



Original Research Article

Spinal block characteristics of intrathecal 1% 2chloroprocaine following addition of dexmedetomidine versus fentanyl in lower abdominal surgery: A prospective randomised controlled double blinded study

Seema Partani¹, Abhineet Singh², Vikram Singh Rathore^{3,*}, Aanal Vyas¹,
Abhay Gondaliya¹, Sunanda Gupta¹

¹Dept. of Anaesthesiology, Geetanjali Medical College and Hospital, Udaipur, Rajasthan, India

²Dept. of Anaesthesiology, ESIC Hospital, Faridabad, Haryana, India

³Dept. of Anaesthesiology, Pacific Medical College & Hospital, Udaipur, Rajasthan, India



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ABSTRACT

Background & Aim: The use of spinal anaesthesia for day care lower abdominal surgeries is limited due to its characteristics like delayed ambulation, urinary retention etc. The ultrashort acting 1% 2chloroprocaine (2CP) shows the properties of ideal local anaesthetic for short duration surgeries. The aim of this study was to compare the efficacy of two different adjuvants (fentanyl or dexmedetomidine) with intrathecal 2CP for spinal block characteristics.

Materials and Methods: A prospective randomised double blinded study was conducted on 126 patients scheduled for short duration lower abdominal surgeries under spinal anaesthesia. They were randomised into 3 groups. Group C received 40µg of 1% 2CP while group F received 2CP + 25µg fentanyl; and group D received 2 CP + 10µgdexmedetomidine. Tactile and engine bar qualities, prerequisite of post usable absence of pain, haemodynamics and sedation score were evaluated.

Results: The segment information, length of medical procedure, beginning of tangible square, an ideal opportunity to arrive at top tactile level were practically identical in every one of the three groups (P>0.05). Span of tactile & engine block & postoperative absence of pain was essentially delayed in bunch D versus bunch F & gathering C (P<0.001).

Conclusion: Intrathecal addition of dexmedetomidine (10µg) & fentanyl (25µg) to 1%2CP brought about an essentially delayed tangible & engine bar with postoperative absence of pain. However, dexmedetomidine was viewed as a preferable adjuvant over fentanyl as far as drawn out length of absence of pain with insignificant secondary effects.

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1. Introduction

An ideal anaesthetic for spinal anaesthesia in ambulatory surgery should provide rapid onset, adequate potency, predictable duration, decreased neurotoxicity along with minimal systemic side effects.¹ 1% 2CP (preservative free) has been approved as spinal local anaesthetic owing

to its faster onset, low incidence of postoperative urinary retention along with better anaesthetic profile for day care surgeries.² Quality of block & prolongation of postoperative analgesia is achieved by different adjuvants to local anaesthetic. The effect of intrathecal fentanyl & dexmedetomidine added to different local anaesthetics for prolongation of subarachnoid block (SAB) is well-established by various studies.^{3,4}

* Corresponding author.

E-mail address: vikram2012.mmc@gmail.com (V. S. Rathore).

Very few studies are available in literature on comparison of intrathecal chloroprocaine with different adjuvants.^{1,5} This study aimed primarily to evaluate & compare the spinal block characteristics of intrathecal 2CP after addition of dexmedetomidine & fentanyl in lower abdominal surgery. The secondary objectives were to measure the hemodynamic parameters & adverse effects with these drug combinations.

2. Materials and Methods

Institutional Ethical Committee (ICE) approval along with written informed patient consent, this prospective randomised double-blind study was conducted at a tertiary care centre from January 2018 to July 2019. All patients of American Society of Anaesthesiologists Physical Status (ASA-PS) I-II between the age group of 18-60 years, posted for lower stomach a medical procedure under spinal sedation were incorporated in this study. Prohibition rules included patient refusal, serious comorbid conditions, any coagulopathy, and disease at nearby site or sensitivity to any of the review drugs.

