Original Research Paper

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COMPARISION OF EFFICACY OF INTRATHECAL 1% 2-CHLOROPROCAINE 3 CC(30 MG) AND 0.5% BUPIVACAINE 3 CC (15 MG) FOR INFRAUMBLICAL SURGERIES.

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ABSTRACT **Introduction:** Anaesthetic agents may limit spinal anaesthesia use due to delayed ambulation, risk of urinary retention, and pain after block regression. An ideal anaesthetic should allow rapid onset and offset of its own effect for early patient discharge with minimal side effects.Low doses of amide linked anaesthetics which are usually administered intrathecally are associated with significant risk of delays in hospital discharge due to urinary renetion and its long duration of action. In the era of day time procedures it is now imporatnt to use new short acting drugs. Addition of silver bisulphite as a preservative in Chloroprocaine in the past caused neurotoxicity making doctors avoid its use. Now preservative free1% 2- Chloroprocaine has been introduced with same efficacy as the earlier one. **Aim:** "Comparision of efficacy of intrathecal 1% 2-chloroprocaine 3 cc (30 mg) and 0.5% bupivacaine 3 cc (15 mg) for infraumbilical surgeries." **Materials And Methods:** The observational double blind study was carried out after ethics committee approval on 26 patients belonging to ASA (American Society of Anaesthesiologists) grade I and II, aged between 18 to 65 years, including either gender, and meeting all inclusion exclusion criteria scheduled for elective lower abdominal surgical procedures under spinal anaesthesia. A well designed proforma will be used in the process. Sample size estimation was done using computer generated sample size estimation and randomisation was done using WINPEPI Application .**Results:** 1% 2-Chloroprocaine has fast onset of action , predictable duration to ambulate the patient and adequate potency without any transient neurological complications and hemodynamic complications as compared to Bupivacaine. The initial study is quite small further large scale will be necessary to ensure patients safety..

KEYWORDS : Spinal anaesthesia, Bupivacaine, Chlororprocaine, day time procedures.

INTRODUCTION

Spinal anaesthesia is achieved by using local anaesthetic drugs injected intrathecally. Low dose spinal anaesthesia is useful for many ambulatory procedures. In the last few years, the number of surgical procedures performed on an ambulatory basis has increased worldwide[1].

Spinal anaesthesia is a reliable and safe technique for surgery of the lower abdomen and lower limbs as well as in pregnancy [2,3,4].However some anaesthetic agents may limit its use for ambulatory surgery, including delayed ambulation, risk of urinary retention, and pain after block regression[5]. The choice of the correct local anaesthetic for spinal anaesthesia is therefore crucial in the ambulatory setting. The ideal anaesthetic should allow rapid onset and offset of its own effect for early patient discharge with minimal side effects[6]

Local anaesthetics are of mainly two types: a) Esters like Cocaine, Procaine and Chloroprocaine which are short-acting and
b) Amides like Lidocaine, Mepivacaine, Bupivacaine and Ropivacaine which are long acting.[4]

Many studies concluded that right local anaesthetic agent if associated with spinal anaesthesia is a suitable technique for ultra-short outpatient procedures[7].Low doses of long-acting local anaesthetics like Bupivacaine, Ropivacaine, and Levobupivacaine i.e. amide linked anaesthetics which are usually administered intrathecally are associated with significant risk of delays in hospital discharge and less reliability of block efficacy, onset, and spread[8].

Short-acting local anaesthetics may therefore represent a valid alternative in this setting. Hence the use of regional anaesthesia in such surgeries got more importance. Lidocaine has been the anaesthetic of choice for years in the context of outpatient procedures. However its use has been associated with a significant risk of transient neurological symptoms (TNS) and hence making most anaesthesiologists abandon it[9,10].

Chloroprocaine from ester group is used as short spinal anaesthetics, as amides are long acting drugs along with problems in voiding and associated with significant risk of delays in hospital discharge and less reliability of block efficacy, onset, and spread [7].Chloroprocaine is an ester which has a shorter duration of action as compared to amides hence making ambulation post operatively easy and possible. Also there is no risk of urinary retention as compared to all other amides. Hence Chloroprocaine was a widely used drug for shorter procedures, However addition of silver bisulphite as a preservative (antioxidant) in the past caused neurotoxicity hence making doctors avoid its use[11].Now preservative free1% 2- Chloroprocaine has been introduced with same efficacy as the earlier one.

