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Comparative evaluation of two different doses of intrathecal dexmedetomidine with chloroprocaine in parturients undergoing elective lower segment cesarean section

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Abstract

Background: Chloroprocaine (CP) an ester type of local anesthetic that has a short half-life. The incorporation of adjuvents lowers dose of local anesthetics and associated side effects .This study is designed to elucidate the dose response relation between 2 different doses of intrathecal dexmedetomidine (ITD) as an adjuvant to 1% CP in lower segment caesarian section . We hypothesized that there may be a dose dependent prolongation of differential analgesia with escalating doses of ITD.

Design: Prospective, interventional, randomized double blind study

Aim / Objective: To study the efficacy and safety of addition of two different doses of dexmedetomidine to intra the calchloroprocaine for elective LSCS with respect to block characteristics.

Method: 90 full term pregnant females were randomly assigned into 3 equal groups and were given intrathecal 1%CP 4ml + 0.5 ml normal saline (group C) or intrathecal 1% CP 4ml +2.5mcg dexmedetomidine (group CD1) or intrathecal 1% CP 4ml + 5mcg dexmedetomidine (group CD2).

Maternal haemodynamics, differential analgesia (DA), time to onset sensory and motor blocks, time to resolution of sensory block to T10, time to first post operative analgesia were noted.

Results: Study showed mean time of DA 7.67, 15, 14.83 mins in C, CD1 and CD2 groups respectively. Mean time to onset sensory block was 1.80, 1.26, 1.30 mins in C, CD1 and CD2groups resp. Mean time to onset motor block was 2.75,2.50 ,2.49 mins ingroupsC,CD1,CD2 respectively. Mean time for regression of block to T10 were 50, 55.33, 55.67 min sin C, CD1, CD2 resp. Time to first post operative analgesia were 95, 103.45, 103.55 mins in C,CD1, CD2 respectively.

Conclusion: Addition of dexmedetomidine to intrathecal chloropropane tends to hasten onset of sensory block, motor block, there was a greater increase in duration of analgesia compared with increase in duration of motor block therefore significant increase in duration of differential analgesia and also delays first analgesic requirement.

Keywords: ITD, Chloroprocaine, LSCS.

Introduction

Spinal anaesthesia has become the most commonly used anesthesia in caesarian sections because it is easy to operate, little impact on body's physiological functions, allows patients to stay awake during surgery and avoids the risks of general anesthesia. Although spinal anesthesia during cesarean section is safer than general anesthesia, the adverse reactions of spinal anesthesia still seriously threaten the safety of maternal and fetal life. These adversere actions mainly include shivering, nausea and vomiting, hypotension, and bradycardia.

Chloroprocaine (CP) an ester type of local anesthetic that has a short half-life, an excellent motor and sensory block and undergoes rapid hydrolysis by pseudo cholinesterase. Since 1996, 2-CP was manufactured without additives and the pH of the solution improved. Multiple studies with healthy volunteers showed good results without complications. They found a predictable time of onset, blockade height and time to complete regression. 2-CP can be used for low-risk Caesarean section in healthy parturients. There is no difference in time to motor block resolution compared to bupivacaine when used in the doses tested in this study. Resolution of motor block seems to be more predictable for 2-CP and may have a benefit on the breast feeding initiation Maes Setal.,(2015).

The incorporation of adjuvants pro longs the duration of spinal anesthesia, improve postoperative analgesia and lowers dose of local anesthetics and associated side effects Dexmedetomidine is a selective α2 agonist with analgesia, sedation, anxiolysis and sympatholytic action. Intrathecal Dexmedetomidine can is administered to induce SA in women undergoing caesarian section, based on a study by Li XX et al., (2019) which did not mention any serious complication when using it during Caesarian.

This study is designed to elucidate the do seresponse relation between 2 different dose so intrathecal dexmedetomidine (ITD) as an adjuvant to 1% CP in lower segment caesarian section. We hypothesized that there may be a dose dependent prolongation of differential analgesia with escalating doses of ITD.