According to Consolidated Standards of Reporting Trials (CONSORT) protocol, an aggregate of 126 patients were arbitrarily partitioned into 3 groups specifically C, D & F of 42 [C - contained 4ml of 1% 2-chloroprocaine (40mg) with 0.5ml normal saline], [D - contained 4ml of 1% 2-chloroprocaine (40mg) with 10µg dexmedetomidine (0.5ml)] & [F - 4 ml (40 mg) of 1% 2-chloroprocaine with fentanyl 25µg (0.5ml)] (42 in each group). Randomisation was performed utilizing PC produced irregular number table. Bunches doled out were fixed inside opaque envelopes to guarantee blinding. Anaesthesiologist who neither played out the SAB, nor recorded the information in the review arranged the review drugs as indicated by randomized gathering. Head anaesthesiologist (who regulated the review drug & recorded the boundaries), medical attendants, surgeon, research collaborator & the patient were additionally dazed to the gathering allotted.

The study drug prepared for group C (control) contained 4ml of 1% 2-chloroprocaine (40mg) with 0.5ml normal saline (NS). Group F: 4 ml (40 mg) of 1% 2-chloroprocaine with fentanyl 25µg (0.5ml) & group D contained 4ml of 1% 2-chloroprocaine (40mg) with 10µg dexmedetomidine (0.5ml in NS). Total volume was kept 4.5ml in all three groups.

A thorough pre-anaesthetic evaluation was done. Patients were educated about the methods of sensory & motor assessments, & visual analogue scale (VAS) from 0-10 (0-3 = no pain, 4-7 = discomfort, 8-10 = severe pain). An 18 gauge cannula was secured & 6-8 ml/kg crystalloid was started preoperatively.

On appearance in activity all standard screens were associated & benchmark boundaries like systolic circulatory

strain (SBP), diastolic pulse (DBP), heart rate (HR), MAP & SpO₂ were recorded. Anaesthesia & careful procedure was normalized. Subarachnoid block (SAB) was performed with aseptic insurances at L3-L4 intervertebral space utilizing 25-gauge Quincke needle in sitting situation with midline approach. Concentrate on drug was injected over a time of 30sec with cephalic direction of needle slant in the wake of guaranteeing the free progression of cerebrospinal liquid. All patients were made prostrate after the medication injection. Hemodynamic boundaries were recorded at 2min span for initial 10 min & afterward 5min stretch till 60 min, & at 15 min stretch from that point till 120 min. Tactile bar was assessed by pinprick technique in a caudal to cephalic course utilizing clean 25 measure gruff needle along the mid-clavicular line bilaterally at the time frame min for 10min, then, at that point, each 5 min till greatest tallness of sensory block was accomplished.

The time of intrathecal injection was noted as zero (0). The time to achieve T10 sensory level (onset of sensory block), time to two segment regression (time taken by sensory block to regress upto two dermatomes from the highest level of sensory block achieved), sensory regression to S2 dermatome (completion of sensory regression) were recorded.

Motor blockade was assessed according to Bromage scale (0=no paralysis, able to flex hips/knees/ankles, 1=able to move knees, unable to raise extended legs, 2=able to flex ankles, unable to flex knees, 3=unable to move any part of lower limb). Time of complete motor block was defined as time from intrathecal injection to Bromage scale 3. The total duration of motor block was defined as time from Bromage scale 3 to Bromage 0. This was assessed every 2 min for 10min till bromage 3 was achieved & then it was reassessed after the completion of surgery, every 5 min till bromage 0 was achieved. If the patient complained of pain during surgery aliquots of intravenous fentanyl 50µg (one or two doses) was administered (partial failure) & if pain persisted, general anaesthesia was given (complete failure). Patients with complete failure were excluded from the statistical analysis. (Figure 1)

Postoperatively pain assessment was done using VAS. Time to request for first analgesia or VAS ≥4 was recorded & injection diclofenac 75mg was given IV, if pain persisted even after 30 min, IV paracetamol 1gm was administered. Total number & total dose of analgesic required in 24hr were recorded.