Bupivacaine from amide group is used as regular spinal anaesthetic drug on large scale as duration of block remains prolonged with smaller doses. However it may provide insufficient anaesthesia.[12] [13]Prolonged interval to first voiding or even urinary retention is noticed on regression of the block.[14]

AIM

"COMPARISION OF EFFICACY OF INTRATHECAL 1% 2-CHLOROPROCAINE 3 CC (30 MG) AND 0.5% BUPIVACAINE 3 CC (15 MG) FOR INFRAUMBILICAL SURGERIES."

OBJECTIVES

1. To determine onset of sensory block.
2. To determine onset of motor block.
3. To determine peak sensory block.
4. To determine peak motor block.
5. To determine regression of sensory block by two segments
6. To determine total sensory block regression.
7. To determine total regression of motor block (on Bromage scale).

MATERIALS AND METHOD

An observational, double blinded study was carried out on 60 patients after ethics committee approval belonging to ASA (American Society of Anaesthesiologists) grade I and II, aged between 18 to 65 years, including either gender, and meeting all inclusion exclusion criteria scheduled for elective lower abdominal or lower limb surgical procedures under spinal anaesthesia including: Perianal abscess, perianal fistula, hemorrhoids, D & E, D & C, bladder stone, suprapubic cystotomy and cervical encirclage. The sample size was calculated using computerized application of WINPEPI assuming the mean SD of Group A and Group B from different studies and mean difference between both groups .At significance level of 0.05 and power of 80% , the sample size in 2 groups was chalked out to 13 per group. Patients were randomised into two groups by WINPEPI as follows:
GROUP I: 30 mg of 1% 2-Chloroprocaine 3cc: 13 patients.
GROUP II: 15 mg of 0.5% Injection Bupivacaine 3cc: 13 patients.

The statistical analysis of gender was done by 'Chi square test' with significance at 0.05 and power of 80%, age distribution by using 'Fischer's exact test' and blockade duration by 'Mann Whitney U Test'

Inclusion Criteria

1. ASA grade I or II fit patients.

2. Ages between 18 and 65 years female and male patients.
3. Patients undergoing any perineal procedures.
4. Heamodynamically stable patients with all routine investigations within normal limits without any other co morbidities.
5. Availability of informed consent.

Exclusion Criteria

1. Patients with ASA physical status III or more.
2. Patients with major neurological, cardiac, respiratory, metabolic, renal, hepatic disease or with coagulation abnormalities.
3. Patients with contraindication for spinal anesthesia.
4. Patients with known allergies to the study drug.
5. Patients who are not consenting to the above study.
6. Patients below 18 years and above 65 years of age.
7. Patients with weight less than 40 kgs and height less than 150 cms.
8. Patients with atypical pseudocholinestarase and patients having genetic deficiency of plasma cholinesterase.
9. Pregnant females of any age group.

MATERIAL REQUIRED

1. Standard anaesthesia machine (Boyle's apparatus).
2. Monitoring equipment like pulse oximeter, ECG monitor, non-invasive blood pressure (NIBP) apparatus.
3. Intravenous cannula 20G.
4. Intravenous fluids-Crystalloids & Colloids.
5. Disposable syringes, disposable sterile gloves, sterile dry hand towel, sterile gown and dressing.
6. Sterile spinal tray having sterile gauze pieces, sponge holding forceps, fenestrated drape, preparation solution, sterile disposable syringes, 26 G Quinke's spinal needle and ampule of 1% 2-Chloroprocaine / 0.5% Injection Bupivacaine.
7. Drugs and equipment necessary for resuscitation. (Ephedrine and Phenylephrine)

PROCEDURE

Pre Anesthetic checkup including general examination , systemic examination, laboratory investigations and consent form signatures were conducted and noted down on the previous day of surgery. Patients were instructed nil by mouth from midnight prior to surgery.

Preoperatively, heamodynamics were noted in the proforma sheet. Preloading of the patient with 500 ml of Ringer's lactate was done after securing intracath.