Aim and Objectives

To study the efficacy and safety of addition of two different doses of dexmedetomidine to intra the cal chloroprocaine for elective LSCS with respect to block characteristics.

Material and methods

A randomised prospective study involving 90 full term pregnant females age 20-40, undergoing elective caesarean section were taken.

Patients who were uncooperative or with contraindicate onto spinal anesthesia, or with cardio vascular, hepatic or renal dysfunction were excluded from this study. Patients were divided into 3 groups.

Group C will receive intra the cal1% chloroprocaine 4ml + 0.5 ml normal saline. Group CD1will receive intra the cal1% CP 4ml+2.5mcg dexmedetomidine Group CD2 will receive intra the cal1% CP 4ml + 5mcg dexmedetomidine.

After obtaining informed written consent from the patients; complete preanaesthetic checkup was done and base line demographic profile was noted.

Following infusion of 10ml/kg of Ringer lactate solution under aseptic and antiseptic precaution the subarachnoid block was given into the L3-4 intrathecal space using a 25G Quincke spinal needle.

After intrathecal injection, patients were positioned in supine position with a wedge below the right buttock. Vital signs were recorded every 2 minutes for first 20 minutes then every 5 minutes intraoperatively.

Primary Outcome Measures

Differential analgesia is defined as time difference from off set of motor blockade to the first analgesic requirement on numerical rating scale≥4.

Secondary outcome measures

- Time to onset sensory block i.e. loss of pinprick sensation at T10.
- Time to onset motor block i.e.bromage score ≥2.
- Time to resolution of motor block (Time frame: Upto 5h after regression of 2 dermatomes) Time period from spinal injection to time when bromage score has returned to 0
- Time to resolution of sensory block to T10 (Time period from spinal injection to time when sensory perception has returned toT10)
- Time to resolution of sensory block toS2
- Time to first postoperative analgesia. (Time frame expected Upto 24 hrs post surgery)Time from spinal injection to first Post-OP analgesia
- APGAR score

Result

All the three groups were comparable in demographic distribution.

It was observed that mean values of intra operative systolic, diastolic and mean blood pressure as well as mean heart rate were lower in CDI and CD2 groups as compared to group C. The difference in systolic diastolic and mean blood pressures was statistically insignificant in between groups CD1 and CD2. Mean values of intra operative heart rate were comparable in groups CD1 and CD 2.

The mean time to onset of sensory block in group C was 1.80±0.41, group CD1 was 1.26 ± 0.43 and group CD 2 was 1.30 ± 0.44 The difference was statistically significant (p=0.001) with CD1 and CD2 groups having a reduced time of onset of sensory block. The difference in time to onset sensory block between CD1 and CD2 was statistically in significant p=0.72

The mean time to onset of motor block in group C was 2.75+0.43, group CD1 was 2.50 + 0.47 and group CD2 was 2.49 ± 0.46. The difference was statistically significant (p=0.047) with CD1 and CD2 groups having a reduced time of onset of motor block and between CD1and CD2 difference was statistically insignificant.

Mean time for regression of block to T10 in group C 50 +8.30 mins, in group CD1was 55.33±6.81 mins and in group CD 2 was 55.67+6.79 which was statistically significant (p=0.005) with CD 1 and CD 2 groupshavingdelayedregressiontoT10ascomparedto group C.

The difference in regression time to bromage I was also statistically significant among the three groups (p=0.001).

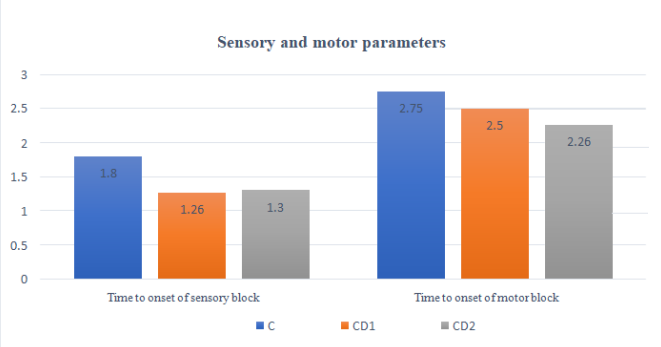
The mean time to first post operative analgesia in group C was 95.33±10.74 mins, in group CD1was103.67+4.90 mins and in group CD2was103.33+5.47min.