Any incidence of hypotension, bradycardia & other adverse effects like nausea, vomiting, pruritus, shivering, sedation, respiratory depression along with any transient neurologic symptoms were recorded. Hypotension (SBP < 20% of baseline) was treated by intravenous bolus of 250 ml ringer lactate & mephentermine 6mg IV as required while bradycardia (HR < 50/minute) was treated with atropine 0.6mg. Patients with sedation scale

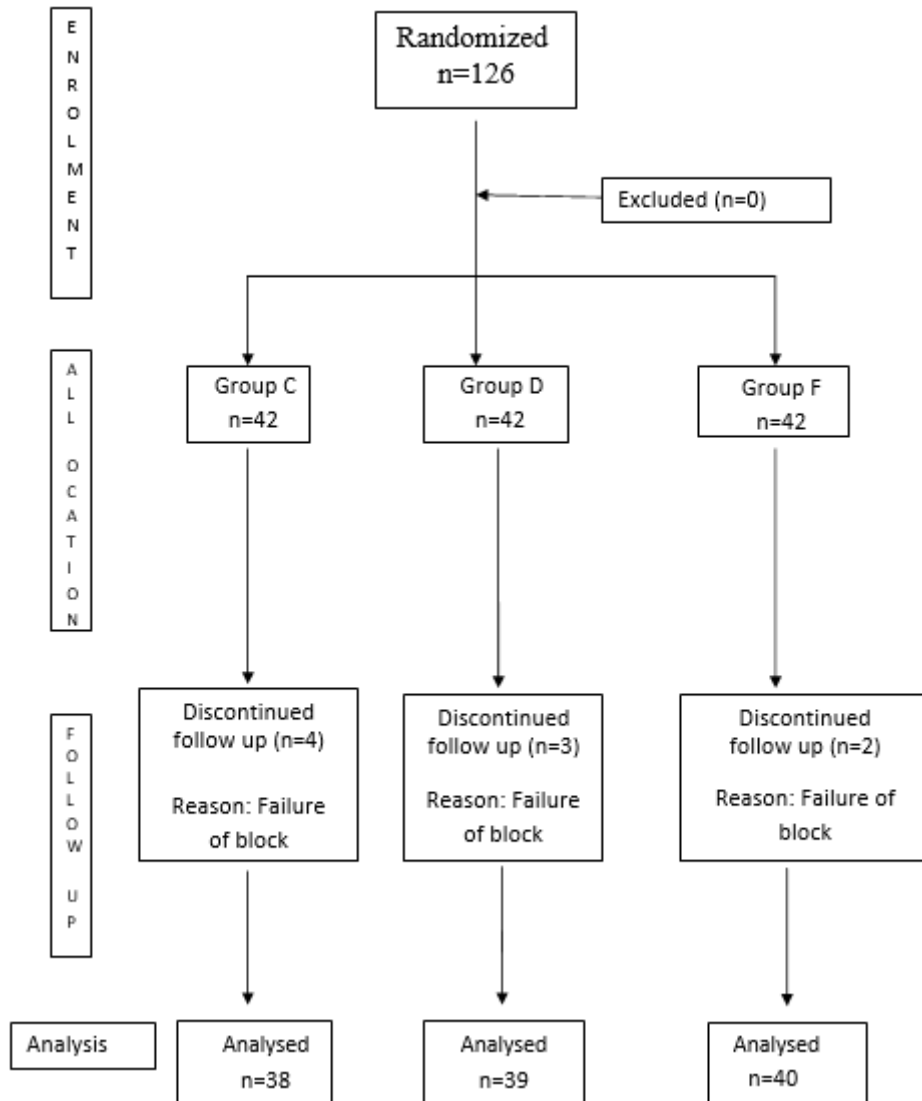


Fig. 1: Consort flow diagram showing patients allocation at different stages of the study

of ≥ 3 were considered as sedated. Rescue anti-emetic IV ondansetron 4mg was given for nausea & vomiting.

