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TO COMPARE THE ANALGESIC EFFECT OF CHLOROPROCAINE (1%) AND ROPIVACAINE(0.5%) IN PERINEAL SURGERIES.

Anaesthesiology

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ABSTRACT

Background: Regional anaesthesia is highly effective both for surgical procedure and postoperative pain management.
Aim: purpose of the study is to compare duration of analgesia , intraoperative analgesic requirements ,hemodynamic effect and side effects in patients undergoing perineal surgeries under spinal anaesthesia with chloroprocaine and ropivacaine
Method: A total number of 60, ASA Grade I and II, age between 20 to 60 years of either gender posted for perineal surgery were selected. Group A and group B divided with 30 cases in each group. A volume of 4ml 0.5% ropivacaine and 4ml 1% chloroprocaine drug was injected in group A and B respectively The sensory and motor blocks(as per modified bromage score) were assessed.
Results: The principle finding observed was , that the spinal anaesthesia with 0.5% ropivacaine can provide a longer duration of analgesia than spinal anaesthesia with 1% 2-chloroprocaine. Dose of rescue analgesia was lower in 0.5% ropivacaine as compared to 1% 2-chloroprocaine. The mean time for two segment regression of sensory block was 151.50± 13.14 minutes versus 110.33 ± 7.98 minutes in groups A and groups B respectively with statistically significant P value< 0.001. The Time for complete regression to S2 (time for full recovery of sensory block) in group A was 291.33±18.38 minutes and in group B was 205.33±11.74 minutes. The difference was statistically significant between the groups P value= <0.001. The mean Duration of motor block was 345.33±17.22 minutes in group A and 252.83±14.00 minutes in group B. The difference was statistically significant between both the groups(P value<0.001). Thus, we observed that the mean duration of motor block in 1% 2-chloroprocaine group was faster than 0.5% ropivacain group. The mean time of duration of analgesic in group A was 200.33±35.48 minutes, and in group B was 125.67±25.58 minutes.
Conclusion: chloroprocaine use resulted in shorter discharge times but ropivacaine was associated with better analgesia and reduced analgesic requirements as compared with chloroprocaine when given intra-thecally. which might make it a more attractive alternative.

KEYWORDS

chloroprocaine, ropivacaine, sensory, motor, rescue analgesia

INTRODUCTION:

Regional anaesthesia is highly effective both for surgical procedure and postoperative pain management. The use of regional anaesthesia for major surgery can be advantageous as it provides not only good pain control extending into postoperative period but also early ambulation, feeding and possibly discharge. Spinal anaesthesia (also known as subarachnoid block or intrathecal anaesthesia) is one of the most often used technique in regional anaesthesia practice. [1] Nevertheless, some of its characteristics may limit its use for ambulatory surgery, including delayed ambulation, risk of urinary retention, and pain after block regression.[2]

Ropivacaine is a long-acting, enantiomerically pure (S-enantiomer) amide local anesthetic, with low lipid solubility, which blocks nerve fibers involved in pain transmission (Aδ and C fibers) to a greater degree than those controlling motor functions (Aβ fibers), thus producing lesser motor blockade with greater sensory motor differentiation..[3] Preservative free Chloroprocaine seems like a promising alternative, being a short acting agent of increasing popularity in recent years.[12] There are few studies comparing the efficacy of chlorprocaine to ropivocaine for regional anaesthesia for short surgical procedures.[5]

In comparison with bupivacaine, Chlorprocaine showed faster offset times to end of anesthesia, unassisted ambulation, and quicker discharge from hospital, and these findings suggest that Chlorprocaine may be a suitable alternative to low doses of long-acting local anesthetics in ambulatory surgery.[6]

METHODOLOGY:

The study included patients undergoing infra-umbilical ambulatory surgery under subarachnoid block at department of anaesthesia, at Sawai Man Singh Medical College and attached group of Hospitals, Jaipur. study was conducted after approval of ethics committee and research review board of the institution. Informed written consent was obtained from all the patients. 60 eligible cases randomly allocated in two study groups A and B using chit in box method. A sample of 30 cases are required at 95% confidence and 80% power to verify the expected difference of 48 ($^{+-}$12.61) minutes in time duration for need of first rescue analgesia in both groups. Patients included for this study who were willing to give consent, age group 20-60yrs,Patient height >145 cm, Patient's body weight 40-80 kg, ASA grade I-II and Patients undergoing elective perineal surgeries (fistulectomy, haemorr hoidectomy). Patients excluded from the study who refused for the consent, patients with history of bleeding disorders or patients on anticoagulants, platelet<75,000, Chronic history of headache and backache or any neurological disease, Severe hypovolemia, anaemia, compromised renal, cardiac or respiratory status,Spinal deformity or infection at the local site, Patient allergic to local anaesthetic drug, Failed spinal block and Pregnant women.

