

# A Comparative Study on the Effect of Addition of Intrathecal Dexmedetomidine to 1% 2 - Chloroprocaine in Spinal Anaesthesia in short Duration Surgeries - A Randomised Control Trial

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**Abstract:** *This study aims to compare the addition of intrathecal dexmedetomidine to 1% 2-chloroprocaine spinal anesthesia for short duration surgeries. A randomized controlled trial was conducted on 60 patients, with 30 in each group. The group receiving dexmedetomidine showed faster onset of sensory and motor block, prolonged duration of effective analgesia, and no significant hemodynamic changes compared to the control group. These findings suggest that dexmedetomidine can be a valuable adjuvant in short duration surgeries.*

**Keywords:** intrathecal dexmedetomidine, 2-chloroprocaine, spinal anesthesia, short duration surgeries, randomized controlled trial

## 1. Introduction

Due to its well-known benefits, including preservation of consciousness, simplicity and ease of use, adequate surgical anaesthesia, minimal interference with blood biochemistry, minimal blood loss, avoidance of general anaesthesia complications, and cost effectiveness, spinal anaesthesia is one of the most widely used anaesthesia techniques for lower abdominal and lower limb surgeries. (1)

Spinal anaesthesia has become increasingly popular for inpatient surgery, but, until recently, its use has been limited in short duration surgeries requiring discharge shortly after operation also known as ambulatory surgeries. 'Ambulatory surgery' in the USA can relate to admissions lasting up to 23 hours, however in the UK it only refers to patients being released from the hospital soon after surgery. (2) A good intrathecal agent for ambulatory surgery should have a quick start of motor and sensory blocking, predictable regression over a reasonable amount of time, and a low incidence of side effects. Prior to the discovery of a high incidence of transient neurologic symptoms (TNS), lidocaine—which previously offered a thick block with quick recovery—was the favoured drug in this situation. However, its usage has now been effectively discontinued. (3) Prior to recently, the only local anaesthetic preparations approved for intrathecal usage in the USA and UK were hyperbaric bupivacaine alone and plain levobupivacaine. Due to their prolonged durations of action, both medications have limited usefulness in the ambulatory situation.

In the UK, plain 2-chloroprocaine 1% was approved for spinal anaesthesia in 2013, following the licencing of

hyperbaric prilocaine 2% in 2010. (4) In 2017, the US Food and Drug Administration (FDA) authorised the use of 1% pure 2-chloroprocaine. The options accessible to the patient and anaesthesiologist for performing spinal anaesthesia for ambulatory procedures have increased thanks to these short-acting medicines, which meet the essential requirements of an excellent intrathecal agent for short-duration or mobile surgery. Since 1952, spinal anaesthesia has been effectively achieved with chloroprocaine, a local anaesthetic with an extremely brief half-life. (5) It was widely used for many years until it was discontinued due to several instances of neurotoxicity following the use of high doses of 2-chloroprocaine for epidural anaesthesia. (6) (7) It was discovered that the neurotoxicity may have been caused by the interaction between low pH and the presence of sodium bisulfite, an antioxidant. (8) (9) A preservative-free formulation was then reintroduced and the pH of the fluid was adjusted. This formulation is now safely used for spinal anaesthesia in healthy volunteers and patients with no issues. (10) Uptil now, 1% 2-chloroprocaine is available in 30, 40, 50 mg, in which, according to one study 30 mg of intrathecal chloroprocaine does not provide adequate sensory and motor blockade. (11) (12) So, in this study 40 mg of chloroprocaine for subarachnoid block was chosen based on results on one study.

Short-duration procedures benefit greatly from the 40-minute action time of 1% 2-chloroprocaine. Adjuvants were, however, added to the postoperative analgesia to lengthen its duration because early postoperative discomfort was frequently seen. (13) Fentanyl and Buprenorphine are commonly used as adjuvants; however, very little literature is available on using Dexmedetomidine as adjuvant with 2-

Volume 12 Issue 6, June 2023

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chloroprocaine. Intrathecal Dexmedetomidine provides better hemodynamic profile and fewer side effects. Different dosages of intrathecal dexmedetomidine like 3mcg, 5mcg, 10mcg, 15mcg and 20mcg have been studied, out of which 10mcg dose was taken in this study as dose dependent fall in blood pressure and bradycardia is noted in above this dose of Dexmedetomidine. (14) (15)

So, this study aims to compare and evaluate addition of 10 mcg intrathecal dexmedetomidine to 40 mg 1% 2 - chloroprocaine in spinal anaesthesia for short duration surgeries.

