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A Comparative Study of Intrathecal Chloroprocaine and Ropivacaine in Day Care Perineal Surgeries

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Abstract

Background: Chloroprocaine has recently been re-introduced into the market after being initially withdrawn due to concerns of neurotoxicity, and is being increasingly used of day care proedures. Ropivacaine is proven to have shorter PACU discharge times as compared to Bupivacaine. This study was designed to compare Chloroprocaine and Ropivacaine for spinal anesthesia in perineal day care procedures.

Methods: A total of 90 patients were enrolled in this randomized double-blind study. Spinal anesthesia was achieved with 4ml of 0.5% Ropivacaine (n = 45) or 4ml of 1% Chloroprocaine (n = 45). The primary endpoint for the study was the time until reaching eligibility for discharge. Secondary outcomes included total requirements of rescue analgesic and patient satisfaction.

Results: Average discharge time was significantly lower with Chloroprocaine (278±12.03 mins) as compared to Ropivacaine (304±10.64 mins). Duration of analgesia was significantly higher with Ropivacaine (170±12.61 mins). Total analgesic requirements were significantly lower with Ropivacaine. Patient satisfaction scores were significantly better with Ropivacaine.

Conclusion: Although chloroprocaine use resulted in shorter discharge times, Ropivacaine was associated with better analgesia, reduced analgesic requirements and better patient satisfaction, which might make it a more attractive alternative.

Keywords: Chloroprocaine, Ropivacaine, Spinal, Day care, Analgesia, Patient satisfaction

Introduction

The search for the ideal local anaesthetic for short surgical procedures is ongoing. Lidocaine has been associated with a high incidence of transient neurological symptoms, and Bupivacaine produces motor and sensory blockade of long duration. Preservative free Chloroprocaine seems like a promising alternative, being a short acting agent of increasing popularity in recent years. While Chloroprocaine was withdrawn from the market in the 1980s because of concerns about neurotoxicity, [1,2] a new formulation without preservatives that has no longer been associated with neurotoxicity [3,4], was introduced

into clinical routine in 2004. Recently published studies in Europe [5-7] have led to a renewed interest in this drug for ambulatory spinal anesthesia. Ropivacaine with its sensorimotor dissociation should also be a favourable alternative. Ropivacaine has a shorter duration of motor blockade than bupivacaine, resulting in quicker PACU discharge times [8].

There are few studies comparing the efficacy of chloroprocaine to Ropivacaine for regional anaesthesia for short surgical procedures. Teunkens [9] et al found that for spinal anesthesia in patients undergoing ambulatory knee arthroscopy, chloroprocaine has the shortest time to complete recovery of sensory and motor block compared with bupivacaine and lidocaine. Lacasse [9] found that post-operative analgesic requirements were more in patients receiving chloroprocaine as compared to bupivacaine.

The aim of this study was to compare discharge times, patient satisfaction scores and the post-operative analgesic requirements in patients undergoing perianal surgeries under spinal anesthesia with chloroprocaine and ropivacaine.

Materials And Methods

This was a double-blind randomized study conducted in patients undergoing perineal surgeries under spinal anesthesia in VIMSAR, Burla between January 2018 and June 2018. Based on previous studies [10,11], a sample size of 74 was required to show a difference of 20% in discharge times, considering an error margin of 5% and a power of 80%. Considering a dropout rate of 10 %, a total of 90 patients were enrolled in the study. Sample size was calculated using ClinCalc.com (©2018 - ClinCalc LLC.) After obtaining approval from the institutional ethics committee and informed consent, 90 patients of age 18-60 years, ASA grade I and II, 40-80 kg body weight and undergoing non-obstetric perineal surgery of less than 60 minutes duration were included in the study. Patients with a history of allergy to the study drugs, history of psychiatric illness, coagulopathy, local infection at injection site and any spinal deformity were excluded from the study. Patients were randomly assigned to one of the two groups, as decided by computer generated randomization schedule. (Figure 1)

GROUP R (n=45):20mg Ropivacaine (4 ml of 0.5% Ropivacaine)