Spinal anesthesia was administerd in the sitting position with due aseptic precautions and drug was given as follows: Group I : Intrathecal inj. of 30 mg 1% 2- Chloroprocaine 3cc and Group II: Intrathecal inj. of 15 mg of 0.5%-Bupivacaine 3cc. Ascent of the sensory block by pin prick method and motor blockade by Bromage Scale were checked and noted alonwith intraoperative, postoperative vitals, side effects of drugs as well as time to void. The regression time for sensory blockade and motor blockade by two segments were checked for and added in proforma. In case of VAS more than 7 ,Inj. Diclofenac 75mg. i.m. stat on demand was administered for rescue analgesia

OBSERVATIONS AND RESULTS

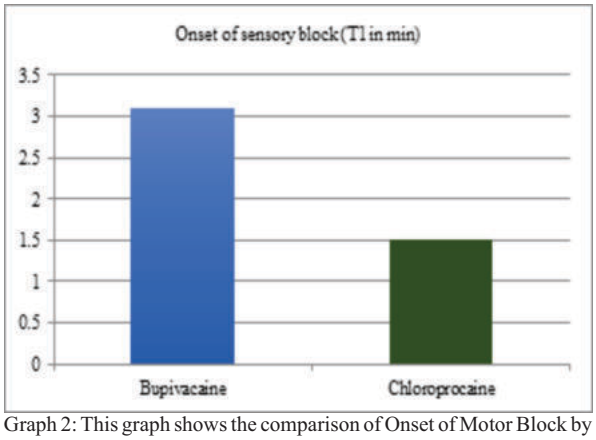
Table 1 and Table 2 : These tables show the sex distribution and mean age of the study participants between Bupivacaine and 1% 2-chloroprocaine groups. Overall, there was a non-significant difference of both the groups statistically (P=0.69) by Chi- square test and 0.43 by Fischer's test respectively.

Gender wise distribution				
Count				
		SEX		Total
		F	M	
Group	1.0	7	6	13
	2.0	8	5	13
Total		15	11	26
Chi-square test: $\chi 2$: 0.15, d.f:01, P:0.69 NS				

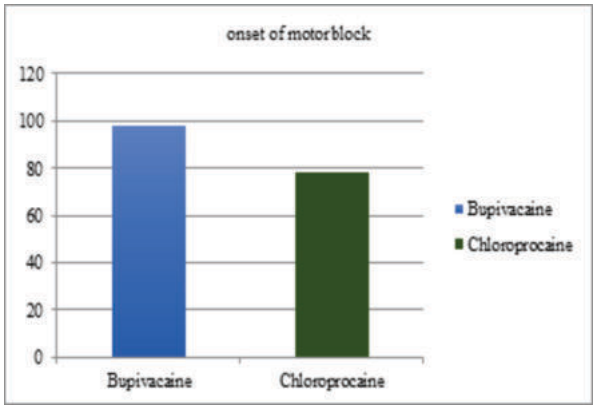
Age Wise distribution				
Count				
		AGE Group		Total
		≤ 30	≥ 31	
Group	1.0	5	8	13
	2.0	8	5	13
Total		13	13	26
Fisher's exact test: 0.43 NS				

1: Bupi: 2: Chloro.

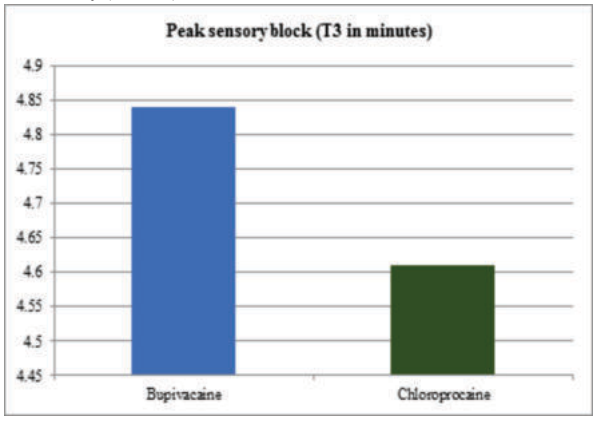
Graph 1: This graph shows the comparison of Onset of Sensory Block by Pin Prick Test (T1 in min) between both groups. Mean duration for Onset of Sensory Block (T1 in min) for the Bupivacaine group was found to be 3.10 ± 1.50 minutes while that of 1% 2-chloroprocaine group was found to be 1.53 ± 0.42 minutes. Overall, there was a significant difference in Onset of Sensory Block of both the groups statistically (P=0.001).



Graph 2: This graph shows the comparison of Onset of Motor Block by Bromage Scale (T2 in sec) between Bupivacaine and 1% 2-chloroprocaine groups. Mean duration for Onset of Motor Block (T2 in sec) for the Bupivacaine group was found to be 97.69 ± 26.92 seconds while that of 60mg 1% 2-chloroprocaine group was found to be 78.53 ± 34.97 seconds. Overall, a Statistically significant difference in Onset of Motor Block of both the groups (P=.03).