## 2. Materials and Methods

In accordance with the study (16), the criterion for sample size with a confidence interval of 95% and a power of 80% was selected as the initial postoperative analgesic requirement. The necessary sample size ended up being 30 people in each group.

Following approval by the institutional ethics committee, a total of 60 patients of either sex between the ages of 18 and 60 who were admitted for elective surgeries under spinal anaesthesia at our Sir Sayajirao Gaekwad teaching hospital were recruited for the prospective randomised control trial between the months of March and October 2021. The Clinical Trial Registry of India (CTRI) received this study's registration (CTRI/2021/04/042870). Patients meeting the inclusion criteria underwent a full pre - anaesthesia examination, and their informed written agreement was obtained.

The study included both sexes of elective patients with physical status categorization grades I and II from the American Society of Anesthesiologists who were scheduled for spinal anaesthesia procedures lasting less than 60 minutes. The study excluded individuals who refused to participate, had absolute or relative contraindications to spinal anaesthesia, were obese (BMI > 30 kg/m<sup>2</sup>), or were pregnant. By using a computer - generated random number table, the study participants were randomly divided into two groups.

The patient was denied food and liquids starting at 10 p. m. the day before surgery. A satisfactory venous access was established the morning before the procedure using an 18G cannula, and preloading was carried out using 10 ml/kg of Ringer's lactate solution. Ondansetron IV injections of 4 mg and glycopyrolate IV injections of 5 mcg/kg were administered to the patients five minutes prior to the onset of spinal anaesthesia. There was no premedication with a sedative. Pulse oximetry, an electrocardiogram, and noninvasive blood pressure monitoring were started as soon as the patient entered the surgery room. Systolic, diastolic, and mean arterial blood pressure were measured at rest. A 0.9% normal saline infusion was started after an 18 gauge intravenous line was set up.

The Group C (n=30) Patients received Inj.2 - Chloroprocaine (1%) intrathecally, 40mg=4ml and Group CD (n=30) received Inj.2 - Chloroprocaine (1%) 40mg (4

ml) + inj. Dexmedetomidine 10 mcg intrathecally (8 drops of Dexmedetomidine with insulin syringe).

Using the test medication that was randomly given to that patient, the attending anesthesiologist administered spinal anaesthesia. A 23 gauge spinal needle was used to perform a lumbar puncture in the L3 - 4 or L4 - 5 interspaces while using aseptic precautions, in the lateral position, and after infiltrating 1 ml of 1% lidocaine. After the CSF began to flow freely, Inj 2 chloroprocaine 1% 40 mg (4 ml) or Inj 2 chloroprocaine 1% 40 mg (4 ml) and 10 mcg of dexmedetomidine were administered. The patients were immediately laid supine following spinal injection. The on - site anesthesiologist assessed the sensory and motor blockades every three minutes for 15 minutes, then every 15 minutes until both sensory and motor block completely disappeared. The patient's heart rate, oxygen saturation, and blood pressure (systolic, diastolic, and mean) were all monitored throughout the procedure.

Onset of the sensory block at L1, peak block height, time to reach peak block height, readiness for surgery (sensory block  $\geq$  T10), time for regression of two segments, regression to L1, and time for complete regression to S2 were all noted as characteristics of the sensory block. The modified Bromage scale was used to evaluate the motor block. It was noted how long it took for a motor block to progress to a modified Bromage score of 3, what it took to attain that score at the conclusion of surgery, and how long it took to reach a modified Bromage score of 0. Additional information was gathered, including the length of the procedure, how long the patient stayed in the post - anaesthesia care unit, when the first postoperative analgesic was needed, and any intraoperative or post - operative problems.

In this study, descriptive and inferential statistical analyses were conducted. Quantitative variables were expressed in form of rate and proportions. Intergroup data were analysed by unpaired t - test and the level of significance was determine 95 % confidence interval. Microsoft Word and Excel were used for data entry and Medcalc software was used for data analysis.

