



Original Research Article

A prospective randomised low dose finding study of preservative free 1% chloroprocaine in spinal anaesthesia for perineal surgeries

VJ Karthik¹, B Kanchanamala^{2,*}, S Kesavalakshmi³, Narasimman³

¹Kilpauk Medical College, Chennai, Tamil Nadu, India

²Government Medical College, Omandurar Government Estate, Chennai, Tamil Nadu, India

³Stanley Medical College, Chennai, Tamil Nadu, India



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ABSTRACT

Background: Ambulatory surgery has become popular in this era which has resulted in the advent of newer short acting anaesthetic drugs to suit early ambulation of post operative patients and discharge and early resumption of daily activities. This in turn reduces cost of care, increased availability of beds for sick patients, lower risk of resistant bacterial strain transmission and faster return to work and social activities.^{1,2} This study was aimed to find out the effective low dose of 1% chloroprocaine for lower limb ambulatory surgeries performed as day care procedures.

Materials and Methods: 93 consented patients were randomized to three groups of 31 each to receive 20 mg, 25 mg and 30mg of 1%chloroprocaineintrathecally. Sensory and motor block was assessed.

Statistical Analysis: The collected data was analysed using IBM.SPSS statistics23.0 Version.

Results: The demographic data in all three groups were comparable. The onset of motor blockade was profound in patients receiving 30 mg of chloroprocaine compared to 20 or 25 mg. The block persisted for longer duration with delayed voiding of urine, delay in unassisted ambulation inpatients receiving 30 mg of 1% chloroprocaine.

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1. Introduction

The development of minimally invasive surgical techniques and short acting anaesthetic drugs has markedly increased in the present day. Paul White claims that more aggressive rehabilitation leads to faster recovery of organ function, fewer surgical complications, reduced mental and physical disability.³ Regional anaesthesia has reduced pain scores and request for rescue analgesia in post anaesthesia care unit. Short acting local anaesthetics like lidocaine have been abandoned because of the transient neurological symptoms associated with it. An ideal anaesthetic agent should allow rapid onset and offset effect. Recent reintroduction of

intrathecal chloroprocaine, prilocaine offer a solution to this problem. Chloroprocaine is an amino ester local anaesthetic with a very short hal life. It has been successfully used for spinal anaesthesia since 1952. Sodium bisulfate was added as a preservative after 1956.⁴ In 1980's several neurological deficits were reported following withdrawal of drug. At present preservative free chloroprocaine is available which has a favourable profile in terms of safety and efficacy. This prospective randomized dose finding study at our institution for patients receiving spinal anaesthesia for perineal surgeries in three different doses with the aim to find out the minimum dose requirement of chloroprocaine.

* Corresponding author.

E-mail address: drkanchanamala@yahoo.com (B. Kanchanamala).

2. Aim

To find out the optimal dose of 1% preservative free chloroprocaine for perineal surgeries.

3. Objective

Primary objective assess the time required for onset of motor block by using Bromage scale and to assess the time required for onset of sensory block.

3.1. Secondary objective

To observe hemodynamic changes after administration of drug. To observe the time taken for the patient to be discharged.

3.2. Study design

Prospective randomized study.

3.3. Sample size

93 patients admitted for perineal surgery in a government tertiary care hospital.

3.4. Inclusion criteria

1. All consented patients
2. Age 18 to 60 years
3. ASA PS I – II
4. Both gender
5. Elective perineal surgeries

3.5. Exclusion criteria

1. Patient refusal
2. Patients with hemodynamic instability
3. Pregnancy
4. Emergency surgeries
5. Obesity BMI-30kg/m²
6. H/O coagulopathy
7. Infection at site
8. H/O Hypersensitivity disorders

4. Methodology

93 Patients in the age group of 18-60 years ASA PS I-II randomized by using randomized computer technique into 3 groups of 31 each.

Group C20-patients were given 20mg of 1% chloroprocaine intrathecally by using 25G Whitacre spinal needle in L3-L4 space.

Group C25-patients were given 25mg of 1% chloroprocaine intrathecally by using 25G Whitacre spinal needle in L3-L4 space.

Group C30-patients were given 30mg of 1% chloroprocaine intrathecally by using 25G Whitacre

spinal needle in L3-L4 space. Each ml contains 10mg,

Pre anesthetic assessment was done and informed consent obtained. In operating room monitors were attached. Baseline parameters recorded (HRNIBP, ECG, SPO₂) 18G IV cannula secured. After insertion of IV cannula an infusion of crystalloid solution started. 500 ml of crystalloid solution given before procedure.