GROUP C (n=45):40 mg Chloroprocaine (4 ml of 1% Chloroprocaine)

After proper pre-anesthetic check, all patients were given Alprazolam 0.5mg and Ranitidine 150mg orally on the day before surgery and were kept nil per orally for a minimum duration of 8 hours. In the operation theatre, monitor showing heart rate, non-invasive blood pressure, ECG and oxygen saturation probe were attached. Baseline parameters like heart rate, respiratory rate, blood pressure and SpO_2 were noted. IV ringer's lactate was started after obtaining venous access. Maintaining asepsis, and after proper skin preparation, Spinal anaesthesia was administered by a 25G Quincke spinal needle in L3-L4 space in left lateral position to the patient using the appropriate drug for each group. Patients of Group R received 4ml of 0.5% Ropivacaine while patients of Group C received 4ml of 1% Chloroprocaine. Patients were immediately made supine, and adequate sensory blockade till T6 dermatome level was checked.

Vital parameters (PR, MAP and SpO2) were monitored throughout the duration of surgery and up to 6 hours post operatively. Pain intensity was measured using the Visual Analogue Scale (VAS) at 30mins,1 hour and then every hour till 6 hours. Duration of analgesia, defined as the time at which there was first demand for analgesic after administration of spinal anesthesia, was noted. The total number of analgesic demands and total analgesic

consumption were noted. Rescue analgesia was provided by Inj. Diclofenac 75mg IV if pain score was 3 or more on VAS, followed by Inj. Tramadol 1mg/kg and then Inj. Paracetamol 1gm IV infusion if needed on subsequent occasions. Adverse effects, if any, were identified and treated. The patient was discharged only if there was complete regression of the block to light touch, ability to void, ability to walk, stable vital signs, no nausea and ability to tolerate liquids by mouth. The primary outcome of this study, i.e., the time to eligibility for discharge from hospital, was measured from the time spinal anesthesia was performed to the time the patient attained all of the discharge criteria. Patient's satisfaction was noted on a 10-point scale ranging from '0' (least satisfaction) to '10' (maximum satisfaction) at the time of discharge.

All data was collected in a pre-described proforma and tabulated using Microsoft® Excel® 2016. Statistical analysis was performed using SPSS (version 22, SPSS Inc, Chicago, IL). Categorical data was compared using the Chi-square test. Parametric data was compared using the independent t-test and non- parametric data was compared using the Mann-Whitney U test. A p value of less than 0.05 was considered statistically significant.

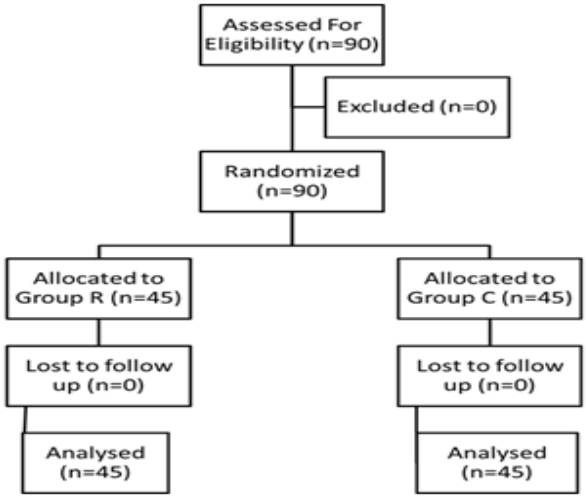


Figure 1: CONSORT Diagram

Results

The comparison between demographic data and duration of surgery in both the groups is shown in Table 1. Both the groups were comparable in terms of demographic profile with no statistical significance. Duration of surgery was 46.32 ± 11.7 mins in group R and 48.71 ± 10.3 mins in group C with a p value of 0.09, hence not significant statistically.