The comparison of differential analgesia among the three groups i.e7.67±6.26 mins vs15.00±9.65 mins vs 14.83

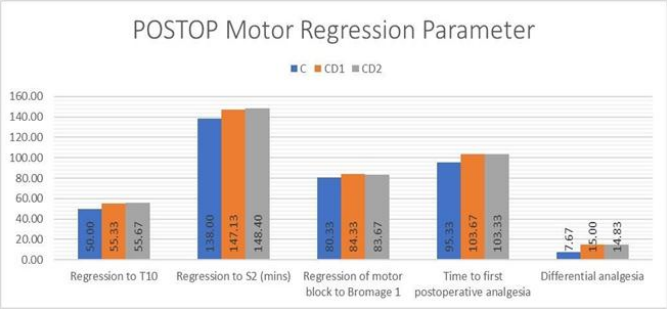
±9.69 mins in groups C, CD1 and CD2 respectively was found to be statistically significant(p=0.002) with increased values in CD1 and CD2groups as compared to C group.

POSTOP REGRESSION	C		CD1		CD2		F-STAT	p-Value
	MEAN	SD	MEAN	SD	MEAN	SD		
Regression toT10	50.00	8.30	55.33	6.81	55.67	6.79	5.63	0.005
Regression toS2	138.00	25.92	147.13	24.14	148.40	23.77	4.63	0.012
Regression of motor block to Bromage 1	80.33	9.99	84.33	9.71	83.67	8.90	13.87	0.001
Time to first postoperative analgesia	95.33	10.74	103.67	4.90	103.33	5.47	11.83	0.001
Differential analgesia	7.67	6.26	15.00	9.65	14.83	9.69	6.97	0.002

Table 1



Graph 1



Graph 2

APGAR Score	C	CD1	CD2	P-Value
1min	9	9	9	1
5min	9.5	10	10	1

Table 2

All the three groups were comparable with respect to neonatal APGAR scores (measures at 1 min and 5min) and the difference between the scores was statistically in significant in between three groups (p.0.05).

Discussion

Recently, 2-CP has been marketed solely for Spinal use. 2-CP can be used for low-risk Caesarean section in healthy parturient. There is no difference in time to motor block resolution compared to bupivacaine when used in the doses tested in this study. Resolution of motor block seems to be more predictable for 2-CP and may have a benefit on the breast feeding initiation (Maes N Setal., 2015).

Intrathecal adjuvants have been found to beneficial in prolongation of motor and sensory blockade as seen with clonidine as an adjuvant to chloroprocaine. In a study by Davis BR (2005), addition of clonidine to 2-chloroprocaine leads to increased motor and sensory blockade as well as block regression time. Hence, considering the utility and safety of intrathecal chloroprocaine in pregnant patients and prolongation of its effects by addition of intrathecal α2 agonists, we designed this prospective, randomized trial to determine the effect of 2 different doses (2.5 and 5 µg) of Intrathecal Dexmedetomidine as an adjuvant to 1% chloroprocaine and subarachnoid block (SAB) characteristics in patients undergoing lower segment cesarean section. An optimal intrathecal dexmedetomidine dose necessary for sensory and motor blockade appears to be inbetween2.5 µg and 10 µg.

But it has been observed that doses higher than 5 mcg are associated with significant adverse effects such as hypotension, bradycardia and excessive sedation Hence for the present study we selected a lower dose 2.5 and 5 µg dexmedetomidine as adjuvant to chloroprocaine so as to find out the benefit of low dose dexmedetomidine and whether that would minimize the adverse effects along with significant analgesia and prolongation of motor and sensory blockade.