With the patient in sitting position, lumbar area painted with antiseptic solution. L3-L4 space identified. Skin infiltrated with 2ml of 2% lignocaine, using 25G Whitacre needle subarachnoid space identified. Free flow of CSF indicated correct needle placement. After that the patient is placed in supine position & patient is evaluated first minute and every 3 minutes for motor blockade by using Bromage scale. Sensory block is assessed by using loss of pain prick sensation (20G hypodermic needle) Readiness of surgery is defined as loss of sensation at T12 level. Vitals are monitored. Motor & sensory block is assessed every 3 minutes for first 15 minute. Maximum level of sensory block is marked when same level of sensory block for 3 consecutive observations are noted. Further assessments were performed every 15 minutes for 1st hour and after that every 1 hour till the home discharge criteria met.

4.1. Home discharge criteria

Stable vital signs. Able to tolerate liquids by mouth, Walk without assistance, Voiding of urine.

Post operatively pain was assessed using VAS score. When VAS score was >5 or if patient demands rescue analgesic was administered in the form of Inj.paracetamol 1g iv.

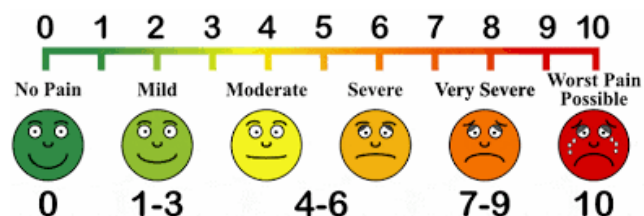


Fig. 1: VAS score statistical analysis

The collected data were analysed with IBM.SPSS statistics software 23.0 version. To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. To find the significant difference in the multivariate analysis the one way ANOVA with Tukey's Post-Hoc test was used. To find the significance in categorical data Chi-Square test was used. In all the above statistical tools the probability value .05 is considered as significant level.

5. Results

5.1. Demographic profile

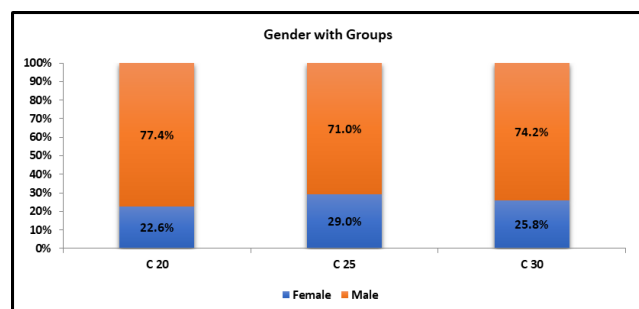


Fig. 2: Gender distribution

The p value of sex distribution was 0.845 which was statistically not significant.

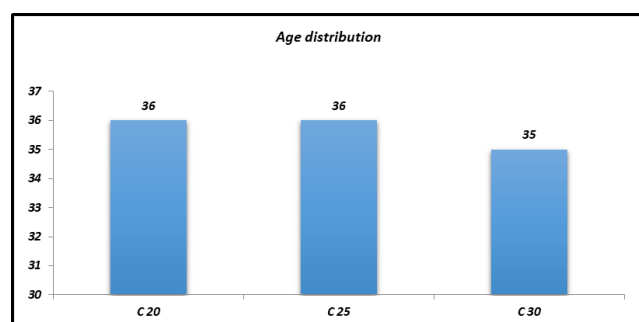


Fig. 3: Age distribution

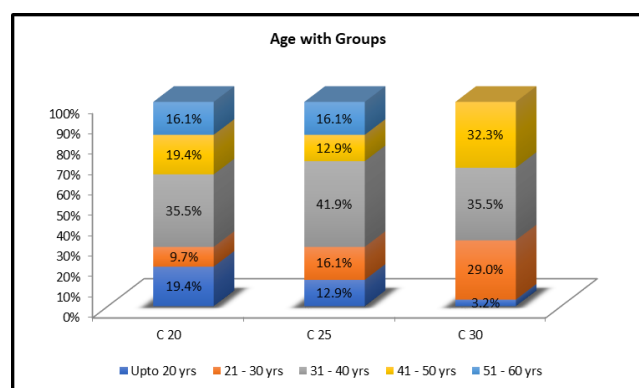


Fig. 4: Age distribution

p value for age distribution for 3 groups (0.64) is statistically not significant.

ASA PS status distribution with groups.

Motor blockade of Bromage scale I was achieved 90.3% in C30 group. Motor blockade II was achieved 90.3% motor block III was achieved in C20 group was 67.7%. The p value was 0.0005 which was statistically highly significant.