Patients received in OT, PAC, written informed consent & fasting status was confirmed. Pre-operative vitals were monitored (PR, BP, RR, SPO2). 18G cannula secured and fluid started and preanaesthestic medication injection ranitidune 50mg, injection metoclpromide 10mg given, patient positioned for spinal anesthesia in sitting position after aseptic precautions, spinal anaesthesia was administered at L3-L4 intervertebral space with selected drug and time noted. Drugs were prepared by other anaesthetist for blinding. A volume of 4ml 0.5% ropivacaine/ 4ml 1% chloroprocaine drug was injected over 30 seconds through a 25-gauge Quincke tip spinal needle the syringe used was wrapped with white paper for blinding. The intrathecal drugs composition depended upon the group to which the patient belonged. Patient was placed in supine position with a 15° head down tilt immediately after spinal injection to achieve level of block of T5-T6. Oxygen (4 l/minutes) was administered via a venti mask. The sensory (with 25G hypodermic needle) and motor blocks(as per modified bromage score) were assessed every two minutes for 15 minutes, then every five minutes for 45 minutes, and then every ten minutes for 60 minutes, and finally every 15 minutes until the sensory block regressed to the S2 dermatome. During surgery, the patient's blood pressure (systolic and diastolic), electro- cardiogram, and pulse oximetry were recorded. Vitals were checked every 5 minutes for 30 minutes and after that every 10 minutes till the end of the surgery. Time when first dose of rescue analgesic was given at VAS=3 or more (total duration of analgesia) noted, Any side effects (hypotension, bradycardia ,nausea, vomiting, pruritus, urinary retention) and time of ambulation noted. Primary outcome of the study was the Mean time of onset of sensory

block, Mean time of onset of motor block, Mean duration of sensory block, Mean duration of motor block, Median VAS score,Mean duration of analgesia, Mean rescue requirement of analgesia dose, Hemodynamic parameter for any side effect

STATISTICALANALYSIS

Quantitative data were summarized in form of mean and SD. Difference in means of two groups was analysed using student's t test. Qualitative data were expressed in form of proportion; difference in proportion was analysed using Chi-square test. Significance of difference of proportion were inferred by chi square test. Significance of difference in mean were inferred by unpaired t test/ ANOVA.

RESULT:

This Hospital based comparative study was conducted with the total Sixty (60), ASA grade I-II adult patients, age group 20-70 years who underwent perineal surgery(perineal, anal day-care surgeries.) of less than 90 minutes were included in the present study.

They were randomly allocated to group A(receiving 20 mg-4ml 0.5%ropivacaine) intra-thecal and group B(receiving 40mg-4ml 1%2-chloroprocaine)intra-thecal during spinal anaesthesia with 30 patients in each group.

All exclusion criteria were ruled out before including the patients in the present study. Both the groups were comparable with respect to age(years), sex, weight (kgs), height(cms.), ASA grade,and duration of surgery**.**In our **study** The mean age in group A was 37.80±9.73 years, and that in group B was 34.20±11.19 years. The P value for age distribution in both the groups is 0.567 which is statistically insignificant, So both the groups were comparable in terms of age .

In group A, 27 patients(90 %) were male and 3 patients(10%) were female and in group B 23 patients(76.66%) were male and 07 patients (23.33 %) were female. The P value for sex distribution is 0.299 which is statistically insignificant ,so both the groups were comparable in terms of sex distribution.

The mean weight of patients in group A was 61.87±5.84kgs and that in group B was 59.90±6.67 kgs. The P value for weight of patients in both the groups is 0.229 which is statistically insignificant, so both the groups were comparable in terms of weight distribution.

The mean height of patients in group A was 163.07±6.30 cms. And that in group B was 163.47±6.12 cms. The P value for weight of patients in both the groups is 0.803 which is statistically insignificant. So, both the groups were comparable in terms of height distribution.

group A, 12 patients (40.00%) were of ASA grade I and 18patients (60.00%) were of ASA grade II. In group B, 11 patients (36.66%) were of ASA grade I and 19 patients (63.33%) were of ASA grade II. The P value for ASA grade is 0.917 which is statistically insignificant, so both the groups were comparable in terms of ASA grading.

maximum cephalad spread (dermatome) in both the groups assessed. Number of patients of maximum cephalad spread to T8 were 2(6.6%) in group A, 2(6.6) in group B.

Number of patients of maximum cephalad spread to T10 were 20 (66.6 %)in group A, 25(83.3%) in group B.