2.1. Statistical analysis

Statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 17, (SPSS, Chicago, IL). Data were presented as mean, standard deviation, median (range), or percentage, as appropriate. Quantitative data were analysed using paired, unpaired t-test & ANOVA while Chi-square test was used to find out the significance of qualitative data for categorical variables. P value less than 0.05 was considered significant. Sample size was determined by a power analysis with alphaerror 5% i.e. confidence level 95%, & beta error to be 20% i.e. power

of study to be 80%. Based on previous study⁴ with 10% clinically acceptable margin, to detect a 30 min difference in the mean duration of the first request for analgesic, the minimum sample size(n) needed was 39 patients in each group (total 117). We decided to include 126 patients [C - contained 4ml of 1% 2-chloroprocaine (40mg) with 0.5ml normal saline], [D - contained 4ml of 1% 2-chloroprocaine (40mg) with 10 μ g dexmedetomidine (0.5ml)] & [F - 4 ml (40 mg) of 1% 2-chloroprocaine with fentanyl 25 μ g (0.5ml)] (42 in each group) considering the possible dropouts.

3. Results

A randomized twofold visually impaired review was directed on 126 patients who underwent lower stomach a medical procedure under spinal sedation. Out of these 4 patients in bunch C, 3 patients in bunch F & 2 patients in bunch D were excluded from factual investigation on account of disappointment of spinal block in these patients. So absolute 117 patients were measurably broke down after withdrawal of 9 patients from this study. (Figure 1)

The patients in all three bunches were practically identical with respect to segment information & span of surgery. (Table 1) Onset of tactile square & time to arrive at top tangible level were similar among three groups ($p>0.05$). The mean relapse time to two fragment tangible level was essentially drawn out in group D (87.31 ± 18.24 min), than in bunch F (70.50 ± 9.73 min) & gathering C (58.29 ± 11.79 min) ($p<0.001$). The length of complete tangible square (relapse to S2 dermatome) was fundamentally drawn out in group D (136.03 ± 21.09 min) & group F (124.5 ± 17.86 min) as contrasted with group C (105.53 ± 20.89 min) ($p<0.001$). Time to reach bromage3 was earliest in group D (5.23 ± 1.69 min) when contrasted with group F (6.48 ± 2.20 min) & gathering C (7.71 ± 3.53 min) while time to finish engine relapse was deferred in bunch D (91.03 ± 23.15) versus group F (82.87 ± 11.76) & group C (73.68 ± 11.72), $p<0.001$.(Table 2)

The mean VAS score was lowest in dexmedetomidine group at all time frames as compared to other two groups. At 1h & 6h patients had significantly decreased VAS score in dexmedetomidine & fentanyl group vs the control group which was more significant in group D as compared to group F ($p<0.001$), (Figure 2). Time to first rescue analgesia required was significantly prolonged in group D (134.49 ± 17.27 min) than group F (116.00 ± 19.16 min) & group C (90.53 ± 17.53 min) ($p<0.001$). Requirement of total dose of rescue analgesia in 24 hours was lowest in group D (142.31 ± 53.85 mg) than group F (174.38 ± 35.58 mg) & group C (222.37 ± 38.02 mg) ($p<0.001$) (Table 3). Patients had a stable haemodynamic profile at all time measurements with no statistical difference between the three groups.(Figure 3)

4. Discussion

Subarachnoid block (SAB) is a favoured choice of sedation for lower abdominal medical procedure yet because of postponed ambulation, urinary maintenance & agony after regression of square might restrict its utilization in mobile surgeries.⁶ The current availability of short acting neighborhood anaesthetic(LA) without neurological shortfall has renewed interest in SAB for short surgeries. The 2-chloroprocaine (2-CP) is an aminoester neighborhood sedative with the most limited span of activity among all established local sedatives because of extremely low protein

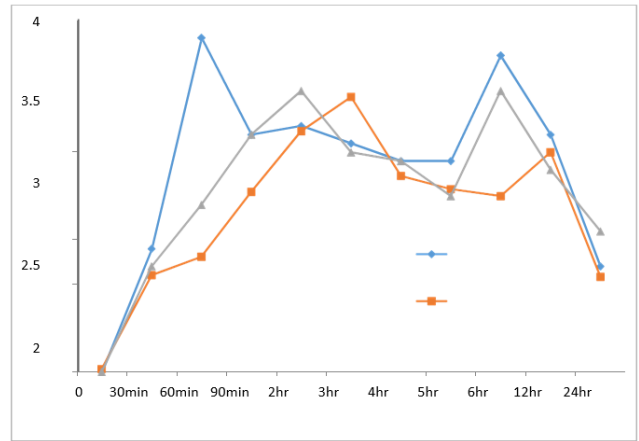


Fig. 2: Graphical representation of visual analogue score(VAS) with time, between three groups