Table 1: Comparison of age distribution

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	14.777 ^a	8	.064
Likelihood Ratio	18.359	8	.019
Linear-by-Linear Association	.049	1	.825
N of Valid Cases	93		

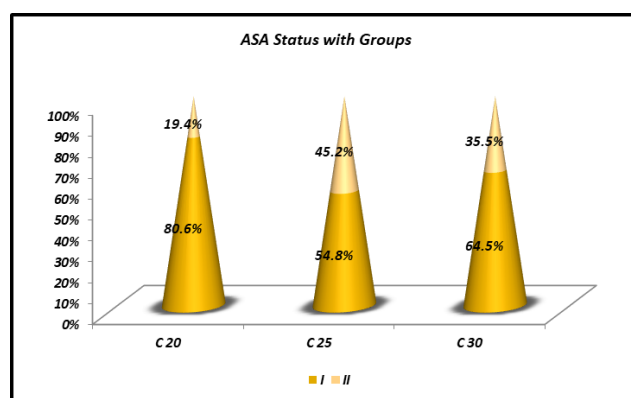


Fig. 5: ASA PS status distribution

Table 2: Comparison as ASA PS status distribution

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	4.742 ^a	2	.093
Likelihood Ratio	4.921	2	.085
N of Valid Cases	93		

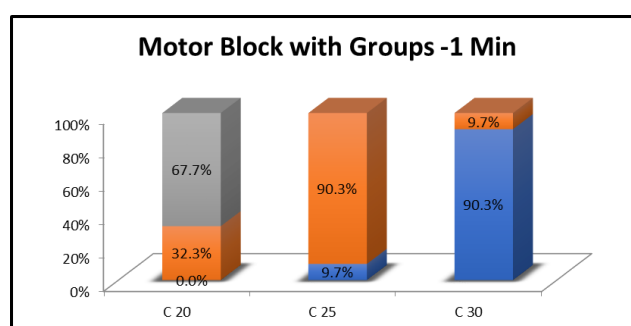


Fig. 6: Motor block in 1 min

Table 3:

	Value
Pearson Chi-Square	90.591 ^a
Likelihood Ratio	105.928
N of Valid Cases	93

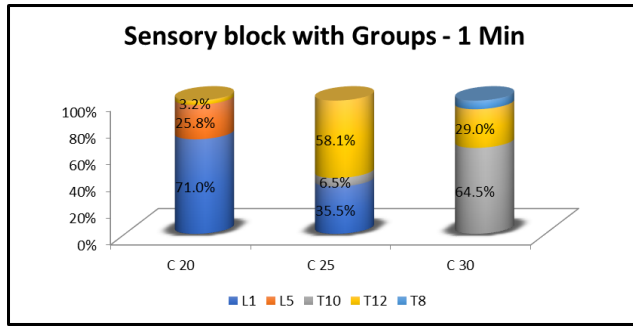


Fig. 7: Sensory block in 1 min

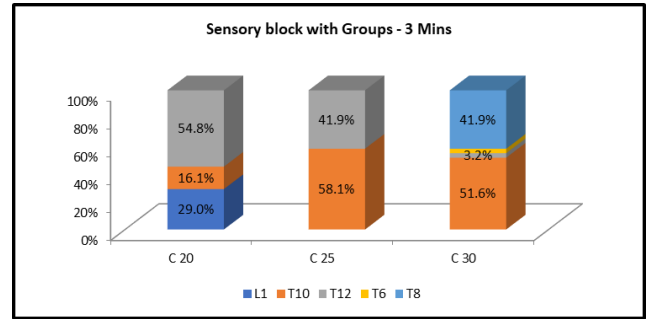


Fig. 9: Sensory block in 3 min

Comparison of sensory block in 1 min T12 was achieved in C20, C25 & C30 groups were 3.2%, 58.1%, 83.5% respectively p value was 0.0005 which was statistically highly significant.

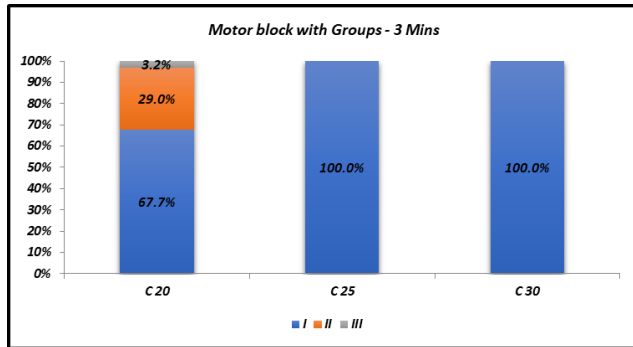


Fig. 8: Motor blockade in 3 mins

Table 4: Comparison of motor block in 3 mins

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	22.410 ^a	4	.0005
Likelihood Ratio	24.499	4	.000
N of Valid Cases	93		

Chi-Square Tests

Table 5: Comparison of sensory block in 3 mins

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	66.958 ^a	8	.0005
Likelihood Ratio	77.565	8	.000
N of Valid Cases	93		

Chi-Square Tests

The comparison of sensory blockade among three groups after 12mins and the p values was 0.005 which was statistically highly significant.

