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Original Research Article

The effect of different doses of chloroprocaine 1% for low dose saddle anaesthesia in outpatient perianal surgery: A prospective randomized study

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ABSTRACT

Aims & Objective: The present study was designed to investigate saddle anesthesia with different doses of chloroprocaine at the same concentration (0.5%, w/v) in terms of extent of sensory and motor block, recovery from block, time for ambulation and time for urinary voiding.

Materials and Methods: The study was conducted in the department of Anaesthesiology of a tertiary healthcare centre of southern Rajasthan. 120 patients of either sex, aged between 20-50 years, with American Society of Anaesthesiologists grade I/II scheduled for elective perianal surgery in lithotomy position (duration < 40 minutes), were enrolled in the study. The patients were divided into three groups (n=40/group), receiving either 10mg, 15mg or 20mg of 1% 2-chloroprocaine in saddle anaesthesia. The effect was noted and compared in terms of extent of sensory and motor block, recovery from block, time for ambulation and time for urinary voiding.

Results: All the three groups were comparable with no statistical difference in terms of age, weight, height, BMI, ASA grading and site of injection among the participants of the groups. Number of patients who were able to move from stretcher to operation table and again from operation table to stretcher without help did not differ significantly among all the three groups. Similarly, there was no statistically significant difference in pre operative and post operative Bromage scores of participants among three groups (p value > 0.05). There was significant difference in the number of anaesthetized dermatomes both pre and post operatively among all the three groups (p value <0.001). Duration of surgery did not differ significantly among the three groups. There was also significant diference in the time for unassisted ambulation post operatively and time for urinary voiding among the three groups (p value < 0.001).

Conclusion: 10 mg chloroprocaine may cause early post operative pain while 30 mg dose may cause delayed unassisted ambulation and urinary voiding postoperatively so 15 mg dose can be used as minimum optimal dose for saddle anaesthesia for ultra-short perianal procedures.

1. Introduction

Spinal anaesthesia is most frequently used technique for lower abdominal surgeries. Perianal surgeries are commonly done under saddle block that targets a small amount of local anaesthetic specifically towards S4–S5 and coccygeal nerve roots.[1] However, its drawbacks such as risk of urinary retention, delayed ambulation and increased hospital stay may limit its use for day care surgeries.[2] Nowadays interest towards ambulatory surgery is increasing, so the requirement of anaesthetic drugs for outpatient regional anaesthesia also increases.[3]

The optimal anesthetic technique would not only provide for excellent operating conditions, but also rapid recovery, nopostoperative side effects, and high patient satisfaction. In addition to increasing the quality and decreasing the costs of the anesthetic services, the ideal anesthetic technique would also improve the operating room (OR) efficiency and provide for an early patient discharge. Saddle anesthesia is effective in patients experiencing perianal surgery in terms

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of analgesic consumption within 24 hours after surgery and aspects of postoperative recovery in view of all aspects of the anesthesia technique.[4–6]

Spinal lidocaine has been the preferred anaesthetic for outpatient spinal and saddle anaesthesia but the occurrence of transient neurologic symptoms (TNS) with its use has led to search for newer and safer alternative.[7] Although bupivacaine is rarely associated with TNS, but its Large doses (>10mg) are associated with delay in micturition[8] while smaller doses (<7.5 mg) frequently lead to block failure.[9]

Chloroprocaine (CP) is an amino-ester local anaesthetic with very short half-life. It was introduced and successfully used for spinal anesthesia since 1952.[10] Chloroprocaine constricts blood vessels resulting in reduced blood loss; this is in contrast to various other local anesthetics e.g. lidocaine. Chloroprocaine was developed as a reliable short acting spinal anaesthetic which has a favorable safety profile to support the growing need for day case surgery.[11–13]

According to volunteer studies, doses of 2-chloroprocaine between 30 and 60 mg can be used in outpatient surgeries.[14–16] We, therefore, conducted this prospective, randomized study to evaluate the minimum effective dose of 1% 2-chloroprocaine in saddle anaesthesia (10mg, 15mg and 20 mg) for perianal surgery. Till date no study has been done comparing theses three dosages. Hence the study was designed to investigate saddle anesthesia with different doses of chloroprocaine at the same concentration (1%, w/v) in terms of extent of sensory and motor block, recovery from block, time for ambulation and time for urinary voiding.