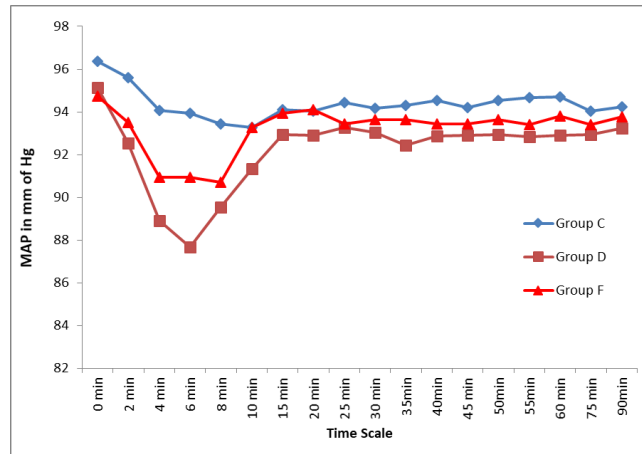


Fig. 3: Comparison of mean arterial pressure (MAP) at various time intervals in three groups

restricting & fast hydrolysis by pseudo cholinesterase. The additive sodium bisulfite & acidic arrangement were ascribed to issues of well-being & possible neurotoxicity with 2CP & prompted its expulsion from active clinical practice for in excess of 10 yrs.^{7,8} The new additive free more up to date planning of 1% 2CP has a great security profile. The beginning stage & complete goal of tactile square after intrathecal organization makes it an alluring choice for SAB in day care surgeries.^{9,10}

Different doses(30-60mg)of 2CP have been used for infraumbilical surgeries of short duration (<60min) under SAB concluding that 40-50mg of 2CP provides adequate SAB while 30 mg produces insufficient spinal block, hence we decided to use 40mg dose considering adequate spinal block.^{10,11} Various studies have observed increased duration of sensory block & enhanced postoperative analgesia with adjuvants like epinephrine, clonidine or fentanyl to 2CP.^{1,3,5} Fentanyl & dexmedetomidine are established

Table 1: Comparison of demographic data and duration of surgery in three groups

	Group C (n=38)	Group D (n=39)	Group F (n=40)	p value
	Mean ±SD	Mean ±SD	Mean ±SD	
Age (years)	50.09 ±8.60	46.24 ±10.95	47.48 ±10.83	0.245
Height (cm)	158.14 ±4.74	157.52 ±6.80	159.21 ±4.15	0.36
Weight (Kg)	71.88 ±7.70	73.55 ±10.57	70.05 ±6.50	0.18
BMI (Kg/m ²)	27.21 ±5.03	29.19 ±3.75	27.14 ±4.71	0.08
ASA PS (grade1/2)	36/7	32/10	33/9	0.99
Duration of Surgery (min)	51.60 ±6.62	53.21 ±14.13	55.83 ±12.97	0.28

Data expressed as mean (standard deviation ±) P >0.05 is non significant. ASA PS: American Society of Anaesthesiologists physical status. BMI: Body Mass Index

Table 2: Comparison of sensory and Motor block characteristics in three groups

Sensory Block Characteristics	Group C (n=38)	Group D (n=39)	Group F (n=40)	ANOVA P value
	Mean ±SD	Mean ±SD	Mean ±SD	
Time to reach T10 sensory level (min)	5.53 ±1.27	4.56 ±1.77	5.00 ±1.54	0.024
Peak sensory level (Thoracic dermatome) (Mean, Range)	T 8 (T6-T9)	T 6 (T6-T9)	T 7 (T6-T9)	0.02 *
Time to reach Peak sensory level (min)	20.18 ±10.52	17.26 ±7.85	18.43 ±9.13	0.38
Time for 2-sensory level regression (min)	58.29 ±11.70	87.31 ±18.24	70.50 ±9.73	<0.001 ***
Duration of sensory block (min)	105.53 ±20.89	136.03 ±21.09	124.5 ±17.86	<0.001 ***
Motor Block characteristics	Group C (n=38)	Group D (n=39)	Group F (n=40) Mean ±SD	ANOVA P value
	Mean ±SD	Mean ±SD		
Time to reach Bromage 3	7.71 ±3.53	5.23 ±1.69	6.48 ±2.20	<0.001 ***
Time to reach Bromage 0	73.68 ±11.72	91.03 ±23.15	82.87 ±11.76	<0.001 ***