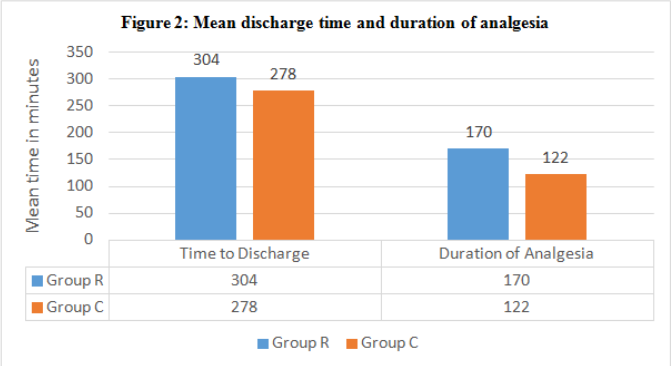
Table 1. Demographic data and Duration of Surgery

Parameter	Group R (n=45) Mean (SD)	Group C (n=45) Mean (SD)	P Value
Age	44 (15)	42 (14)	0.632
Sex (M/F)	24/21	26/19	0.074
Weight in kg	54.26 (12.3)	56.19 (15.1)	0.081
Height in cm	165.3 (9.6)	164.5 (8.4)	0.74
Duration of Surgery in min	46.32 (11.7)	48.71 (10.3)	0.09

Table 2 and Figure 2 shows the comparison between time of discharge and duration of analgesia in both the groups. The time of discharge in group R was 304 ± 10.64 mins and in group C was 278 ± 12.03 mins with a p value of <0.001. The mean duration of analgesia was 170 ± 12.61 minutes in Group R and 122 ± 10.56 minutes in Group C. The p value was <0.001.

Table 2. Discharge time and Duration of analgesia

Data	Group R Mean (SD)	Group C Mean (SD)	P Value
Time to Discharge in min	304(10.643)	278 (12.032)	<0.001
Duration of Analgesia in min	170 (12.61)	122(10.56)	<0.001



The VAS scores of both groups at various times have been compared in Table 3. The VAS scores of both groups were similar at 30 mins. VAS scores were lower in Group R at 1,2,3,4,5 and 6 hours, with statistically significant values at 1,2,4 and 6 hours. A Graphical representation of the mean VAS Scores at various times intervals for both Groups are shown in Figure 3.

Table 3. VAS Scores

Time	VAS 0		VAS 1		VAS 2		VAS 3		VAS 4		VAS 5		
	R	C	R	C	R	C	R	C	R	C	R	C	P Value
30 min	43	39	2	6	0	0	0	0	0	0	0	0	0.141
1 hour	40	38	5	7	0	0	0	0	0	0	0	0	0.001
2 hours	8	0	30	0	7	10	0	16	0	17	0	2	<0.001
3 hours	0	0	0	0	15	1	16	31	14	13	0	0	0.073
4 hours	0	0	0	0	13	1	23	23	9	18	0	3	<0.001
5 hours	0	0	0	0	34	14	11	25	0	6	0	0	0.052
6 hours	0	0	0	0	18	11	26	18	1	16	0	0	0.002

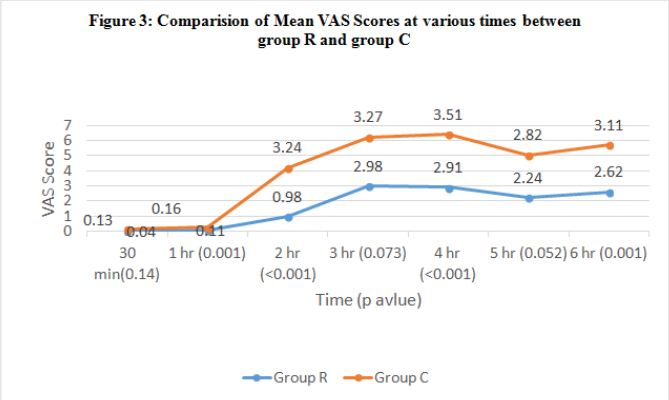


Table 4 compares the analgesic requirements between the two groups. The mean number of doses of analgesic required was 1.49 ± 0.50 in Group R and 2.22 ± 0.42 in Group C (p< 0.001). In Group R, 23 patients could be managed with one dose of rescue analgesic alone. Although 22 patients in Group R and 35 in Group C required 2 doses also 10 patients in Group C required 3 doses.