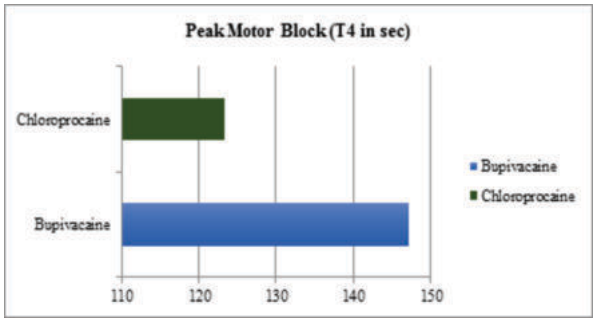


Graph 3: This table and graph shows the comparison of Peak Sensory (T3 in min) between 30mg and 60mg of 1% 2-chloroprocaine groups. Mean duration for Peak Sensory (T3 in min) for the Bupivacaine group was found to be 4.84 ± 1.28 minutes while that of 1% 2-chloroprocaine group was found to be 4.61 ± 1.23 minutes. Overall, a non-significant difference in Peak Sensory (T3 in min) of both the groups was seen statistically (P=0.68).

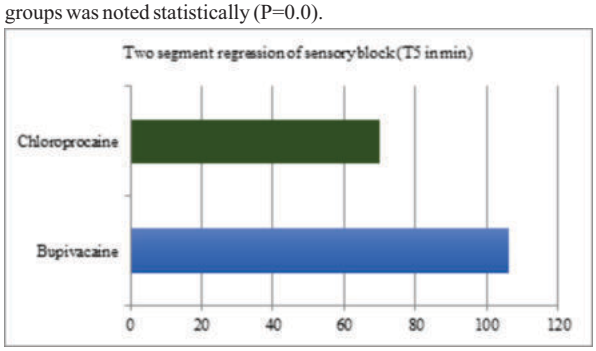


Graph 4: This table and graph shows the comparison of Peak Motor (T4 in sec) between both groups. Mean duration for Peak Motor (T4 in sec) for the Bupivacaine group was found to be 147.15 ± 58.05 seconds while that of 1% 2-chloroprocaine group was found to be 123.30 ± 13.74 seconds. Overall, a non significant difference in Peak Motor (T4

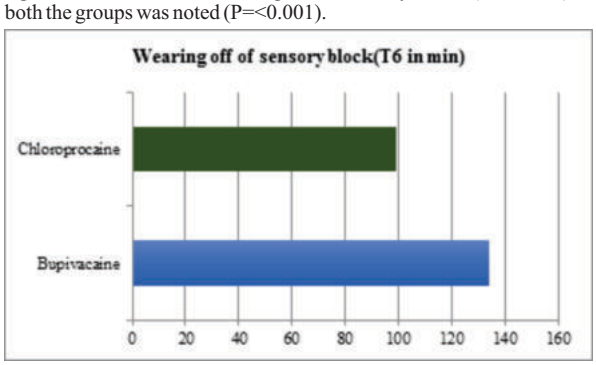
in sec) of both the groups was noted statistically (P=0.39).



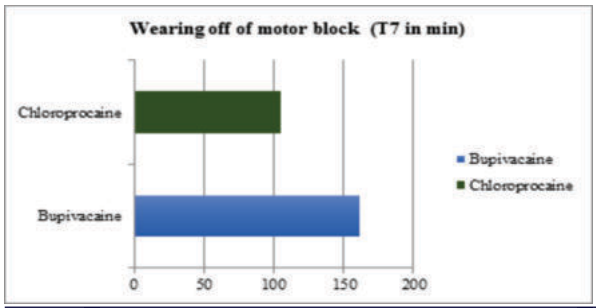
Graph 5: This table and graph shows the comparison of Two Segment Regression of Sensory Blockade (T5 in min) between both groups. Mean duration for Two Segment Regression of Sensory Blockade (T5 in min) for the Bupivacaine group was found to be 106.07 ± 10.41 minutes while that of 1% 2-chloroprocaine group was found to be 70.30 ± 11.98 minutes. Overall, a significant difference in Two Segment Regression of Sensory Blockade (T5 in min) of both the groups was noted statistically (P=0.0).