## 3. Results

Total 60 patients were enrolled in this study in which patients were randomly assigned into two groups of 30. Group C (n=30) were patients receiving Inj.1% 2 - Chloroprocaine (40 mg) intrathecally and group CD (n=30) were patients receiving Inj.1% 2 - Chloroprocaine (40 mg) + 10 mcg of dexmedetomidine intrathecally. The groups were similar in terms of age and sex with mean age of patients in Group C was 41.3 $\pm$ 10.33 years and 41.43 $\pm$  8.15 years in Group CD. There were 8 ASA class I and 22 ASA class II patients in Group C as compared to 11 ASA class I and 19 ASA class II patients in Group CD. Mean duration of surgery in Group C was 50.83 $\pm$ 16.35 minutes and 56.33 $\pm$ 14.61minutes in Group CD.

The mean pre - operative hemodynamic parameters like pulse rate, systolic and diastolic blood pressure and SpO<sub>2</sub>

were similar among two groups with no significant difference as shown in table 1.

The sensory block characteristics like onset of block, time to reach peak block, time to two segmental dermatomal regression and time to regress sensory block up to L1 dermatome from highest level of block were observed among groups as shown in table 2. Significant difference is observed among all the parameters which suggest that patients receiving chloroprocaine with dexmedetomidine (group CD) were having lesser time of onset of anaesthesia, faster achieving peak level and prolonged regression time compared to patients receiving chloroprocaine (group C).

For motor block, time of onset of motor block, time for maximum Bromage score and duration of motor block parameter were taken, as shown in table 2. Significant difference was observed among all parameter among both the groups. the onset motor block and time to reach maximum Bromage score was faster and for longer duration in Group CD compared to group C.

Table 3 shows mean pulse rate, systolic and diastolic blood pressures were compared among both the groups pre - operatively and post - block. Intergroup and intragroup comparison among groups did not show any significant difference suggesting no changes in pulse rate and blood pressure among these groups pre - operatively.

Table 4 shows post - operative changes in mean pulse rate, systolic and diastolic blood pressures among both groups. Intergroup and intragroup comparison among groups did not show any significant difference suggesting no changes in pulse rate and blood pressure among these groups post - operatively.

Parameters mentioned in table 5 like mean duration of analgesia, surgery and first rescue analgesia requirement among two groups were observed. It was found that Group CD provided longer post - operative effective analgesia of  $478 \pm 12.14$  minutes compared to Group C of  $105 \pm 9.37$ . In addition to this, it was indicated that the need of first post - operative effective analgesia is quite longer in Group CD ( $478 \pm 12.14$  minutes) than Group C ( $105 \pm 9.37$  minutes). However, no statistically significant difference was noted in duration of surgery. There was no need for supplementation of GA in any case. The patients were followed till discharge for neurological complications.

The intra operative and post operative complications in both the Groups. Intraoperatively, bradycardia was observed in 1 patient (3.3%) in Group C and in 2 (6.6%) patients in Group CD but pulse was within physiological limits, so no treatment was required. In Group C, 1 (3.3%) patient and in Group CD, 2 (6.6%) patients developed hypotension. Hypotension was easily treated with IV fluids, oxygen and Inj. Ephedrine 5 mg IV. Nausea and vomiting were seen in 2 (6.6%) patients of Group C and 2 (6.6%) patients of Group CD. It was treated with Inj. Ondansetron 0.15mg/kg iv. No other complications like shivering, respiratory depression, urinary retention or transient neurological deficits were noted in both the groups. Post operative period was uneventful in all cases in both the groups.

#### 4. Discussion

Due to its simplicity, quick onset of anaesthesia, total muscular relaxation, and cost - effectiveness, spinal anaesthesia is the most popular regional anaesthetic treatment. In the current investigation, the duration of spinal anaesthesia and the actual duration of postoperative analgesia were both prolonged by the addition of dexmedetomidine to two chloroprocaine. Both groups shared similar sensory and motor aspects of spinal anaesthesia.