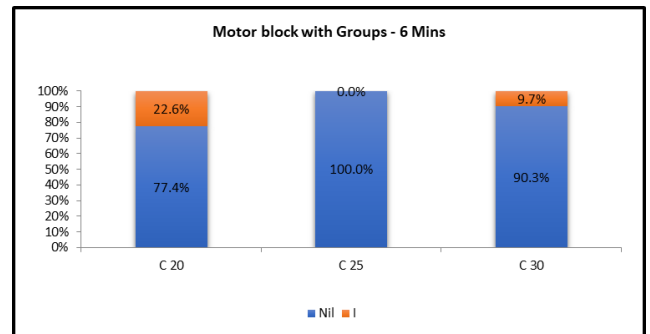


Fig. 10: Motor block in 6 min

Table 6: Comparison of motor block in 6 mins

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	8.292 ^a	2	.016
Likelihood Ratio	10.654	2	.005
N of Valid Cases	93		

Chi-Square Tests

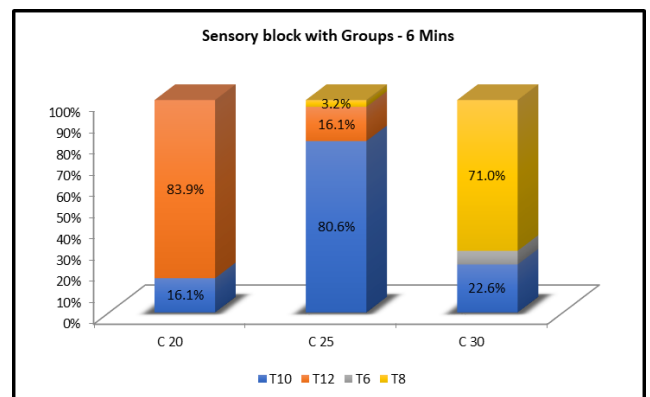
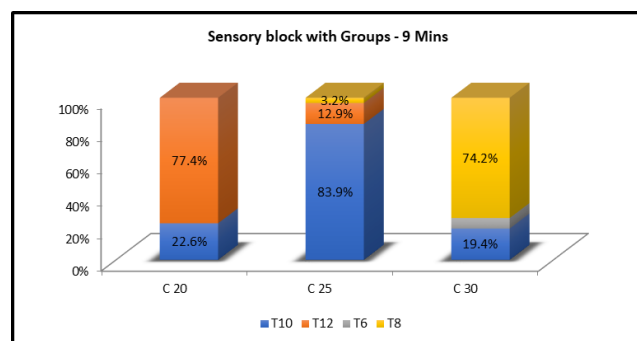


Fig. 11: Sensory block in 6 minutes

Table 7: Comparison of sensory block in 6 mins

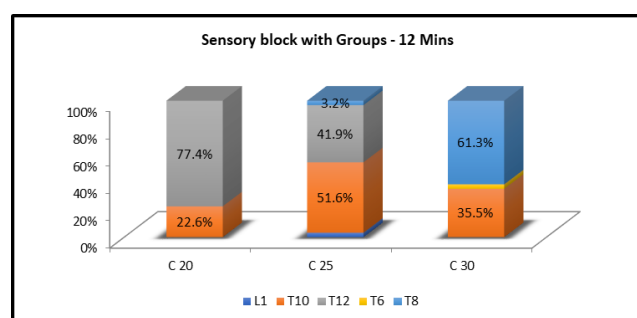
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	100.775 ^a	6	.0005
Likelihood Ratio	105.796	6	.000
N of Valid Cases	93		

Chi-Square Tests

**Fig. 12:** Sensory block in 9 minutes**Table 8:** Comparison of sensory block in 9 mins

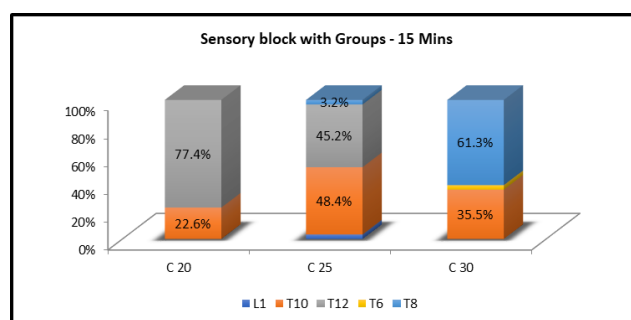
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	101.217 ^a	6	.0005
Likelihood Ratio	105.469	6	.000
N of Valid cases	93		