2. Materials and Methods

Set-up: It was a prospective study conducted in the department of Anaesthesiology of a tertiary healthcare centre of southern Rajasthan.

2.1. Sample size

A total of 120 patients (40 in each group) were calculated at 80% power and type 1 error pf 0.05 using sensory and motor blockage as primary outcome measure from a previous study done by Ying Zhang et al. using different dosesof chloroprocaine on saddle anaesthesia in perianal surgeries.[17]

2.2. Inclusion criteria

1. Patients with American society of anaesthesiologists (ASA) status I or II.
2. Age ranges between 20 years to 50 years.
3. Patients scheduled for elective perianal surgery in lithotomy position (duration< 40 minutes).

2.3. Exclusion criteria

1. Patients with associated cardiopulmonary disease, Diabetes, thyroid disorder, CNS abnormalities or any other co morbidities.
2. ASA grade ≥ 3
3. Patients receiving a major opioid for chronic analgesic therapy.
4. Patients who were not fit or ready for SA.
5. Patients who were not willing to participate or unable to give consent.

2.4. Intervention

The patients were divided into three groups (n=40/group), receiving either 10mg, 15mg or 20mg of 1% 2-chloroprocaine in saddle anaesthesia and were randomised using chit in box method.

Monitoring was done with pulse oximetry, automated non invasive blood pressure and electrocardiogram. Procedure were performed over side table (stretcher) in operation theatre sunder strict aseptic conditions, dural puncture was performed at L3-L4 or L4-L5 interspace using midline approach with the patient in sitting position by using a 27 Gauge Quincke needle with the orifice directed caudally. Anaesthetic drug was given according to the allocated group i.e. either 10mg, 15mg or 20mg of 1% plain 2-chloroprocaine. Patients were remained in sitting position for 5 minutes following the injection. Patients were then shifted to main operation table for the procedure. Vitals were checked every 2 minutes for first 10 minutes then every 5 minutes till end of surgery and then every 15 minutes for 1 hour postoperatively.

2.5. Primary outcome

Primary outcome was assessed as the degree of sensory and motor blocade after injection, which were observed and recorded for each group separately. The adequacy of sensory block was tested by pin prick using a 22 G needle radially, starting from anal orifice in different diagonal directions. Number of anaesthetized dermatomes were noted preoperatively and postoperatively. Patients were eligible for surgery when the sensory block has reached the S5 segment. Motor block was assessed using Bromage scale (0 = no motor block, 1 = able to flex ankle and bend knees, 2 = able to flex ankle, and 3 = full motor block). Successful saddle block was defined as adequate sensory and motor block to be able to proceed with surgery without need for any drug administration. Any drug supplementation either intravenous or local, if required was noted. The ability of patient to position himself/herself for surgery was noted.

Table 1: Demographic data of study participants in each group

Variable	Chloroprocaine-10 mg (n=40)	Chloroprocaine-15 mg (n=40)	Chloroprocaine-20 mg (n=40)
Age, years (mean ± SD)	39.03±7.7	38.83±7.63	38.4±8.12
Weight, kg (mean ± SD)	68.85±4.09	66.03±5.36	65.78±6.77
Height, cm (mean ± SD)	159.5±5.24	161.9±5.94	162.68±6.78
BMI (Kg/m^2)	27.16±2.50	25.26±2.56	24.90±2.67
ASA (I/II)	34/6	33/7	35/5
Site of injection (L3/L4, L4/L5)	36/4	35/5	36/4

2.6. Secondary outcome

The incidence of side effects such as nausea, vomiting etc. and times for first occurrence of pain around perianal region, time for unassisted ambulation and time for urinary voiding were assessed and reported as secondary outcome. Criteria for home discharge were as follows: complete recovery of saddle block, stable vital signs, able to walk unassisted, voiding without difficulty and adequate control of pain.[18]

2.7. Ethical clearance

Approval from institutional ethical committee was taken before starting the study and well-informed consent was also taken from all the patients involved in the study.

2.8. Statistical method

All qualitative data are expressed in absolute and relative frequencies and all continuous variables as mean SD those are approximately normally distributed. The differences between categorical variables were analysed by the Chi Square and Fisher Exact test. The difference between the three dosage are compared with Kruskal Wallis test and for post hoc used Mann Whitney U test, then used Bonferroni corrected p value < 0.017 statistical significance and rest of the test the probability value of <.05 was considered to indicate statistical significance for the analysis. Statistical analyses were performed with SPSS software package for Windows v. 15.0 (SPSS Inc., Chicago, IL, USA).

