ISSN 2515-8260 Volume 10, Issue 01, 2023

Type of the Manuscript: Research article

INTRAPERITONEAL INSTILLATION OF BUPIVACAINE VS BUPIVACAINE WITH DEXMEDITOMIDINE FOR POST OPERATIVE ANALGESIA IN LSCS

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Objective: The purpose of this study is to compare the antinociceptive effect of intraperitoneal application of bupivacaine and bupivacaine in combination with dexmedetomidine after LSCS.

Method: Each patient was randomly assigned to one of the two groups of 30 patients each using random table. Group A Patients who received instillation of 20cc of 0.5% Bupivacaine diluted to 40cc with NS intraperitoneally, a total of 40cc. Group B patients who received instillation of 20cc Bupivacaine 0.5% diluted till 40cc with NS with Dexmedetomidine 50mcgs intraperitoneally, a total of 40cc. The patient was blind to the drug injected. All patients underwent thorough medical evaluation and routine lab investigations a day prior to surgery **Result;** In the present study mean age of Bupivacaine group was 26 and Bupivacaine with Dexmedetomidine study group was 25.65.There was statistically significant difference between two groups of patients in terms of pulse rate and , Systolic BP all the time.The mean VAS as per data, the gradual increase of the VAS scores is comparable, and showed statistical significance between two groups. Comparisons of pain between two groups by Visual Analogue Scale scores were statistically significant at all time point except 6,8 and 24 hour.This study also showed that Bupivacaine provided adequate analgesia for the first 1 to 2 hours when compared to Bupivacaine+Dexmed, which provided adequate analgesia for about 4 to 6 hours. **Conclusion:** We concluded that the administration of the intraperitoneal local anaesthetic agent, Bupivacaine in combination with dexmedetomidine can effectively reduce the need for prescribing postoperative analgesic drugs as well as decrease postoperative pain severity in minimal surgery..

Key words : Post Operative Analgesia, Bupivacaine, Dexmeditomidine ,Intraperitonial Instillation

ISSN 2515-8260 Volume 10, Issue 01, 2023

INTRODUCTION

The rate of caesarean delivery has been growing over the past few decades, and it is one of the furthermost commonly performed surgeries in the world, with nearly 18.5 million caesarean deliveries performed every year [1].

Pain after caesarean delivery is a complex experience that is adapted to each patient. The degree of tissue injury starts a response in the pain matrix, forming peripheral sensitization and central pain pathways to fear, anxiety, and frustration. Patients have stated worries about pain during and after caesarean delivery as their highest importance [3] Locoregional analgesia signifies a component of the multimodal pain management method that provided benefits after CS. [4] One of these methods is the wound infiltration that displayed the possibility to lessen the use of opioids post-CS [5].

Bupivacaine is one of widely used local anaesthetic agent, belongs to Amide group of local anaesthetics. They act by binding to specific sites in voltage-gated Sodium channels and thereby preventing the transmission of nerve impulses (conduction blockade) It is also usually injected into surgical wound sites to decrease pain for many hours after surgery. In contrast to other local anaesthetics it has a long period of action. It is also the furthermost toxic to the heart when administered in huge doses.

Dexmedetomidine has been developed as the one of the commonly used drugs in anaesthesia due to its hemodynamic, sedative, anxiolytic, analgesic, neuroprotective and anaesthetic sparing effect. High selectivity of dexmedetomidine to α2-receptors has been broken grounds in area of anaesthesia practice. Dexmedetomidine possesses hypnotic, sedative, anxiolytic, sympatholytic and analgesic properties without producing significant respiratory depression. Its sympatholytic effect reduces mean arterial pressure and heart rate by falling norepinephrine release.

The intravenous administration of dexmedetomidine before induction of anaesthesia attenuates sympathetic-adrenal responses to laryngoscopy and endotracheal intubation. It also provides improved haemodynamic stability during intraoperative period [2]. Though dexmedetomidine is only registered for IV use, multiple ways for administration have been examined. With extravascular administration, one can evade the high peak plasma levels normally seen after IV administration. After oral management, a wide first-pass effect is observed, with a bioavailability of 16% [6]. Dexmedetomidine is riveted over the intranasal and buccal mucosae, a feature that might be of aid when using dexmedetomidine in uncooperative kids or geriatric affected role [6].