Chi-Square Tests

**Fig. 13:** Sensory block in 12 min**Table 9:** Comparison of sensory block in 12 mins

	Value	Df	Asymp.Sig. (2-sided)
Pearson Chi-Square	65.294 ^a	8	.0005
Likelihood Ratio	77.355	8	.000
N of Valid Cases	93		

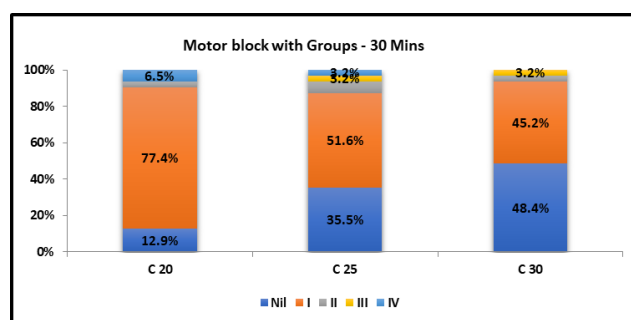
Chi-Square Tests

**Fig. 14:** Sensory block in 15 min**Table 10:** Comparison of sensory block in 15 mins

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	64.156 ^a	8	.0005
Likelihood Ratio	76.853	8	.000
N of Valid Cases	93		

Chi-Square Tests

The comparison of sensory blockade among three groups after 15 mins and the p value was 0.0005 which was statistically highly significant.

**Fig. 15:** Motor block in 30 min**Table 11:** Comparison of motor block in 30 mins

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	46.302 ^a	8	.0005
Likelihood Ratio	51.261	8	.000
N of Valid Cases	93		

Chi-Square Tests

The comparison of sensory blockade among three groups after 30mins and the p value was 0.0005 which was statistically highly significant.

Comparison of sensory block in all three groups after 30 minutes. Lowest level of sensory block L5 in C20 group was 3.2%. Highest block of T8 in C30 group was 19.4%. The p value was 0.0005 which was statistically significant.

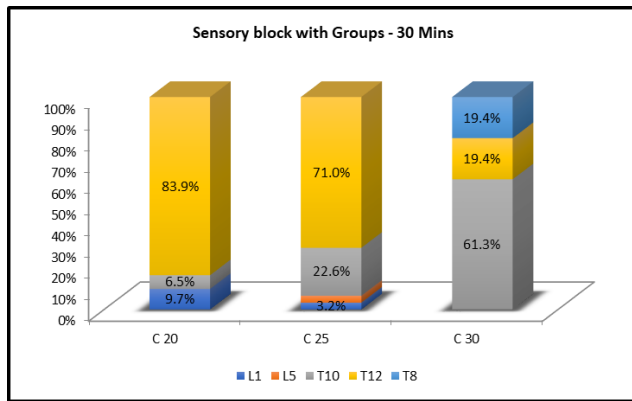


Fig. 16: Sensory block in 30mins

Table 12:

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	46.302 ^a	8	.0005
Likelihood Ratio	51.261	8	.000
N of Valid Cases	93		
N of Valid Cases	93		

Chi-square test

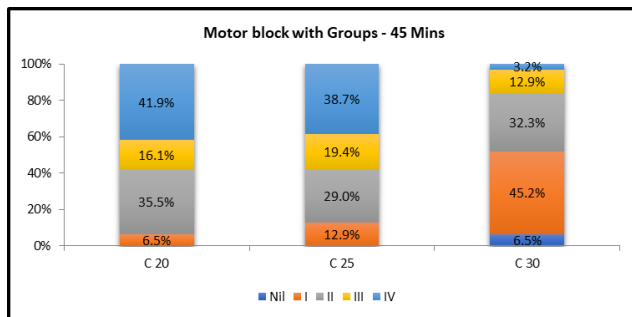


Fig. 17: Motor block in 45 min

Table 13: Comparison of motor block in 45 mins

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	27.231 ^a	8	.001
Likelihood Ratio	30.903	8	.000
N of Valid Cases	93		

Chi-Square Tests

Table 14: Comparison of sensory block in 45mins

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	36.389 ^a	8	.0005
Likelihood Ratio	41.236	8	.000
N of Valid Cases	93		

