group with p value <0.001 which is statistically significant.

Sell *et al* (2008)^[1] noted that the time to complete the motor block regression had variations in time found for the motor block (P 5 0.3)

Casati *et al.* (2006)^[3] in their study noted Spinal block resolution and ambulatory recovery were faster in the Chlor-30 group (60 [41–98] min and 85 [45–123] min) than in the Chlor-40 group (85 [46–141] min and 180 [72–281] min) and the Chlor-50 group (97 [60–169] min and 185 [90–355] min) (P 0.001 and P 0.003, respectively).

Sell *et al.* (2008)^[1] noted that there were no complications associated with spinal anaesthesia and no transient neurological symptoms (TNS) were identified during the 3-day follow-up.

Casati *et al* (2006)^[3] in their study noted that at 24-hour and 7-day follow-up, no transient neurological symptoms were reported. We conclude that while 40 and 50 mg of 2-chloroprocaine provide adequate spinal anaesthesia for outpatient procedures lasting 45–60 min, 30 mg produces an inadequate period of the spinal block. There were no major complications in any group and no one required supplemental anaesthesia or analgesia during the procedure in the study.

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