Number of maximum cephalad spread to T12 were 8(26.6%) in group A, 3(10%) in group B. The P value was comparable between all the groups. (P value = 0.243 NS).

The mean time to reach peak block sensory height (minutes) in group A was 12.50±1.68 minutes, and in group B was 7.50±1.53 minutes. The difference was statistically significant between both the groups. (P value<0.001)

The mean time to reach peak block motor height (minutes) in group A was 17.77±1.74 minutes, and in group B was 12.70±1.74 minutes. The difference was statistically insignificant between both the groups.(P value >0.001)

Pulse rate was comparable at all the times in both the groups and the difference was found to be statistically significant at 25 to 35minutes. (p<0.001).

Mean arterial pressure was comparable at all times in both the groups and the difference was found to be statistically significant at 25 to30 minutes. (p <0.001).

The mean duration of surgery (in minutes) in group A was 52.83±15.96 minutes and that in group B was 55.17±13.10 minutes. The P value for duration of surgery in both the groups is 0.538 which is statistically insignificant ,so both the groups were comparable in terms of duration of surgery.

The mean time for two segment regression of sensory block (minutes) in group A was 151.50±13.14 minutes, and in group B was 110.33±7.98 minutes. The difference was statistically significant between the two groups.(P value : group A vs group B= <0.001).

The mean time to full recovery of sensory block (minutes) in group A was 291.33±18.38 minutes, and in group B was 205.33±11.74 minutes. The difference was statistically significant between the two groups (P value: group A vs group B = <0.001).

The mean duration of motor block (minutes) in group A was 345±17.22 minutes, and in group B was 252.83±14.00 minutes. The difference was statistically significant between the two groups.(P value : group A vs group B = <0.001).

VAS score was more in group B as compared to group A from 30 minutes to 60 minutes and the difference was statistically not significant.

All patients received rescue analgesia at approximate 200.33±35. 48 minutes, in group A. VAS score was more in group B at120 minutes and360 minutes difference was statistically significant.

All patients received rescue analgesia at approximate 125.68±25.58. minutes in group B, and VAS score became non-significant at180 and 240 minutes in both the groups.

The mean time of first analgesic requirement (minutes) in group A was 200.33±35.48 minutes, and in group B was 125.67±25.58 minutes. The difference was statistically significant between the two groups. (P value<0.001).

dose of rescue analgesic requirement in both the groups. The mean number of dose of rescue analgesic requirement in group A was 1.47±0.51, and in group B was 2.27±0.45. The difference was statistically significant between the two groups.(P value<0.001).

Intraoperative adverse events noted the prevalence of intraoperative Bradycardia Group A was 6.67% and in Group B was 3.33%. The difference was found to be statistically nonsignificant (p- value 1.00) . The prevalence of intraoperative hypotention in Group A was 6.67% and Group B 3.33%. The difference was found to be statistically nonsignificant (p- value 1.00)

The prevalence of intraoperative nausea in Group A was 6.67% and Group B was 10% .The difference was found to be statistically nonsignificant (p- value 1.00)

The prevalence of intraoperative vomiting in Group A was 3.33% and in Group B was 3.33% .The difference was found to be statistically nonsignificant (p- value 0.472)

The prevalence of intraoperative headache in Group A was 3.33% and Group B was 6.67% .The difference was found to be statistically nonsignificant (p- value 1.00)

The prevalence of intraoperative pruritis in Group A was 0.00% and Group B was 3.33% .The difference was found to be statistically nonsignificant (p- value 1.00)

The prevalence of urinary retention in Group A was 6.67% and in Group B was 0.00% The difference was found to be statistically nonsignificant (p- value 0.472)

Table No. 1 : Patients Demographics

Variables	Group A	Group B	P value
Age (years)	38.56±11.32	40.66±14.40	0.52

Sex (M:F)	19:13	22:10	0.602
Weight(kg)	68.28±9.31	67.09±10.44	0.632
Height(cms.)	161.41±7.04	161.72±6.62	0.855
ASA grade-I	23	17	0.197
ASA grade-II	9	15	
Duration of surgery(minutes)	35.33±4.30	38,23±4.90	0.821

ASA : American society of anesthesiology
Cms : Centimeters
Kg : Kelograms
(M:F) :Male Female ratio

Table No: 2 Comparison Of Spinal Anaesthesia Parameters In Two Groups Of Patients.