Chi-Square Tests

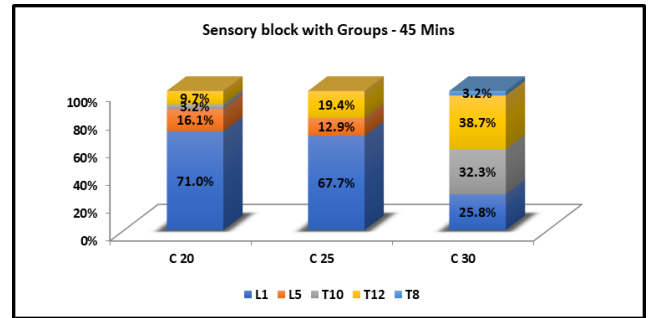


Fig. 18: Sensory block in 45 min

The comparison of sensory blockade among three groups after 45 minutes was compared and L1 in C20 patients was 72%, T8 in C30 patients was 3.2%. The p value was 0.0005 which was statistically significant.

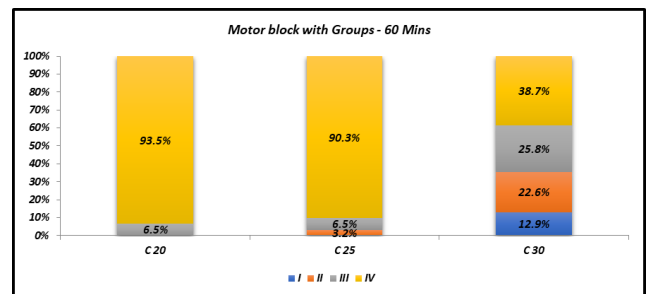


Fig. 19: Motor block in 60 min

Table 15: Comparison of motor block in 60 mins

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	32.663 ^a	6	.0005
Likelihood Ratio	34.730	6	.000
N of Valid Cases	93		

Chi-Square Tests

The comparison of residual motor blockade among three groups, Bromage scale IV in C20, C25 and C30 groups were 93.5%, 90.3% and 38.7%. The p value was 0.0005 which was statistically highly significant.

The comparison of sensory block regression after 60 mins, no blockade in C20, C25 & C30 were 58.1%, 41.9%, 2.4% respectively and the p value is 0.0005 which was statistically highly significant.

Motor and sensory block in 120 mins:

There was no residual motor blockade after 120 minutes.

There was no significant heart rate variability in all three groups after drug administration.

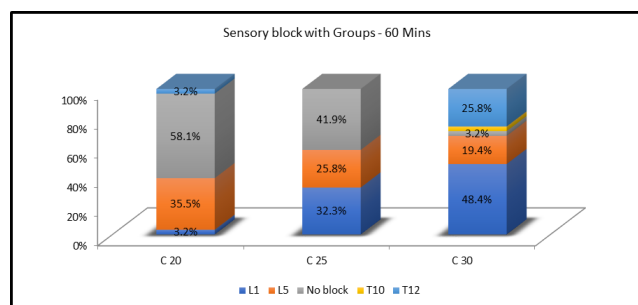


Fig. 20: Sensory block in 60 min

Table 16: Comparison of sensory block in 60mins

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	42.115 ^a	8	.0005
Likelihood Ratio	51.452	8	.000
N of Valid Cases	93		