This study was conducted with a purpose of comparison for antinociceptive consequence of intraperitoneal application of bupivacaine and bupivacaine in combination with dexmedetomidine after LSCS.

MATERIAL & METHODS:

METHODOLGY

This randomised, prospective, single blind controlled study was carried out over a period from October 2020 to October 2021 after obtaining approval from Institutional Ethics Committee and written informed consent from the patients. Sample size was calculated using published data of a

ISSN 2515-8260 Volume 10, Issue 01, 2023

previous study based on the power of study. 60 ASA Grade I and II patients undergoing elective caesarean section for various indication with uncomplicated pregnancy of 18 to 55yrs of age were included in the study.

INCLUSIONCRITERIA:

1.Patient undergoing elective surgery.
2.American Society of Anaesthesiologists grade1and 2
3.Age20-55years
4.Weight 40-70Kg
5.Pregnant females

EXCLUSIONCRITERIA:

1.Patient's refusal to participate in the study
2.Allergy to study drugs
3.Patient's with uncontrolled cardiovascular disease, hepatorenal disease, bronchospastic disease. (ASA grade3 or more)
4.Emergency surgeries
5.Patients taking any adrenergic or psychotropic drug

Each patient was randomly assigned to one of the two groups of 30 patients each using random table. Group B Patients who received instillation of 20cc of 0.5% Bupivacaine diluted to 40cc with NS intraperitoneally, a total of 40cc. Group BD patients who received instillation of 20cc Bupivacaine 0.5% diluted till 40cc with NS with Dexmedetomidine 50mcgs intraperitoneally, a total of 40cc. The patient was blind to the drug injected. All patients underwent thorough medical evaluation and routine lab investigations a day prior to surgery. On the day of surgery after confirmation of fasting status the patient were shifted to OT and multipara monitors were attached. Baseline SBP, DBP, SPO2, pulse rate was recorded. I.V. line was accessed with a 20 G cannula. All patients received inj. Ondensetron 4mg iv and inj. Metoclopramide 10 mg iv for aspiration prophylaxis before surgery. After all routine monitoring of vitals having electrocardiography (ECG), Noninvasive blood pressure (NIBP), pulse oximetry (SPO2) under all aseptic precautions caesarean section were carried out under spinal anaesthesia using 25 Gauge Spinal needle.

After incising all the layers of skin and subcutaneous tissue and separation of rectus muscle was done. Parietal peritoneum was opened and a small median transverse hysterotomy incision had been made and after delivery of the baby and the placenta, uterine closure, using continuous nonlocking double layer closure, with or without exteriorization of uterus was completed. Patients received intraperitoneal instillation of either 20 cc of Bupivacaine 0.5% diluted till 40cc with NS (Group B) or 20 cc of Bupivacaine o.5% diluted till 40cc with NS along with 50mcgs of Dexmedetomidine randomly. Vitals SBP, DBP, SPO2, pulse rate was recorded. Care was taken that blood accumulating into the pelvis after closing the uterine incision and hematomas carefully wiped out with surgical towels leaving a more or less ‘‘dry’’ pelvis before the fluid was instilled. This was followed by closing the abdomen in different layer [7]

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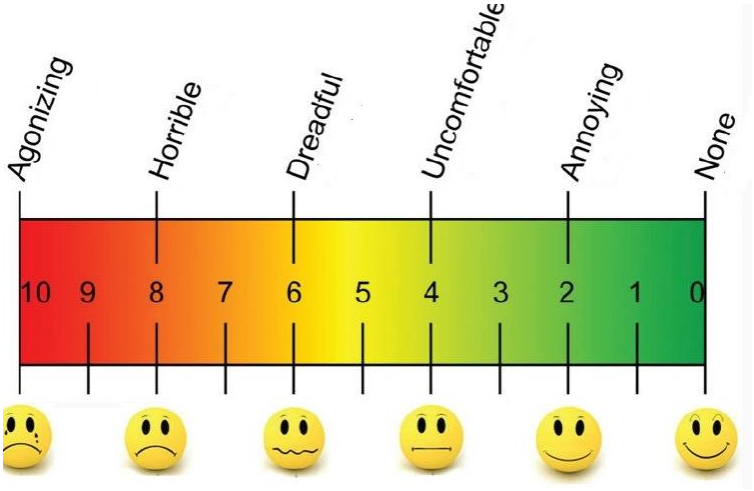
Follow up and assessment:

After the completion of operative procedure pain was monitored 10 mins before instillation to subsequently 15mins,30 mins, 1,2,4,6,12, 24 hrs after instillation in the Post Anaesthesia Care Unit. VAS were performed to assess global abdominal pain. As per requirement of the patient injection diclofenac intravenously as a form of rescue analgesia was given to maintain VAS <5 and the time was noted. The total analgesic requirement for 24 hrs. was recorded.