	Group A (N=30)		Group B (N=30)		Result (p value)
	Number	%	Number	%	
Bradycardia	2	6.67	1	3.33	1.00 (NS)
Hypotension	2	6.67	1	3.33	1.00 (NS)
Nausea	2	6.67	3	10.00	1.00 (NS)
Vomiting	1	3.33	1	3.33	0.472 (NS)
Headache	1	3.33	2	6.67	1.00 (NS)
Pruritus	0	0.00	1	3.33	1.00 (NS)
Urinary retention	2	6.67	0	0.00	0.472 (NS)

N : Total number of patients
NS : Nonsignificant
S : Significant (Values are in mean+ SD)

Table No: 3 Side Effects Compared In Both The Groups N: Number Of Cases

Mean time to reach peak motor block height (minute)	17.77+_1.74	12.70+_1.74	<0.007 (NS)
Mean duration of surgery (minute)	52.83+_15.96	55.17+_13.10	0.538 (NS)
Mean time to 2 segment sensory regression(minute)	151.50+_13.14	110.33+_7.98	<0.001 (S)
Time for compete regression to S2 (minute)	291.33+_18.38	205.33+_11.74	<0.001 (S)
Total duration of motor block	345.33+_17.22	252.83+_14.0	<0.001 (S)
Mean time for first rescue analgesia	200.33+_35.48	125.67+_25.58	<0.001 (S)
Mean number of doses for rescue analgesia in 24hours(3doses)	1.47+_0.51	2.27+_0.45	<0.001 (S)

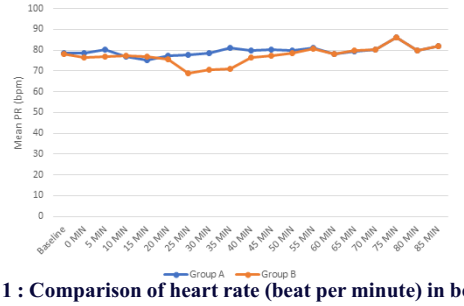

Figure 1 : Comparison of heart rate (beat per minute) in both the groups.

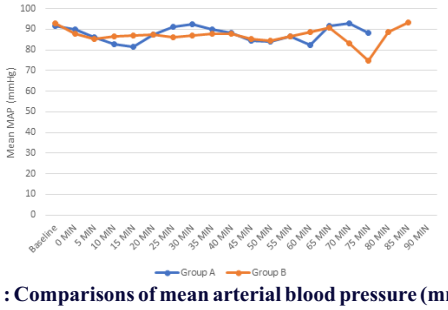

Figure 2 : Comparisons of mean arterial blood pressure (mmhg) in both the groups.

DISCUSSION:

The aim of the study was to compare intrathecal 0.5% ropivacaine with 1% 2-chloroprocaine in perineal surgeries. The principle finding observed was , that the spinal anaesthesia with 0.5% ropivacaine can provide a longer duration of analgesia than spinal anaesthesia with 1% 2-chloroprocaine. Dose of rescue analgesia was lower in 0.5% ropivacaine as compared to 1% 2-chloroprocaine.

In this study 60 patients were selected and divided into 2 groups with 30 patients in each group. In group A– patients were given 20mg (4ml) 0.5% plain ropivacaine intrathecal (4ml ropivacaine) and in group B - patients were given 40mg (4.0ml) of preservative free plain 1% 2-chloroprocaine as intrathecal anaesthetic agent. We assessed onset and regression of sensory block by dermatome level, onset and regression of motor block by Modified Bromage Score, assessed highest level of sensory block achieved, time to complete recovery from sensory and motor block. We also watched for hemodynamic parameter i.e. Blood pressure (Systolic, diastolic, mean BP), Pulse rate (PR)and SPO2, intraoperative analgesia, post-op analgesia, assessment of pain by Visual Analogue Scale, assessed time to rescue analgesia, and any intraoperative complications were also noted.

In our study, both the groups were comparable with respect to age, sex, height, weight and ASA physical status, duration, and type of surgery. Similar findings were seen in study done by Soumya et al.[7]

Changes in HR and MAP were similar in both the groups in our study, and similarly, other clinical studies have found no difference in the hemodynamic profile between isobaric bupivacaine and ropivacaine.[8,9]

The mean time for two segment regression of sensory block was 151.50± 13.14 minutes versus 110.33 ± 7.98 minutes in groups A and groups B respectively with statistically significant P value< 0.001. Thus, we observed that difference in mean time for two segment regression was significantly shorter in group B. Our results were similar to previous study by Bhaskara B.,et al[10]

Time for complete regression to S2 (time for full recovery of sensory block) in group A was 291.33±18.38 minutes and in group B was 205.33±11.74 minutes. The difference was statistically significant between the groups P value= <0.001.Our observations were consistent with the results of some previous studies in a similar study by Bhaskara B.,et al [10]

VAS score was more in group B as compared to group A from 120 minutes and 360 minutes the difference was statistically significant. All patients received rescue analgesia at approximate 200.33±35. 48minutes, in group A.VAS score was more in group B from 150 minutes to 210 minutes and difference was statistically significant.All patients received rescue analgesia at approximate224.66± 12.05 minutes in group B, and VAS score became non-significant at 240 minutes in both the groups.