3. Results

All the three groups were comparable with no statistical difference in terms of age, weight, height, BMI, ASA grading and site of injection among the participants of the groups. (Table 1)

The adequacy of sensory block was tested by pin prick using a 22 G needle radially, starting from anal orifice in different diagonal directions. Number of anaesthetized dermatomes were noted preoperatively and postoperatively. Motor block was assessed using Bromage scale (0 = no motor block, 1 = able to flex ankle and bend knees, 2 = able to flex ankle, and 3 = full motor block). Patient's ability to move from stretcher to operation table and again from opeartion table to strecher without help was also noted. Duration of surgery, time for feeling of first postoperative pain, time for unassisted ambulation and time for urinary voiding also noted for all three groups (Table 2).

4. Discussion

Saddle anesthesia, also called caudal anesthesia, refers to numbness around the groin, across the buttocks and through the perineum, the flesh between the buttocks. When it occurs spontaneously, it can be a sign of damage to the spinal cord or even a symptom of a medical emergency. In both cases, some neurological testing can be used to determine the extent of the loss of sensation.

Chloroprocaine is an amino-ester local anaesthetic. It has faster onset, shorter half-life (45 to 53 min) and lesser incidences of adverse effects like transient neurologic syndrome (TNS), urinary retention, delayed ambulation and spinal hypotension. But it lacks immediate postoperative analgesia.[19,20] It is a good alternative local anaesthetic to medium-acting (Lidocaine) and long-acting local anaesthetics (Bupivacaine) for outpatient spinal anaesthesia.[20,21]

In present study, the same concentration (1%) of different doses (10 mg, 15 mg, 20 mg) of chloroprocaine was applied to saddle anaesthesia to investigate the feasibility and superiority of suitable dose of chloroprocaine in saddle anaesthesia for outpatient perianal surgery.

A retrospective review of 672 patients was performed by Campiglio GL et al. in 2010 in patients suitable for spinal anesthesia in surgical procedures of less than 60 minutes duration using 30-40mg chloroprocaine and found that chloroprocaine has a motor block lasting for 40 minutes, a rapid onset time of 3-5 minutes (9.6 min ± 7.3 min at 40 mg dose; 7.9 min ± 6.0 min at 50 mg dose) and a time to ambulation of 90 minutes without complications.[22]

Table 2: Degree of sensory and motor block, post-operative pain in various groups

Variable	Chloroprocaine-10 mg (n=40)	Chloroprocaine-15 mg (n=40)	Chloroprocaine-20 mg (n=40)	p value < 0.05	Post hoc	p value Bonferroni adjusted < 0.017
Patients able to move from stretcher to operation table without help (Yes/No) *	40 /0	38/2	30/10	0.163^{F}		
					10mg vs 15mg	0.494^{F}
					15mg vs 20mg	0.675^{F}
					10mg vs 20mg	0.116^{F}
Patients able to move from operation table to stretcher without help(Yes/No) *	40/0	40/0	31/9	0.328^{F}		
					10mg vs 15mg	-
					15mg vs 20mg	0.494^{F}
					10mg vs 20mg	0.494^{F}
Bromage score preop†	0(0,0)	0(0,1)	0(0,2)	0.120^{K}		
					10mg vs 15mg	0.155^{U}
					15mg vs 20mg	0.376^{U}
					10mg vs 20mg	0.042^{U}
No. of anesthetized dermatomes preop ‡	3.5(2.25,4)	4(3,5)	5(5,6)	< 0.001^{K}		
					10mg vs 15mg	0.001^{U}
					15mg vs 20mg	< 0.001^{U}
					10mg vs 20mg	< 0.001^{U}
Bromage score postop †	0(0,0)	0(0,0)	0(0,1)	0.133^{K}		
					10mg vs 15mg	1.000^{U}
					15mg vs 20mg	0.155^{U}
					10mg vs 20mg	0.155^{U}
No. of anesthetized dermatomes postop ‡	3(2,3)	4(3,4)	5(5,5)	< 0.001^{K}		
					10mg vs 15mg	< 0.001^{U}
					15mg vs 20mg	< 0.001^{U}
					10mg vs 20mg	< 0.001^{U}