For short - term spinal anaesthesia, numerous intermediate and long - acting local anaesthetics, such as lignocaine, mepivacaine, prilocaine, and bupivacaine, have been employed at lower dosages. However, various side effects, such as the potential for urine retention, slowed ambulation, and pain during block retreat, might restrict their use. (17) According to a study, intrathecal prilocaine and 2 - chloroprocaine are more effective and predictable anaesthetics than low - dose and unilateral bupivacaine spinal anaesthesia, giving anesthesiologists greater options. (18)

When compared to clonidine, dexmedetomidine exhibits more selectivity for the 2 receptor (2/1 1600: 1) than the latter. (19) Numerous studies have demonstrated that 2 receptor agonists, when given intrathecally, will increase the analgesia brought on by low - doses of local anaesthetics like bupivacaine due to synergistic effects with few haemodynamic side effects. (20) In one such trial, it was discovered that the combination of low dose bupivacaine, dexmedetomidine, and fentanyl gave sufficient anaesthesia for all lower abdominal procedures with hemodynamic stability. Dexmedetomidine, however, has a therapeutic advantage over fentanyl in that it promotes the propagation of the block and provides sustained post - operative analgesia. (21)

In our study, the mean time for onset of sensory block at L1 level  $2.09 \pm 0.02$  minutes in Group C and  $1.39 \pm 0.015$  minutes in Group CD and the difference was statistically highly significant. Thus, it appears that the onset of sensory level is faster in group CD. The mean time for onset of sensory block at L1 level in other studies with plain chloroprocaine were  $2.22 \pm 1.05$  minutes (22),  $3.11 \pm 1.53$  minutes (23) and  $2.5 \pm 0.9$  minutes (24) respectively. While mean time for onset of sensory block at L1 in chloroprocaine and dexmedetomidine group in some studies were  $2.01 \pm 0.63$  minutes (15) and  $4.7 \pm 1.2$  minutes (25) respectively.

A study in 2020 found two segment sensory regression time was  $50.9 \pm 10.1$  min. in plain 1% 2 - Chloroprocaine group. (26) In addition to this, a study of 2004 found two segment sensory regression time was  $45 \pm 16$  minutes in 1% 2 - Chloroprocaine group. (27) In our study the mean time for two segmental dermatomal regression was  $55.2 \pm 14.18$  minutes in Group C and  $85.86 \pm 16.33$  minutes in Group CD which was significant among two groups.

The mean time to regress sensory block up to L1 dermatome from highest level of block was  $68.5 \pm 13.00$  minutes in

Group C and 106.16±11.64 minutes in Group CD in our study. In support to this a study in 2014 noted that time to regress sensory block up to L1 dermatome was 82 minutes in plain 2 - chloroprocaine group. (28) All these findings suggest that Dexmedetomidine prolongs sensory block when used intrathecally with local anesthetic.

A study in 2020, observed that onset of motor block in 1% 2 - Chloroprocaine was 3.0±0.6 min. which was 2.14±0.019 min. in our control group. (26) In addition, study of 2016, had observed that onset of motor block with hyperbaric bupivacaine + 10 mcg of Dexmedetomidine was 2.33±0.57. (15) While the mean onset of motor block in Group C was 2.14±0.019 minutes and was 1.51±0.02 minutes in Group CD in our study. Similarly, time to attain maximum Bromage grade was 3.42±0.032 minutes in Group C and it was 2.46±0.026 minutes in Group CD. In study of 2019, time to reach maximum bromage score of 3 was 4.69+/- 2.07. in group received 40 mg of chloroprocaine. (23) In one study of 2018 observed that Dexmedetomidine 5mcg when added to hyperbaric bupivacaine, maximum bromage score had achieved in 4.80±1.74 min. compare to plain bupivacaine which was 5.55±1.67 min. (29) Further, the mean duration of motor block was 70.16±17.29 minutes in Group C and 86.43±15.81 minutes in Group CD. A study of 2017 observed that 5 mcg Dexmedetomidine when added to hyperbaric bupivacaine the duration of motor block is 234±61.71 min. compare to 177±56.9 min in plain bupivacaine group. (30) In a study of 2017 was observed that Dexmedetomidine 5 mcg added to hyperbaric bupivacaine will prolong the motor blockage of 239±22.7. min. compare to 203±10.9 in plain bupivacaine group. (31)

Spinal anaesthesia produces sensory, motor and sympathetic blockade. Sympathetic blockade may produce hypotension and change in pulse rate. There may be bradycardia or tachycardia and hypotension during surgery. (32) However, results of our study show for Intragroup and intergroup comparison showed that there were no significant change in pulse rate, Systolic blood pressure and diastolic blood pressure intra - operatively and postoperatively at various intervals. Most of the other studies did not find any

significant change in mean pulse rate, mean systolic blood pressure and mean diastolic pressure intra and post operatively with 1% 2 - Chloroprocaine 40mg plain or given with other adjuvants intrathecally. (23) (12) (30)