Our trial showed that there was a greater increase in the duration of analgesia compared with the increase in duration of motor block thereby equating to a significant increase in the duration of Differential Analgesia (DA) ie 7.67mins vs 15mins vs 14.83 mins in C. CD1 andCD2groups respectively which stands in accordance to a study by **Bi Y Hetal., (2020)**.

In our study the differential analgesia was increased with addition of dexmedetomidine but no significant difference was noted with two doses of detomidine i.e 2.5 mcg and 5 mcg in contrast to study by **Gupta M et al., (2016)** wherein increasing the dosage of ITD from 2.5µgto resulted in a significant increase in DA (differential analgesia). Hence differential analgesia is dose dependent in studies by **Bi Y Hetal.,(2020)**and **Gupta Metal., (2016).**

The time to onset of sensory block was significantly shortened with addition of dexmedetomidine i.e. 1.80 mins vs 1.26 mins vs 1.30 mins (P 0,001) in C, CD1 and CD2groups respectively which was in accordance with study by **BI YH et al., (2020)** and in contrast to study by **Meitei AJ et al., (2016)** where addition of dexmedetomidine to intra the cal bupivacaine for caesarean section did not has ten the on set of block.

Regression of sensory blockade to T10 and to S2 were significantly prolonged with addition of dexmedetomidine with regression to S2 being 138 minvs 152.33 minsvs 153.27 mins and mean time of regression to bromage1 i.e80 vs 90 vs90.33in groups C,CD1,CD2 respectively as in accordance with **Meitei AJ et al., (2016**) who observed significant prolongation in regression to T10 and S1 and motor block regression with addition of dexmedetomidine.

A study conducted by **Li XX et al., (2019)** to evaluate the efficacy of intra the cal dexmedetomidine added to low dose bupivacaine in caesarean section proved prolongation of both sensory and motor blockade with addition of dexmedetomidine which is in accordance to our study. Or study showed that increase in motor and sensory blockade was comparable with two doses of dexmedetomidine (2.5 mcg and 5 meg) used our study; similar dose independence of varied doses of dexmedetomidine (2.5/3 vs 5) have been reported by **Bi VH et al., (2017)** who used low dose bupivacaine with intrathecal dexmedetomidine (3and 5 meg) in lower segment caesarean section.

Hence it suggests that co-administration of dexmedetomidine 2.5 and 5 meg to chloroprocaine prolonged the duration of sensory and motor blockade as also suggested by **Meitei AJ et al., (2016)**; **Bi Y-H et al., (2017)** and **Bi YH et al., (2020)**, observed prolonged motor and sensory blockade with Smeg than with 3mcg dose which stands in contrast to our study that observed no significant difference in between 2.5 and 5 meg intra the caldexmedetomidine.

Time to first postoperative analgesia was increased with addition of Intra the caldexmedetomidine to chloroprocaine with mean time to first analgesia being 95minsvs 103.45 mins vs 103.55 mins in C, CD1 and CD2 groups respectively as in accordance with study by **Li XX et al., (2019)** and **Bi YH et al., (2020)** but our study is contrast with study of **Bi YH et al.,** (2017) where no difference was observed in time to first rescue analgesic with addition of 3meg and 5meg doses of dexmedetomidine.

The incidence of hypotension (20%) and bradycardia (16%) were higher with dexmedetomidine group than with chloroprocaine (6.67%) which was easily managed with Injection phenylephrine 100meg intravenous stat and Injection Atropine 0.6 mg Intra venous stat

respectively. Intra the caldexmedetomidine has a substantial hemodynamic effect, causing hypotension and bradycardia **Hall et al., (2001)**. Intrathecal local anesthetics block the sympathetic out flow and reduce the hemodynamic parameters during the intraoperative period. However, this short-term lower blood pressure did not affect the Apgar score in accordance with **Teymouraian Hetal;(2018).**

Conclusion

Addition of dexmedetomidine to intrathecal chloropropane in patients undergoing elective LSCS tends to hasten onset of sensory block, motor block, there was a greater increase induration of analgesia compared with increase induration of motor block therefore significant increase in duration of differential analgesia and also delays first analgesic requirement

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