

Original research article

A comparative study of motor parameters between intrathecal chlorprocaine and chlorprocaine with fentanyl for short duration urological, perianal and lower limb surgeries

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Abstract

CP is an amino-ester local anesthetic with a very short half-life. It was introduced and has been successfully used for spinal anesthesia since 1952. Sodium bisulfite was then added as a preservative after 1956 to the commercially available CP preparation. The drug was used as an epidural anesthetic for obstetric patients. After obtaining the approval from institutional review board and the ethical committee, 60 ASA Grade I and Grade II patients who met inclusion and exclusion criteria who were undergoing short duration urology, lower limb and perianal surgeries were selected. The independent 't' test result shows that there is a significant difference in mean of return to bromage 0 (min) between the groups with Chlorprocaine with fentanyl group taking longer time to bromage 0 (<0.001*). The independent 't' test result shows that there is a significant difference in mean of time to rescue analgesia(min) between the groups with Chlorprocaine with fentanyl group requiring longer time for analgesia(<0.001*).

Keywords: Intrathecal chlorprocaine, fentanyl, lower limb surgeries

Introduction

Spinal anesthesia with cocaine was first accomplished on 16th august 1898 by August Karl Gustar Bier at Royal Surgical Hospital, university of Kiel for patients undergoing ankle restriction due to tuberculosis [1].

It is the most convenient anesthetic technique that offers reduced stress response and improved pain relief [2].

In the last few years, the number of surgical procedures performed on an ambulatory basis has increased worldwide. Spinal anesthesia is a safe and reliable technique for surgery of the lower abdomen and lower limbs. Nevertheless, some of its characteristics may limit its use for short duration surgery for whom prolonged motor block is not needed, including delayed ambulation, risk of urinary retention, and postoperative pain after block regression [3].

The choice of the correct local anesthetic for spinal anesthesia is therefore crucial: the ideal anesthetic should allow rapid onset and offset of its own effect for faster patient ambulation with minimal side effects. In the past, the lack of the ideal spinal local anesthetic and the availability of fast-acting drugs such as remifentanyl and propofol have made general anesthesia the preferred choice for short outpatient procedures.

Although low doses of long-acting local anesthetics such as bupivacaine, ropivacaine, and levobupivacaine are usually administered intrathecally for short duration procedures, they are associated with significant risk of delays in hospital discharge and less reliability of block efficacy, onset, and spread [4].

Short-acting local anesthetics may therefore represent a valid alternative in this setting. Lidocaine has been the anesthetic of choice for years in the context of short duration procedures. Nevertheless, its use has been associated with a significant risk of transient neurological symptoms (TNS) and most anesthesiologists have therefore abandoned its use. Mepivacaine has been associated as well with transient neurological symptoms. The recent re-introduction of intrathecal articaine, chlorprocaine (CP), and prilocaine may offer a solution in the ambulatory setting, with a slightly faster profile for CP.

CP is an amino-ester local anesthetic with a very short halflife. It was introduced and has been successfully used for spinal anesthesia since 1952. Sodium bisulfite was then added as a preservative after 1956 to the commercially available CP preparation. The drug was used as an epidural anesthetic for obstetric patients. In the early 1980s, several reports of neurologic deficits possibly associated with inadvertent intrathecal injection of large volumes of CP during labor analgesia were published. Since a solution of 2 mg/mL sodium bisulfite and low pH without CP similarly led to irreversible block only at low pH, the preservative sodium bisulfite was often considered to be responsible for neural damage in an acidic environment [5].

All preservatives and antioxidants have been removed from currently available two of the three preparations of CP. Now preservative-free 2-chloroprocaine is available as a 10 mg/mL solution, which was recently approved by the European Medicine Agency for intrathecal use, while it is currently available in the United States as a bisulfite-free solution as well as with preservative, although at a lower dose (sodium bisulfite =1.8 mg/mL versus 2.0 mg/mL of the original preparation). Due to availability of preservative-free solutions and since human studies have been conducted with the bisulfite-free CP, the bisulfite containing formulation is not indicated for intrathecal administration [6].

Methodology

Study Design: Double blind randomised controlled study

Study Population: After obtaining the approval from institutional review board and the ethical committee, 60 ASA Grade I and Grade II patients who met inclusion and exclusion criteria who were undergoing short duration urology, lower limb and perianal surgeries were selected.

Study Duration: From preanesthetic evaluation until complete regression of motor and sensory block. Discontinuation criteria: Failed subarachnoid blocks, patients complaining of pain intraoperatively due to block regression before the surgery is completed.

Sample Size determination: To strengthen the power of the study the required sample size is rounded to 60; 30 for Chloroprocaine group and 30 for Chloroprocaine with Fentanyl.

Sampling Technique: These patients were randomly allocated into two groups by a computer generated randomization chart with 30 in each group

- **Group A:** Patients received 35mg of preservative free, isobaric 1% chloroprocaine hydrochloride with 0.5mL of sterile water intrathecally (4 mL).
- **Group B:** Patients received 35mg of preservative free, isobaric 1% chloroprocaine hydrochloride with Injection fentanyl 25mcg (0.5mL) intrathecally (4 mL).