The duration of effective analgesia was 105±9.37 minutes for Group C and 478±12.14 minutes in Group CD which indicated longer postoperative effective analgesia in CD Group as compared to C Group. Further the time for first rescue analgesia in Group C was 105±9.37 min. which was comparable with a study which noted that time of first rescue analgesia needed postoperatively was 90.48±17.97min. in plain 2 - Chloroprocaine group. (26) A similar study observed same thing and time for first rescue analgesia in their 2 - chloroprocaine group was 100.45±20.41 min. (33) In contrast, time for first rescue analgesia in Group CD was 478±12.14 minutes. To support this a study of 2017 noted that first rescue analgesia needed postoperatively at 370±20.20 minutes. (31)

In this study, hardly any intraoperative complications like bradycardia, hypotension and nausea and vomiting were found among both the study groups. in addition to it, there was not a single case of complication in both the groups postoperatively which suggest the safety profile of both dexmedetomidine and chloroprocaine. Such findings are also found in few studies. (23) (15)

## 5. Conclusion

This study demonstrates that adding 10 mcg intrathecal dexmedetomidine to 40 mg 1 2chloroprocaine in spinal anesthesia for shortduration surgeries leads to faster onset of sensory and motor blocks, prolonged duration of effective postoperative analgesia, and no significant changes in heart rate or blood pressure. These findings suggest that dexmedetomidine can be a valuable adjuvant in enhancing the quality and duration of spinal anesthesia for short duration surgeries, improving patient outcomes and satisfaction.

**Table 1:** Mean Pre – Operative hemodynamic parameters

Parameters	Group C	Group CD	P VALUE
Pulse rate/minute (Mean±SD)	94.43±8.70	93.96±7.86	>0.05
Systolic BP (mm hg) (Mean±SD)	118.66±13.82	120±11.74	>0.05
Diastolic BP (mm hg) (Mean±SD)	79.66±7.18	78.33±6.98	>0.05
Spo2% (Mean±SD)	98.06±1.08	98.33±0.60	>0.05

**Table 2:** Assessment of Sensory and Motor Block

S. No.	Parameter	Group C Mean±SD	Group CD Mean±SD	p Value
1	Time to onset of anesthesia at L1 (min)	2.09±0.02	1.39±0.015	<0.0001
2	Time to achieve peak sensory level (min)	3.42±0.026	3.22±0.029	<0.0001
3	Time to two segmental dermatomal regression (min)	55.23±14.18	85.86±16.33	<0.0001
4	Time to regress sensory block up to L1 dermatome from highest level of block	68.5±13.00	106.16±11.64	<0.001
<b>ASSESSMENT OF MOTOR BLOCK</b>				
1	Time for onset of motor block (min)	2.14±0.019	1.51±0.02	<0.0001
2	Time for maximum Bromage score (min):	3.42±0.032	2.46±0.026	<0.0001
3	Duration of motor block (min)	70.16±17.29	86.43±15.81	<0.0001