Chi-Square Tests

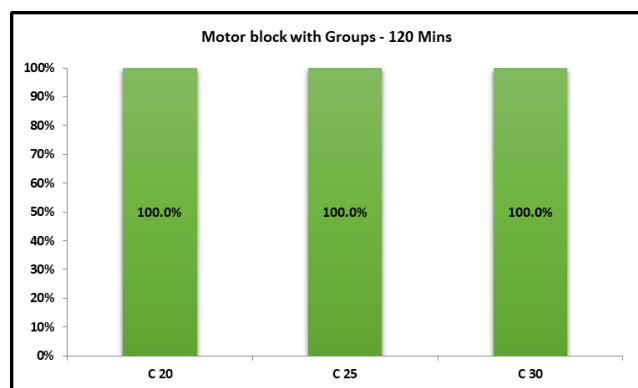


Fig. 21: Motor and sensory block in 120min

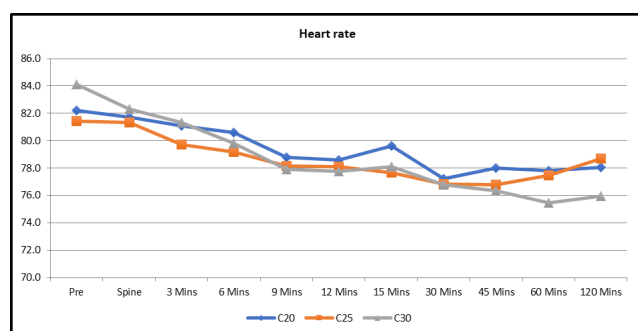


Fig. 22: Heart rate variability

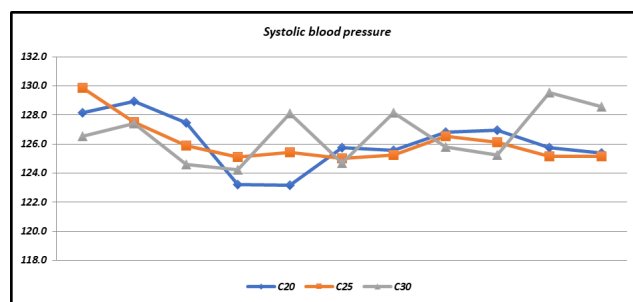


Fig. 23: Systolic blood pressure variability

There was no significant change in systolic blood pressure in all three groups after drug administration.

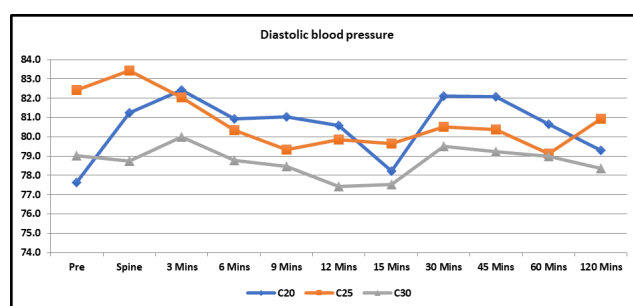


Fig. 24: Diastolic blood pressure variability

There was no significant change in diastolic blood pressure in all three group after drug administration.

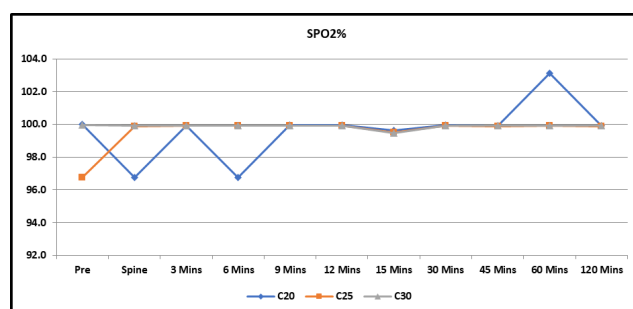


Fig. 25: SPO2 variability

There was no significant change in SPO2 in all three groups after drug administration.

The comparison of voiding time among three groups C20, C25, C30 were 4.13, 5.15, 6, 68 respectively. The p value was 0.0005 which was statistically highly significant.

The comparison of walking without assistance among three groups C20, C25 & C30 were 24.445, 41.50, 65.94 respectively. The p value is 0.0005 which was statistically highly significant.

Table 17: Comparison of voiding time and walk without assistance

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Voiding Time	C 20	31	4.13	0.65	0.12	3.89	4.37	3.00	5.50
	C 25	31	5.15	0.66	0.12	4.90	5.39	4.00	7.00
	C 30	31	6.68	0.83	0.15	6.37	6.98	4.50	8.50
	Total	93	5.32	1.27	0.13	5.05	5.58	3.00	8.50
Walk w/o assistance	C 20	31	2.55	0.46	0.08	2.38	2.72	2.00	3.50
	C 25	31	3.01	0.57	0.10	2.80	3.22	2.00	4.00
	C 30	31	3.79	0.92	0.17	3.45	4.13	3.00	8.00
	Total	93	3.12	0.85	0.09	2.94	3.29	2.00	8.00

Anova

Table 18: Comparison of voiding time and walk without assistance

		Sum of Squares	df	Mean Square	F	Sig.
Voiding time	Between Groups	102.275	2	51.138	98.626	.0005
	Within Groups	46.665	90	.519		
	Total	148.941	92			
Walk w/o assistance	Between Groups	24.445	2	12.222	26.507	.0005
	Within Groups	41.500	90	.461		
	Total	65.945	92			

6. Discussion

Today the majority of the patients undergo surgery or diagnostic needs do not need to stay overnight in the hospital because of the safe and fast ambulatory anesthesia that is provided to these day care surgeries. This has reduced the cost of care inspite of providing efficient and effective post operative care including pain relief.

This prospective, randomised study was designed to find the least effective dose of 1% chloroprocaine that can be safely administered to the patient.

It was described in the study by KOPAZ et al⁵ (2005) even no dextrose added plain 20mg/ml of chloroprocaine shows hyperbaric effects caused by a density of 1.00123g/ml at 37degree C. So the application of the SAB in the lateral position leads to block insufficiency.