Table 4. Analgesic Requirements

No. of Analgesic doses	Group R	Group C
1	23	0
2	22	35
3	0	10
4	0	0
Mean No. of doses (SD)	1.49 (0.50)	2.22 (0.42)
P value	< 0.001	

The patient's satisfaction scores of both groups have been compared in Table 5. The mean patient satisfaction score in Group R was 8.11 ± 0.86 and that in Group C was 5.27 ± 1.27 (p<0.001). In Group R satisfaction scores of 8 and 9 was given by 18 and 17 patients respectively, whereas such scores in Group C were given by only 3 and 0 patients.

Table 5. Patient's Satisfaction score

Patient Satisfaction Score	Group R	Group C
1	0	0
2	0	0
3	0	1
4	0	14
5	0	13
6	2	9

7	8	5
8	18	3
9	17	0
10	0	0
Mean score (SD)	8.11 (0.86)	5.27 (1.27)
P value	<0.001	

Discussion

There is a high prevalence of benign proctological diseases like haemorrhoids and anal fissures and their current treatment trends are towards ambulatory surgery [12]. The characteristics of an ideal spinal anesthetic agent in day care setting would include a rapid onset of a reliable block providing adequate surgical anesthesia of appropriate duration, rapid recovery of sensory and motor block and minimal side-effects [13].

Chloroprocaine is a short-acting amino-ester local anaesthetic with low incidences of side effects and a very short duration of action [14]. Ropivacaine, a long-acting amide local anesthetic agent, is a pure S(−) enantiomer of propivacaine. Ropivacaine has lower lipid solubility than bupivacaine, which is responsible for its lower penetration into myelinated motor fibers and thus lesser motor blockade with greater sensory-motor differentiation [15]. In this study we aimed to compare discharge times, patient satisfaction scores and the post-operative analgesic requirements in patients undergoing perianal surgeries under spinal anesthesia with chloroprocaine and ropivacaine.

Mean discharge time in the Chloroprocaine group was 278 minutes in our study, which was similar to that of Lacasse et al [10] (277 minutes). Mean discharge time with Ropivacaine 0.5% was 304 minutes. VAS scores were consistently lower in the Ropivacaine group, as compared to the Chloroprocaine group, which is probably due to the quicker regression of sensory block with Chloroprocaine. The time to first demand of analgesia was 170 minutes in the Ropivacaine group as compared to 122 minutes in the Chloroprocaine group. The time to demand of rescue analgesia in case of Ropivacaine was greater in our study than in the study by Singhal and Agrawal [16].

The total analgesic requirements in the Chloroprocaine group in our study was significantly higher than the Ropivacaine group. This correlates with the findings of Teunkens [9] and Lacasse [10]. None of the patients in Ropivacaine group required more than two doses of analgesic, however, all patients in the Chloroprocaine group required two or more doses of analgesic. Pain control is a vital criterion for discharge in day care surgeries [17]. It is the most common post-operative complication. It is not permissible to send patients home in pain and recommending them simply to take analgesic drugs when needed; in fact, this may compromise the whole outcome of the surgical procedure. Ropivacaine appears to be a better alternative than Chloroprocaine in this regard. The patient's satisfaction scores were also consistently higher with Ropivacaine than Chloroprocaine in our study.

There are a few limitations in our study. Hemodynamic parameters of both groups were not compared. Block characteristics like onset, duration and regression of sensory and motor block were not compared.

Conclusion

Ropivacaine 0.5% provides longer duration of analgesia, reduced analgesic requirements and better patient satisfaction as compared to Chloroprocaine 1% in patients undergoing day care perianal surgeries, without prolonging discharge times by much. Keeping in view, reduced requirement of analgesia and patient satisfaction,

Ropivacaine 0.5% might be considered a better alternative for day care perianal surgeries than Chloroprocaine.