Continued on next page

Table 2 continued

Duration of surgery ‡(Minutes)	8(7.25,10)	9(7,11)	9(7,11)	0.813^{K}		
					10mg vs 15mg	0.748^{U}
					15mg vs 20mg	0.854^{U}
					10mg vs 20mg	0.481^{U}
Time for first postop pain ‡(minutes)	49.5(45.25,56)	71.5(62.25,78)	97(90.25,104.5)	$< 0.001^{K}$		
					10mg vs 15mg	$< 0.001^{U}$
					15mg vs 20mg	$< 0.001^{U}$
					10mg vs 20mg	$< 0.001^{U}$
Time for unassisted ambulation ‡(minutes)	86(66.5,84)	96(81.25,102)	118(108,134.25)	$< 0.001^{K}$		
					10mg vs 15mg	$< 0.001^{U}$
					15mg vs 20mg	$< 0.001^{U}$
					10mg vs 20mg	$< 0.001^{U}$
Time for urinary voiding ‡(minutes)	110 (98.25,121.5)	115 (108,124.75)	137.5 (126.5,150)	$< 0.001^{K}$		
					10mg vs 15mg	0.031^{U}
					15mg vs 20mg	$< 0.001^{U}$
					10mg vs 20mg	$< 0.001^{U}$

Data are numbers of patients (*), median and range (†) or median and interquartile range (‡). Statistical test: ^{U} U test; ^{K} Kruskal–Wallis; ^{F} Fisher's exact test.

In present study, number of patient who were able to move from stretcher to operation table and again from operation table to stretcher without help did not differ significantly among all the three groups (p value > 0.05). Similarly, there was no statistically significant difference in pre operative and post-operative Bromage scores of participants among three groups (p value > 0.05). The results were in contrary to the results obtained by V Gebhardt et al. who performed a similar study in 2016 and found that 30 mg chloroprocaine causes significantly profound and clinically relevant motor block compared to 10 and 20 mg ($P \leq 0.0004$).[23]

There was significant difference in the number of anaesthetized dermatomes both pre and post operatively among all the three groups (p value <0.001). Duration of surgery did not differ significantly among the three groups. Number of dermatomes anaesthetized in 15 mg group and 20 mg group were higher than 10 mg group.

The average time after which the patient first felt the pain after surgery was 49.5 minutes in 10 mg group, 71.5minutes in 15 mg group and 97 minutes in 20 mg group. The difference was significant among the groups. There was also significant difference in the time for unassisted ambulation post-operatively and time for urinary voiding among the three groups (p value < 0.001). This means that time for unassisted ambulation and urinary voiding was significantly less in 10 mg group and 1 mg group than 20 mg group.

Acute urochesis i.e. inability to urinate is a common complication following anorectal surgery independent of the type of anaesthesia. It is due to various risk factors such as increased intravenous fluids, surgical procedure, postoperative pain or overdose of anaesthetic agent. The innervation in saddle area and urinary system belong to the same nerve segment (S2-S4), which leads to uroschesis in postoperative. In our study, none of the patient required cathterisation for urochesis. The results were similar to study performed by Zhang Y et al. in 2014.[17]

Though duration of surgery was not affected by amount of drug used in present study, 10 mg dose causes early post operative pain while 30 mg dose causes delayed unassisted ambulation and urinary voiding postoperatively so 15 mg dose can be used as optimal dose to avoid limitations of 10mg and side effects of 30 mg dose.

5. Conclusion

Plain chloroprocaine 1% is an appropriate drug for low dose saddle anaesthesia in outpatient perianal surgery. Even a smaller dose of 15 mg can be used as an optimal dose in these ultra-short procedures. The limitations of low dose or side effects of higher dose of CP thus can be avoided.

6. Limitations of Present Study

The study included a small sample size with very short duration. Only ultrashort peranal procedures were included in the study so different result could be found with longer duration procedures. The comparison with other anaesthetic agent could have been added to understand the role of CP in better way.

7. Strength of Present Study

Till now no study has been performed to evaluate the role of these three doses of CP. In addition, in present trial no adverse events related to higher doses of anaesthtic agents occurred. The present findings might therefore contribute to promote further research in the field of safe and short duration anaesthesia for ambulatory surgeries.

8. Conflict of Interest

No conflict of interest exists. No financial relationship exists between authors and products or procedures related to the article.

9. Author Contribution

Study concept, data collection and analysis and write-up, statistics, final proof: Dr. Shweta Jain.

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