Subarachnoid block was performed in the L3-L4 space in the sitting posture by using 25Gwhitacre needle. Pencil point needle was used to reduce the incidence of post dural puncture headache.

ANIRAB PAL et al (2011)⁶ conducted the study in 320 obstetric patients posted for cesarean section under subarachnoid block. They were randomly assigned into groups W and Q where 25G Quincke and 25G Whitacre needle used. The incidence of post dural puncture headache was 5% in group W and 28.12% in group Q. The p value was <0.001 which was statistically significant. In our study 25G Whitacre needle was used.

On analyzing the demographic profile, the distribution of gender, age in all three groups were comparable.ASA-PS also comparable. There was no significant difference

between three groups.

Intra operatively and post operatively vitals heart rate, systolic blood pressure, diastolic blood pressure,spo2 were monitored. There were no statistically significant in all three groups.

The onset of motor block sensory block was assessed after 1 min of drug administration. Motor blockade was achieved after 1 min in C20, C25 & C30 groups were 0%, 9.7% & 90.3% respectively.100% motor block was achieved in all three groups within 6 min. Readiness of surgery is defined as the sensory blockade of T12. Maximum sensory block was the level of block achieved in 3 consecutive test. After 1 min T12 was achieved in C20, C25 & C30 groups were 3.2%, 64.6% & 93.5% respectively.100%sensory block was achieved in all three groups within 6 min.

Dr. Kannan Bojaraaj et al⁷ (2017)compared the 1%chloroprocaine (group A)with 0.5%bupivacaine (group B)for perineal surgeries. Onset of motor and sensory block was compared. Group A showed faster onset of motor block (p 0.004) and fast regression of sensory (p=0.001) and motor block (0.005).

Gebhardt et al⁸(2017) compared 3 doses 10mg, 20mg and 30mg for perineal surgeries. The expansion of sensory(p<0.005) motor block (0.0086) gained with increasing doses. At 30mg profound motor block occur. Doses of 10mg and 20mg led to significantly earlier discharge compared to 30mg (p=0.0003) and concluded that 20mg can be recommended dose.

In our study also profound motor block occur in C30 group compared to C20&C25 groups. The p value was

0.0005 which was statistically highly significant.

Once T12 was achieved patient was put in lithotomy position. Sensory block was assessed every 3 min for first 15 min then every 15 min for first 1 hour. After that every hour till home discharge was met. Motor block was also assessed once procedure was done and patient in supine position. Regression of block also assessed.

YOOS et al (2005)⁹ compared spinal chloroprocaine (40mg) with small dose of bupivacaine(7.5mg). Time to discharge (including time to regression, ambulation, spontaneous voiding) was significantly longer with bupivacaine (191±80min) compared to chloroprocaine (113±14 min). In our study motor block after 60 min Bromage score IV in C20, C25, C30 were 93.5%, 90.5%, 38.7% respectively and the p value was 0.0005 which was statistically highly significant. Sensory block after 60 min was assessed. No residual blockade in C20, C25, C30 groups were 58.1% 41.9% and 3.2% respectively. The p value was 0.0005 which was statistically highly significant.

No residual motor blockade and sensory blockade in all three groups after 120 min.

Patients were monitored every hour till home discharge criteria was met. Unassisted ambulation, self voiding of urine was monitored. Mean duration of unassisted ambulation for C20, C25, C30 groups were 2.55, 3.01, 3.79 respectively. Mean voiding time for C20, C25, C30 groups were .13, 5.15 & 6.66 respectively. The patients receiving 30mg had late voiding time and late ambulation compared to 20mg, 25mg.

CASATI et al (2006)¹⁰ compared three different doses of chloroprocaine in patients undergoing lower limb surgeries. They concluded that block resolution and time to recovery of ambulation were dose related.

7. Summary

To summarize the demographic profile in all three groups are comparable. The onset of motor block was profound in patients receiving 30mg of chloroprocaine compared to 20 & 25mg. There was a delay in the block regression, voiding of urine, unassisted ambulation in patients receiving 30mg compared to 20mg & 25 mg.

8. Conclusion

Subarachnoid block using short acting local anesthetics have faster onset and faster block regression. Using the optimal dose avoids profound block and helps the patients meet discharge criteria earlier. Our study concluded that 20mg of 1% preservative free chloroprocaine is the optimal dose for ambulatory perineal surgeries without any

complications.

9. Source of Funding

None.

10. Conflict of Interest

None.

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Author biography

VJ Karthik, Associate Professor

B Kanchanamala, Associate Professor

S Kesavalakshmi, Assistant Professor

Narasimman, Assistant Professor

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