The mean Duration of motor block was 345.33±17.22 minutes in group A and 252.83±14.00 minutes in group B. The difference was statistically significant between both the groups(P value<0.001). Thus, we observed that the mean duration of motor block in 2-chloroprocaine group was faster than 0.5% ropivacain group. Our results were similar to some earlier studies, in a study done by Marie-Andre´e Lacasse et al [6]

The mean time of duration of analgesic in group A was 200.33±35.48 minutes, and in group B was 125.67±25.58 minutes. The difference was statistically significant with P value<0.001. Our results coincide with previous study by Subha Soumya dany,et al. [7]

Mean time of duration of analgesia were 217.2±17.5 minutes vs 283.1±20.2 minutes(P value < 0.001). In similar study by Arvind Khare et al.[11]

The mean number of doses of analgesic required was 1.47 ± 0.51 in Group A and 2.27 ± 0.45 in Group B (p< 0.001). In Group A, 16 patients could be managed with one dose of rescue analgesic alone. Although 14 patients in Group A and 22 in Group B required 2 doses also 8 patients in Group B required 3 doses. Our results are also similar to a study done by Subha Soumya dany,et al [7]

The results of our study show that there were minimal variations in

intraoperative hemodynamic parameters (mean heart rate, mean blood pressure and oxygen saturation) There was no significant change in both Groups A and B ($p > 0.001$). There was decrease in mean blood pressure and mean heart rate at baseline (0 min),5 min,10 min,15 min, 20 min in both Groups A and B which was not significant ($p > 0.001$) but at 25 min to 35 min pattern of decrease in mean heart rate and mean blood pressure was statistically significant ($p < 0.001$). decrease in mean heart rate and mean blood pressure became non-significant after bradycardia responded well to single dose of atropine and Hypotension treated by mephenteramine. Our results were in agreement with most of the previous similar studies by Arvind Khare et al.[11]

In terms of side effects; In group A there were 2,2,2 ,2 incidence of bradycardia, hypotension, nausea,urinary retention and 1,1 incidence of vomiting,headache , no incidence of pruritis respectively.In group B there were 1,1,1,1 incidence of bradycardia, hypotension ,vomiting, pruritis and 2 incidence of headache, 3 incidence of nausea, no incidence of urinary retention respectively in recovery room. Post-dural puncture headache and transient neurological symptoms were not observed in any patients as we followed-up the patient for the first 24hrs after recovery from uneventful spinal anaesthesia. The difference was statistically not significant between the two groups.(P value>0.001). In a similar study by Bhaskara B.et al[11]

Limitations of our study

First, in the majority of the available studies, patients are discharged once recovery from motor block has been obtained, and ambulation is possible. In our study patient were discharged according to surgical condition. One of the biggest limitations of our study is that it was not perfectly double-blinded. Since the block in the 2-chloroprocaine group regressed earlier and faster, the blinded observer could guess the group to which the patient had been assigned. Although this limitation was identified prior to the enrolment of the first patient, no better alternative to the protocol was determined. An additional limitation of our study was determining the precision of the sensory level of the block within two dermatomal levels by pin prick . This imprecision was minimized by having the same blinded observer responsible for collecting all data during the entire study.

CONCLUSION:

In patients undergoing spinal anaesthesia for perineai day-care surgeries, chloroprocaine 40 mg was found the shorter time to two segment regression and complete recovery of sensory and motor block, when compared with ropivacaine 20 mg.The duration of analgesia was significantly shorter with chloroprocaine 40mg, when compared with ropivacaine 20mg. The number of dose of rescue analgesic requarments for postoperative pain was significantly highre for chloroprocaine as compared with ropivacaine. There were no differences in onset of sensory block, level of maximal cephalad spread, duration of surgery, haemodynamic parameter, adverse events or the incidence of TNS and demographic parameters (age, sex, weight, height, ASA) between the two groups.

This suggests that although chloroprocaine use resulted in shorter discharge times but ropivacaine was associated with better analgesia and reduced analgesic requirements as compared with chloroprocaine when given intra-thecally. which might make it a more attractive alternativeanaesthesia and smooth emergence are needed to prevent post operative sore throat (POST) in patients undergoing spine surgery.

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