Graph 6: This table and graph shows the comparison of Wearing off of Sensory Block (T6 in min) between both groups. Mean duration for Wearing off of Sensory Block (T6 in min) for the Bupivacaine group was found to be 134.38 ± 16.76 minutes while that of 1% 2-chloroprocaine group was found to be 99.23 ± 14.52 minutes Overall, a significant difference in Wearing off of Sensory Block (T6 in min) of both the groups was noted (P=<0.001).



Graph 7: This table and graph shows the comparison of Wearing off of Motor Block (T7 in min) between Bupivacaine and 1% 2-chloroprocaine groups. Mean duration for Wearing off of Motor Block (T7 in min) for the 30mg 1% 2-chloroprocaine group was found to be 161.00 ± 17.98 minutes while that of 1% 2-chloroprocaine group was found to be 105.15 ± 17.89 minutes. Overall, a significant difference in Wearing off of Motor Block (T7 in min) of both the groups was noted statistically (P=<0.001).



DISCSSUSION

The purpose of this study was to compare 1% 2-Chloroprocaine with bupivacaine for spinal anesthesia in an ambulatory surgery setting in day care surgeries.Our principal finding was that spinal anesthesia with 1% 2-Chloroprocaine can provide a satisfactory surgical block while permitting an earlier discharge from hospital than spinal Bupivacaine.

On comparison with hyperbaric spinal bupivacaine 15 mg, it resulted in a significantly faster regression of the block, shorter time to ambulation and micturition, and earlier discharge from hospital.

DEMOGRAPHIC DATA ACROSS THE GROUPS:

- The age wise distribution of cases in our study group showed mean age of the particpants in both groups was 30.61 year. Overall, statistically non-significant difference in age of both the groups was seen statistically (Fischers test at 0.43).
- The gender wise comparison of the Bupivacaine group revealed that there were 6 males and 7 females while in 1% 2-chloroprocaine group there were 7 males and 8 females. Overall, a non-significant difference in gender of both the groups was noted statistically (P=.069).

COMPARISON OF SENSORY AND MOTOR BLOCK:

Marie-Andrée Lacasse, Jean-Denis Roy, Et all.[18] studied Comparison of bupivacaine and 2-chloroprocaine for spinal anesthesia for outpatient surgery and concludedSpinal 2-chloroprocaine provides adequate duration and depth of surgical anesthesia for short procedures with the advantages of faster block resolution and earlier hospital discharge compared with spinal bupivacaine. The average time for complete regression of the sensory block was 146 min in the 2-CP group and 329 min in the bupivacaine group, a difference of 185 min. Hence the sensory block regression was faster in 1% 2-Chloroprocaine group.

Our study showed that the regression of sensory block in Bupivacaine group was 134.38 min while that of Chlororprocaine group was 99.23 min that is difference of 35.15 min. Hence the sensory block regression was faster in 1% 2-Chlororprocaine group. Hence our study has been comparable with the above study.

C Camponovo, H Wulf , Et all.[19] studied Intrathecal 1% 2-chloroprocaine vs. 0.5% bupivacaine in ambulatory surgery: a prospective, observer-blinded, randomised, controlled trial .
The parameters were comparable with our study as follows:

Parameters	Campanovo C,Wulf H, Et all.		Khanvelkar H, Joshi,Et all.	
	Chloropro-caine 50 mg	Bupiva-caine 10 mg	Chloropro-caine 30 mg	Bupiva-caine 15 mg
Onset of motor block	5 min	6 min	1.3 min	1.6 min
Onset of sensory block	Non Significant	Non Significant	1.5 min	3.1 min
Maximum sensory block	8.5 min	14 min	Non Significant	Non Significant
Maximum motor block	Non Significant	Non Significant	Non Significant	Non Significant
Regression of sensory block	105 min	225 min	99 min	134 min
Regression of motor block	100 min	210 min	105 min	161 min

CONCLUSION

In conclusion , we found that 1% 2-Chloroprocaine has fast onset of action , predictable duration to ambulate the patient and adequate potency without any transient neurological complications and hemodynamic complications. The initial study is quite small further large scale will be necessary to ensure patients safety.