Significant p<0.05, *** Highly significant p< 0.001, p> 0.05 is non significant

Table 3: Requirement of post operative rescue analgesic doses in three groups

Data of rescue analgesic	Group C (n=38)	Group D (n=39)	Group F (n=40)	P value
Time to 1st rescue analgesic (min)	90.53 ±17.43	134.49 17.27	116.00 ±19.16	<0.001 ***
Total no of rescue analgesic doses in 24 hrs(n)	3.0 ±0.4	1.9 ±0.72	2.3 ±0.47	<0.001 ***
Total dose of rescue analgesics in 24 hrs (mg)	222.37 ±38.02	142.31 ±53.85	174.38 ±35.58	<0.001 ***

adjuvants to LA for potentiation of spinal block. Intrathecal fentanyl follows up on narcotic receptors in the dorsal horn of spinal rope & accordingly decreases instinctive & physical pain.¹² α_2 receptor agonist when regulated intrathecally produces absence of pain by discouraging arrival of C-fiber transmitters & by hyperpolarisation of post synaptic dorsal horn neurons. The prolongation of tactile & engine square of LA may be a synergistic impact optional to various component of activity of LA & intrathecal adrenoreceptor agonist.^{12,13} There is a scarcity of writing with dexmedetomidine as an adjuvant to 2CP for SAB hence this present review was intended to contrast

dexmedetomidine & fentanyl as adjuvant with intrathecal 2CP for lower stomach a medical procedure.

We observed that onset of sensory block & time to achieve peak sensory block level were found to be comparable among the three groups (p>0.05), however the number of patients who achieved T6 block level were more (n= 26, 61.9%) in group D than group F (n=15, 45.23%) & C (n=11, 35.7%) though it was found to be statically insignificant (P>0.05). Besides patient characteristics, injection technique, dose & properties of drug, the extent of neural block is also determined by density of agents.^{14,15} Density of dexmedetomidine

(1.17 gm/cm³) & sodium chloride 0.9% (2.16 gm/cm³) is higher than fentanyl (1.1 gm/cm³).¹⁵ In present study normal saline was added to dexmedetomidine to get equal volume in three groups therefore the solution with dexmedetomidine was denser. Since a density difference as small as 0.0006 g/ml may influence the spread of LA in spinal canal, the differences in drug mixture density could be an explanation for the increased level of blockade in group D. Similar increase in block level in adjuvant groups was also observed in other studies.^{4,16}

Previous studies^{5,17} observed significant decrease in time to two segment regression of sensory block with plain 2CP than the adjuvant groups ($p < 0.001$), which is in accordance to present study where we observed a decrease in regression time in group C versus group D & group F ($p < 0.001$), where there is a delay by 20 min on average in group D than group F ($p < 0.001$). Gupta R et al¹⁸ & Thada B et al⁴ observed significantly prolonged two segment regression time in patients who received dexmedetomidine with an average difference of 40 min with fentanyl group, which could be attributed to the longer acting bupivacaine used in their study.