VISUAL ANALOGUE SCALE (VAS)

VAS use a vertical or horizontal line with words that convey "no pain" at one end and "worst pain" at the opposite end. The patient is asked to place a mark along the line that best indicates the level of pain. When using VAS clinician should explain the patient about this scale clearly.

VISUAL ANALOGUE SCALE (VAS) [38]



- 0-no pain
- 1-3- mild pain
- 4-7- moderate pain
- 8-10- intense pain

Observation and Results

The demographic data pertaining to Age, Weight, duration of surgery and ASA physical status was comparable in both groups and was not significant. ANOVA is applied for age and duration of surgery .P value<0.05 is considered significant t test applied.

Table 1: Demographic Parameters of patients

Parameters	Group A	Group B
Age in years	26.00±2.85	25.65±3.6
Weight in kgs	65.11±7.8	62.75±7.1
Duration of surgery (min.)	45.34±4.5	46.04±4.1

Table-2 Comparison of mean VAS Score over 24 hrs

VAS score	Bupivacaine		Bupivacaine+Dexmed		P value
	Mean	SD	Mean	SD	
10 min	0.00	0.11	0.00	0.12	0.20
15 min	0.00	0.11	0.01	0.09	0.00
30 min	0.22	0.09	0.00	0.10	0.00
1 Hr	0.95	0.10	0.43	0.61	0.00
2 Hr	2.02	0.49	0.97	0.60	0.00
4 Hr	2.85	0.50	1.89	0.75	0.039
6 Hr	2.82	0.58	2.64	0.98	0.38
8 Hr	2.70	0.67	2.80	0.95	0.13
12 Hr	2.89	1.94	3.10	0.95	0.01
24 Hr	4.39	2.04	4.29	1.01	0.74

The above table shows comparison of mean VAS score at at 0 min, 15 min, 30 min, 1 hr, 2 hr, 4 hr, 6 hr, 8 hr, 12 hr and 24 hr. p value was <0.05 and is significant.

Table-3: Rescue Analgesia in bupivacaine and bupivacaine with dexmedetomidine study group

Rescue Analgesia	Bupivacaine	Bupivacaine+Dexmed
10 min	0	0
15 min	0	0
30 min	0	0
1 Hr	0	0
2 Hr	7	0
4 Hr	15	4
6 Hr	16	12
8 Hr	19	18
12 Hr	22	18
24 Hr	24	20

This data found that both Bupivacaine and Bupivacaine with Dexmedetomidine study group are equally effective . This showed that Bupivacaine provided adequate analgesia for the first 1to 2 hours when compared to Bupivacaine+Dexmed, which provided adequate analgesia for about 4 to 6 hours and also the time taken for need for first rescue analgesia and also the number of rescue analgesia needed is reduced in Group BD than in Group B.

Table-4: Showing comparision of heart rate in between two groups at various time intervals during the study.(p value is <0.05)and is significant

heart rate	Bupivacaine		Bupivacaine+ Dexmed		P value
	Mean	SD	Mean	SD	
10 min	80.67	1.40	79.05	2.01	0.01
15 min	79.83	1.15	77.53	1.82	0.02
30 min	81.50	1.22	78.82	2.28	0.02
1 Hr	80.50	1.20	78.28	1.88	0.01
2 Hr	80.70	1.15	78.05	1.40	0.01
4 Hr	81.63	1.03	77.97	1.63	0.01
6 Hr	81.27	1.20	79.46	2.07	0.00
8 Hr	80.57	1.01	78.94	2.17	0.02
12 Hr	81.67	1.12	78.50	1.90	0.00
24 Hr	80.47	1.14	78.80	2.21	0.00

Heart rates were recorded from 10 min(before instillation) to 24 hours respectively in both groups. There was statistically significant difference between two groups of patients in terms of Heart rate all the time. Variation in trendline between two groups in all time duration is probably due to better pain relief in Bupivacaine with Dexmedetomidine study group when compared to Bupivacaine.