References

1. Reisner LS, Hochman BN, Plumer MH. Persistent neurologic deficit and adhesive arachnoiditis following intrathecal 2-chloroprocaine injection. Anesth Analg. 1980;59:452–454.
2. Ravindran RS, Bond VK, Tasch MD, Gupta CD, Luerssen TG. Prolonged neural blockade following regional analgesia with 2-chloroprocaine. Anesth Analg. 1980;59:447–451.
3. Hejtmanek MR, Pollock JE. Chloroprocaine for spinal anesthesia: a retrospective analysis. Acta Anaesthesiol Scand. 2011; 55:267–272.
4. Drasner K. Chloroprocaine spinal anesthesia: back to the future? Anesth Analg. 2005;100:549–552.
5. Casati A, Fanelli G, Danelli G, Berti M, Ghisi D, Brivio M, Putzu M, Barbagallo A. Spinal anesthesia with lidocaine or preservative free 2-chlorprocaine for outpatient knee arthroscopy: a prospective, randomized, double blind comparison. Anesth Analg 2007; 104: 959–64.
6. Casati A, Danelli G, Berti M, Fioro A, Fanelli A, Benassi C, Petronella G, Fanelli G. Intrathecal 2-chloroprocaine for lower limb outpatient surgery: a prospective, randomized, double-blind, clinical evaluation. Anesth Analg 2006; 103: 234–8.
7. Sell A, Tein T, Pitkanen M. Spinal 2-chloroprocaine: effective dose for ambulatory surgery. Acta Anaesthesiol Scand 2008; 52: 695–9.
8. Malhotra R et al. Duration of motor block with intrathecal ropivacaine versus bupivacaine for caesarean section: a meta-analysis. Int J Obstet Anesth (2016), http://dx.doi.org/10.1016/j.ijoa.2016.03.004
9. Teunkens A, Vermeulen K, Van Gerven E, Fieuws S, Van de Velde M, Rex S. Comparison of 2-chloroprocaine, bupivacaine, and lidocaine for spinal anesthesia in patients undergoing knee arthroscopy in an outpatient setting: a double-blind randomized controlled trial. Regional anesthesia and pain medicine. 2016 Sep 1;41(5):576-83.
10. Lacasse MA,Roy JD,Forget J,Vandenbroucke F,Seal RF,Beaulieu D et al,Comparison of bupivacaine and 2-Chlorprocaine for spinal anesthesia for outpatient surgery:a double blind randomized trial.Can J Anesth(2011)58:384-91
11. Shaheena Parveen, Masrat Jan, Asif Hussain et al, Efficacy and Appropriate Dosage of Isobaric Ropivacaine for Spinal Anesthesia in Patients Undergoing Elective Lower Limb Orthopaedic Surgeries (IOSR-JDMS) e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 15, Issue 1 Ver. I (Jan. 2016), PP 08-12
12. Hemping-Bovenkerk A, Moellmann M. Anaesthesia in ambulatory surgery. Anaesth Intensivmed 2014; 55: 228–44.
13. Luck JF, Fettes PD, Wildsmith JA. Spinal anaesthesia for elective surgery: A comparison of hyperbaric solutions of racemic bupivacaine, levobupivacaine, and ropivacaine. Br J Anaesth 2008;101:705-10.
14. Goldblum E, Atchabahian A. The use of 2-chloroprocaine for spinal anaesthesia. Acta Anaesthesiologica Scandinavica. 2013 May;57(5):545-52.
15. Simpson D, Curran MP, Oldfield V, Keating GM. Ropivacaine: A review of its use in regional anaesthesia and acute pain management. Drugs 2005;65:2675-717.
16. Singhal S, Agrawal G. A comparative study of ropivacaine 0.5% versus ropivacaine 0.75% for spinal

anesthesia in lower limb orthopedic surgery in ASA Grade – I/II adult patients: A prospective study. Asian Pacific Journal of Health Sciences. 2018 Apr-June;5(2):65-74.

17. Palumbo P, Tellan G, Perotti B, Pacilè MA, Vietri F, Illuminati G. Modified PADSS (post anaesthetic discharge scoring system) for monitoring outpatients discharge. Ann Ital Chir. 2013 Nov 1;84(6):661-5.