We found a significant delay in complete sensory block regression in group D versus group F & C ($p < 0.001$), & this delay with dexmedetomidine was also significant when compare to fentanyl ($p < 0.05$). Similarly another $\alpha 2$ agonist clonidine (15 μg) was found to prolong the sensory block regression when added intrathecally to 1% 2-CP (30 mg).⁵ Various other studies have reported a prolongation in time to complete sensory block regression with dexmedetomidine & fentanyl when added to bupivacaine which was more significant with dexmedetomidine.^{3,18–20}

A significant early onset & prolonged duration of motor block was noted in patients receiving dexmedetomidine as compare to fentanyl group in our study ($p < 0.001$). The improved quality of block with dexmedetomidine could be explained by the tendency of $\alpha 2$ receptor agonists to bind with motor neurons in the dorsal horn of the spinal cord.^{5,18}

Analgesic effects of $\alpha 2$ agonists are mediated by $\alpha 2$ receptor binding in central & spinal cord. Pain transmission is suppressed by hyperpolarization of interneurons & reduction of the release of proprioceptive transmitters such as substance P & glutamate.²¹ In the immediate postoperative period, we noted that there was a significant delay in time to request for first rescue analgesia & a significant decrease in total dose of analgesic requirement in 24 hour with dexmedetomidine as compare to fentanyl & plain 2CP ($p < 0.05$). This is further supported by various studies on these two adjuvants with intrathecal bupivacaine.^{3,13}

Dexmedetomidine also has an anxiolytic & sedative effect which occurs by stimulation of central pre & post synaptic $\alpha 2$ receptors located in locus ceruleus.²¹ We observed that the mean sedation score was significantly more in group D versus group F & group C, ($p < 0.05$).

However, this was in acceptable range (< 4) & patients remained easily arousable & co-operative which may be due to sparing of supraspinal central nervous system (CNS) for excessive drug exposure resulting in robust analgesia without heavy sedation. Intrathecally administered $\alpha 2$ agonists have a dose dependant sedative effect.²² The highly significant sedation score observed by Eid HEA et al.²³ can be attributed to higher dose of dexmedetomidine (15 μg) while Kanazi GE et al¹³ did not report sedation in any patient, where dexmedetomidine was used in low dose (3 μg).

Although episodes of hypotension & bradycardia were more in group D than group F & C but no significant difference in the hemodynamic parameters were observed among three groups ($p > 0.05$). The pre & postsynaptic activation of $\alpha 2$ adrenoreceptors in the CNS inhibits sympathetic activity & increased vagal activity causing decrease in the heart rate & blood pressure.²² Incidence of bradycardia was 10.25% in group D while 5.26% & 2.5% in group C & F respectively. Naaz S et al²⁴ also observed a decrease in heart rate with dexmedetomidine in a dose dependent manner. They reported decrease in HR in 10% patients receiving 10 μg of dexmedetomidine. In contrast Mahendru et al³ observed no significant hemodynamic changes in dexmedetomidine group probably because of the low dose (5 μg) of intrathecal dexmedetomidine used in their study.

Incidence of adverse effects like nausea, vomiting, shivering, pruritus, respiratory depression were negligible in our study which is similar to findings in other studies.^{17–19,25}

Our study had a few limitations. Small sample size in present study prevents drawing a conclusion about safety profile of this LA for spinal injection. Use of Electromyography & peripheral nerve stimulator, could have provided better assessment of motor & sensory blockade. We studied only Young & healthy patients of ASA grade I & II & in future studies, the effect on the elderly patients with comorbidities could be further investigated. Further clinical studies with larger sample size are required to determine the efficacy & safety of 1% 2 chloroprocaine with different doses of dexmedetomidine to confirm the findings of present study.

5. Conclusion

We concluded that preservative free 1% 2CP is a reliable & safe local anaesthetic agent for SAB in ambulatory day care surgery. Both adjuvants (dexmedetomidine & fentanyl) improved the quality of block (sensory & motor) along with postoperative analgesia, however dexmedetomidine was found to be superior to fentanyl.

6. Source of Funding

Nil.

7. Conflict of Interest

There is no conflict of interest.


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Author biography

Seema Partani, Professor

Abhineet Singh, SR Anaesthesiology

Vikram Singh Rathore, Associate Professor  <https://orcid.org/0000-0001-5374-1097>

Aanal Vyas, JR Anaesthesiology  <https://orcid.org/0000-0003-0863-5556>

Abhay Gondaliya, JR Anaesthesiology  <https://orcid.org/0000-0002-0637-3129>

Sunanda Gupta, Professor & HOD

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