REFERENCES

1. Dunning K, Liedtke E, Et all. studied "Outpatient surgery centres draw cases away from hospitals, impact resident training volume. J Surg Educ. 2008;65(6):460–644.
2. Förster JG. Short-acting spinal anaesthesia in the ambulatory setting. Curr Opin Anaesthesiology 2014;27(6):597–604.
3. Alley EA, Mulory MF. Neuraxial anaesthesia for outpatients. Anaesthesiology Clin. 2014;32(2):357–369.
4. Obstetric Anaethesia Handbook 5th Edition By Sanjay Datta, Bhavani Shankar Kodali, Scott Segal Page 16 to 26
5. Mulroy MF, Salinas FV, Larkin KL, Polissar NL. Ambulatory surgery patients may be discharged before voiding after short-acting spinal and epidural anaesthesia. Anaesthesiology. 2002;97(2):315–319.
6. Förster JG, Rosenberg PH. Revival of old local anaesthetics for spinal anaesthesia in

ambulatory surgery. Curr Opin Anaesthesiol. 2011; 24(6):633–637.
7. Claudio Companovo spinal 1% 2 Chloroprocaine v/s General Anaesthesia for ultra-short outpatient procedures".Acta Biomed (2014) Dec 17;85(3):265-8
8. Liu SS, Ware PD, Allen HW, Neal JM, Pollock JE. Dose-response characteristics of spinal bupivacaine in volunteers: clinical implications for ambulatory anaesthesia. Anaesthesiology. 1996;85(4):729–736.
9. Pollock JE. Transient neurologic symptoms: etiology, risk factors, and management. Reg Anesth Pain Med. 2002;27(6):581–586.
10. Freedman JM, Li DK, Drasner K, Jaskela MC, Larsen B, Wi S. Transient neurologic symptoms after spinal anaesthesia: an epidemiologic study of 1863 patients. Anaesthesiology. 1998;89(6):633–641.
11. Aaron J.Gissen, Sanjay Datta and Et all. "The Chloroprocaine Controversy: I. Is Chloroprocaine Neurotoxic? Regional Anaesthesia and Pain Medicine 9(3).July 1984
12. Liu SS, Ware PD, Allen HW, Neal JM, Pollock JE. Dose-response characteristics of spinal bupivacaine in volunteers: clinical implications for ambulatory anesthesia. Anesthesiology 1996; 85: 729-36.
13. Ben-David B, Solomon E, Levin H, Admoni H, Goldik Z. Intrathecal fentanyl with small-dose dilute bupivacaine: better anesthesia without prolonging recovery. Anesth Analg 1997; 85: 560-5.
14. Breebaart MB, Vercauteren MP, Hoffmann VL, Adriaensen HA. Urinary bladder scanning after day-case arthroscopy under spinal anaesthesia: comparison between lidocaine, ropivacaine, and levobupivacaine. Br J Anaesth 2003; 90: 309-13.
15. "Bupivacaine Hydrochloride", CAS Number: 14252-80-3 The American Society of Health-System Pharmacists. Archived from the original on 2015-06-30. Retrieved Nov 28, 2019.
16. APP Pharmaceuticals. Sensorcaine (bupivacaine hydrochloride injection, USP), Sensorcaine-MPF (bupivacaine hydrochloride injection, USP), Sensorcaine with epinephrine (bupivacaine hydrochloride and epinephrine injection, USP), and Sensorcaine-MPF with epinephrine (bupivacaine hydrochloride and epinephrine injection, USP) prescribing information. Schaumburg, IL; 2010 Feb.
17. APP Pharmaceuticals. Sensorcaine-MPF spinal injection (bupivacaine hydrochloride in dextrose injection, USP) prescribing information. Schaumburg, IL; 2010 Feb.
18. Lacasse MA, Roy JD, Forget J, Vandenbroucke F, Seal RF, Beaulieu D, McCormack M, Massicotte L. Comparison of bupivacaine and 2-chloroprocaine for spinal anesthesia for outpatient surgery: a double-blind randomized trial. Can J Anaesth. 2011 Apr;58(4):384-91. doi: 10.1007/s12630-010-9450-x. Epub 2011 Jan 4. PMID: 21203878.
19. Camponovo C, Wulf H, Ghisi D, Fanelli A, Riva T, Cristina D, Vassiliou T, Leschka K, Fanelli G. Intrathecal 1% 2-chloroprocaine vs. 0.5% bupivacaine in ambulatory surgery: a prospective, observer-blinded, randomised, controlled trial. Acta Anaesthesiol Scand. 2014 May;58(5):560-6. doi: 10.1111/aas.12291. Epub 2014 Mar 6. PMID: 24601887.
20. Remmington 21st Edition Volume II Page 1481.
21. Martindale 35th Edition "The Complete Drug Refrence " Volume II Page 1697.
22. K.D.Tripathi 7th Edition Chapter on Local Anaesthetics.