Results

Table 1: Time to motor Bromage 3(min)

Motor Parameter	Chloroprocaine (F(%)/Mean ± SD)	Chloroprocaine with Fentanyl (F(%)/Mean ± SD)	P Value
Time to motor Bromage 3(min)	2.73±0.98	4.2±1.095	<0.001*

*-Significant

The independent ‘t’ test result shows that there is a significant difference in mean of time to motor Bromage 3(min) between the groups with Chloroprocaine with fentanyl group taking longer time to bromage 3(<0.001*).

Table 2: Return to Bromage 0 (min)

Motor Parameter	Chloroprocaine (F(%)/Mean ± SD)	Chloroprocaine with Fentanyl (F(%)/Mean ± SD)	P Value
return to bromage 0 (min)	68.67±6.288	82.67±6.915	<0.001*

*-Significant

The independent ‘t’ test result shows that there is a significant difference in mean of return to bromage 0 (min) between the groups with Chloroprocaine with fentanyl group taking longer time to bromage 0(<0.001*).

Table 3: Comparison of Motor (Bromage Scale) between the two groups

Motor (Bromage scale)	Chloroprocaine (F(%)/Mean ± SD)	Chloroprocaine with Fentanyl (F(%)/Mean ± SD)	P Value
0 Min	0±0	0±0	-
2 Min	2.5±0.731	1.8±0.61	<0.001*
4 Min	3±0	2.8±0.407	0.009*
6 Min	3±0	3±0	-
8 Min	3±0	3±0	-
10 Min	3±0	3±0	-
15 Min	3±0	3±0	-
20 Min	3±0	3±0	-
30 Min	3±0	3±0	-
40 Min	2.9±0.305	3±0	0.078
50 Min	2.17±0.747	3±0	<0.001*
60 Min	1.2±0.887	2.87±0.346	<0.001*
70 Min	0.24±0.577	1.63±0.89	<0.001*
80 Min	0±0	0.43±0.728	0.002*
90 Min	0±0	0.07±0.254	0.155
100 Min	0±0	0±0	-
110 Min	0±0	0±0	-

*-Significant

The results shows that there is a significant difference in motor (Bromage scale) between the groups at 2, 50, 60,70minutes.

Table 4: Time to micturition

Motar Parameter	Chloroprocaine (F(%)/Mean ± SD)	Chloroprocaine with Fentanyl (F(%)/Mean ± SD)	P Value
Time to micturition (min)	113.13±10.78	124.71± 7.17	<0.001

The independent 't' test result shows that there is significant difference in mean of time to micturition (min) between the groups(<0.001).

Table 5: Time to rescue analgesia

Motar Parameter	Chloroprocaine (F(%)/Mean ± SD)	Chloroprocaine with Fentanyl (F(%)/Mean ± SD)	P Value
Time to rescue analgesia (min)	100.67±26.38	179.67±33.37	<0.001*

*-Significant

The independent 't' test result shows that there is a significant difference in mean of time to rescue analgesia(min) between the groups with Chloroprocaine with fentanyl group requiring longer time for analgesia(<0.001*).

Discussion

Table 6: Comparison of time to micturition and time to rescue analgesia

Study	Drugs used	Time to micturition (min)	Time to rescue analgesia(min)
Kararmaz A <i>et al</i> [7],	4 mg B+ 25 F+DW	-	-
	7.5 mg 0.5% B	-	-
Ozgun cuvas <i>et al</i> , [8]	12.5 mg 0.5%LB	-	-
	11 mg 0.5%LB+15	-	-
Vaghadia <i>et al</i> , [9]	35 mg 2% L+15F	-	-
	40 mg 2% CP+15F	-	-
Lacasse <i>et al</i> , [10]	40 mg 2% CP	271	-
	7.5 mg 0.75% B	338	-
Vath and Kopacz, [11]	40 mg 2%CP+saline	95 9	-
	40 mg 2% CP+20 F	104 7	-
Present study	35 mg 1%CP+0.5mL DW	113.13	100.67
	35 mg 1%CP+ 25%SW	124.71	179.67

CP- Chloroprocaine, B-Bupivacaine, L- Lignocaine, LB-Levobupivacaine, DW- Distill water, F- Fentanyl, SW- Sterile water

Some of the studies stated above have compared the time to micturition. None of the studies have

described the time to postoperative analgesia.

In the present study, time to micturition for chloroprocaine group is 113.13 min and chloroprocaine with fentanyl group is 124.71min which is comparable to Vath and Kopacz study. But most of the urology patients and some patients who underwent perianal surgeries were catheterised. Time to micturition could not be standardized as the factors such as site of surgery, pain and patient factors affects it.

Time to post op analgesia in chloroprocaine group is 100.67min and in chloroprocaine with fentanyl group is 179.67min which is statistically significant. There was wide variation due to the different kind of surgeries included in the study. Surgeries like URS and EVLT are less painful requiring less analgesia and surgeries like fistulectomy, debridments are painful requiring analgesic medication. So time to post op analgesia could not be standardized in the present study^[12].

Further studies involving same type of surgeries will throw light on these parameters.

Conclusion

- In the present study, time to micturition for chloroprocaine group is 113.13 min and chloroprocaine with fentanyl group is 124.71min which is statistically significant.
- In the present study time to post op analgesia in chloroprocaine group is 100.67min and in chloroprocaine with fentanyl group is 179.67 which is statistically significant.
- In the present study, time to motor bromage 0 in chloroprocaine group is 68.67±6.288 min and chloroprocaine with fentanyl group is 82.67±6.915 which is statistically significant

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