**Table 3: Pre - Operative and Operative Changes in Mean Pulse Rate, Systolic and Diastolic BP**

Time	Group C		Group CD		Inter Group Comparison
	Pulse/Minute (Mean +SD)	Intra Group p Value	Pulse/ Minute (Mean +SD)	Intra Group p Value	
Pre -Operative	94.43±8.70		93.96±7.86		>0.05
Post Block					
1 MIN	89.36±10.70	>0.05	90.86±11.19	>0.05	>0.05
5 MIN	93.96±9.76	>0.05	92.66±8.43	>0.05	>0.05
15 MIN	91.36±9.76	>0.05	90.03±8.84	>0.05	>0.05
30 MIN	87.9±10.91	>0.05	85.96±11.36	>0.05	>0.05
60 MIN	95.6±8.01	>0.05	95.1±8.09	>0.05	>0.05
90 MIN	92.4±7.86	>0.05	91.36±7.57	>0.05	>0.05
	<b>Systolic BP (mm Hg) Mean +SD</b>	<b>Intra Group p Value</b>	<b>Systolic BP (mm Hg) Mean +SD</b>	<b>Intra Group p value</b>	
PRE - OP	118.66±13.82	>0.05	120±11.74	>0.05	>0.05
Post Block					
1 MIN	119. ±13.73	>0.05	119.33±13.87	>0.05	>0.05
5 MIN	120±10.41	>0.05	120.36±10.72	>0.05	>0.05
15 MIN	121.8±9.17	>0.05	120.3±10.13	>0.05	>0.05
30 MIN	118.76±13.56	>0.05	121.43±12.48	>0.05	>0.05
60 MIN	123.66±10.66	>0.05	123±10.22	>0.05	>0.05
90 MIN	119.93±11.14	>0.05	120.2±9.83	>0.05	>0.05
	<b>Diastolic BP (mm Hg) Mean +SD</b>	<b>Intra Group p Value</b>	<b>Diastolic BP (mm Hg) Mean +SD</b>	<b>Intra Group p Value</b>	
Pre - Operative	79.66±7.18	>0.05	78.33±6.98	>0.05	>0.05
Post Block					
1 MIN	80±8.30	>0.05	79.33±8.27	>0.05	>0.05
5 MIN	83±7.61	>0.05	82.16±8.47	>0.05	>0.05
15 MIN	81.33±7.42	>0.05	82±7.26	>0.05	>0.05
30 MIN	79.66±8.08	>0.05	79.33±7.84	>0.05	>0.05
60 MIN	81.33±7.30	>0.05	81±7.11	>0.05	>0.05
90MIN	82.36±8.06	>0.05	81.93±8.17	>0.05	>0.05

**Table 4: Post - Operative Changes in Mean Pulse Rate, Systolic and Diastolic BP**

Time	Group C		Group CD		Inter Group Comparison
	Pulse/Minute (Mean +SD)	Intra Group p Value	Pulse/ Minute (Mean +SD)	Intra Group p Value	
Immediate post op.	87.9±10.91	>0.05	89.06±11.42	>0.05	>0.05
1 HOUR	93.2±7.63	>0.05	93.63±8.28	>0.05	>0.05
2 HOUR	87.93±16.86	>0.05	88.6±16.95	>0.05	>0.05
3 HOUR	95.4±7.46	>0.05	95.3±6.82	>0.05	>0.05
4 HOUR	87.76±16.83	>0.05	88.03±16.88	>0.05	>0.05
	<b>Systolic BP (mm Hg) Mean +SD</b>	<b>Intra Group p Value</b>	<b>Systolic BP (mm Hg) Mean +SD</b>	<b>Intra Group p Value</b>	
Immediate post op.	118.76±13.56	>0.05	118.43±13.58	>0.05	>0.05
1 HOUR	120.53±10.90	>0.05	119.7±8.86	>0.05	>0.05
2 HOUR	124.6±9.41	>0.05	124.86±10.25	>0.05	>0.05
3 HOUR	123±10.55	>0.05	122.1±9.55	>0.05	>0.05
4 HOUR	124.26±9.39	>0.05	124.26±9.41	>0.05	>0.05
	<b>Diastolic BP (mm Hg) Mean +SD</b>	<b>Intra Group p Value</b>	<b>Diastolic BP (mm Hg) Mean +SD</b>	<b>Intra Group p Value</b>	
POST OPERATIVE					
IMMEDIATE	79.66±8.08	>0.05	79±8.03	>0.05	>0.05
1 HOUR	84.03±7.80	>0.05	82.93±8.29	>0.05	>0.05
2 HOUR	80.66±6.91	>0.05	80.33±7.18	>0.05	>0.05
3 HOUR	80.33±6.68	>0.05	80.66±6.91	>0.05	>0.05
4 HOUR	80.66±7.39	>0.05	81.33±7.30	>0.05	>0.05

**Table 5: Duration (in minutes) of Various Parameters**

Parameter	Group C Mean±SD	Group CD Mean±SD	p Value
Duration of Effective Analgesia (Minutes)	105±9.37	478±12.14	<0.0001
Duration of Surgery (Minutes)	50.83±16.35	56.33±14.61	>0.05
Duration of First Rescue Analgesia Requirement (Minutes)	105±9.37	478±12.14	<0.0001

**Financial support and sponsorship**

None

**Conflicts of Interest**

Nil

**CTRI nubmer: CTRI/2021/04/042870****References**

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