Table-5: showing comparision in systolic blood pressure in between two groups at various time intervals during the study.(p value is <0.05) and is significant.

SBP	Bupivacaine		Bupivacaine+Dexmed		P value
	Mean	SD	Mean	SD	
10 min	116.19	1.49	114.66	1.95	0.26
15 min	115.63	1.72	113.68	1.68	0.00
30 min	114.77	2.24	112.89	2.13	0.00
1 Hr	114.34	1.97	112.54	1.29	0.04

2 Hr	114.64	2.17	113.11	2.14	0.00
4 Hr	114.25	1.96	113.12	2.16	0.02
6 Hr	114.24	2.31	113.18	1.74	0.00
8 Hr	113.72	1.67	112.97	1.74	0.01
12 Hr	112.09	2.06	113.20	2.20	0.88
24 Hr	111.59	1.85	114.00	1.95	0.00

Systolic BP were also recorded from 10 min to 24 hours respectively in both groups. There was statistically significant difference between two groups of patients in terms of Systolic BP all the time except for 10 min and 12 hr. Variation in trendline between two groups in all time duration is probably due to better pain relief in Bupivacaine with Dexmedetomidine study group when compared to Bupivacaine.

DISCUSSION

In this study we compared antinociceptive effect of intraperitoneal application of bupivacaine and bupivacaine in combination with dexmedetomidine after LSCS.

1. Distribution of average age

The prospective, randomized, single blind comparative study was carried out in pregnant women of age between [4, 5]. 20-55 years. Group1 Patients who received instillation of 20 cc of 0.5% bupivacaine diluted to 40 cc with NS intraperitoneally total 40 cc (Grp B). In Group 2: Patients who received instillation of 20 cc of 0.5% bupivacaine diluted to 40 cc with NS intraperitoneally with dexmedetomidine 50mcg. Total 40cc (Grp BD). Informed written consent is taken for participation in the study in a language that patient easily understands mean age of Bupivacaine group was 26 and Bupivacaine with Dexmedetomidine study group was 25.65 which goes in accordance with previous studies by Rapolu et al. [8] and Deshmukh et al., [9].

2. Pulse rate in Bupivacaine and Bupivacaine with Dexmedetomidine study group

In the present study, Pulse rates were recorded from 10 min to 24 hours respectively in both groups and found that There was statistically significant difference between two groups of patients in terms of pulse rate all the time. Variation in trendline between two groups in all time duration is probably due to better pain relief in Bupivacaine with Dexmedetomidine study group when compared to Bupivacaine which was similar to the study done by Rapolu et al. [8] and Patel et. al., [10].

3. Systolic BP in each group

In our study, Systolic BP was obtained were recorded from 10 min to 24 hours respectively in both groups. There was statistically significant difference between two groups of patients in terms of Systolic BP all the time. Variation in trendline between two groups in all time duration is probably due to better pain relief in Bupivacaine with Dexmedetomidine study group when compared to Bupivacaine. Deshmukh et al., [9] also found the same results.

Rapolu et al. (8) recorded the same data that there was statistically significant difference between two groups of patients in terms of systolic blood pressure from 1 hour to 12 hours. Patel et. al., [10] also recorded the Changes in systolic blood pressure at different time interval. There was statistically significant difference between two groups of patients in terms of systolic blood pressure from 1 hour to 12 hours.

4. VAS (Visual Analogue Scale)

Pain score using VAS scale at frequent interval. VAS (Visual Analogue Scale) in each group was obtained at 10 min, 15 min, 30 min, 1 hr, 2 hr, 4 hr, 6 hr, 8 hr, 12 hr and 24 hr. The mean VAS as per graph-5, the gradual increase of the VAS scores is comparable, and showed statistical significance between two groups. Comparisons of pain between two groups by Visual Analogue Scale scores were statistically significant at all time points except 6,8 and 24 hour. Similar results were found by Rapolu et al. [8] that there was statistically significant difference in VAS pain score at 6, 8, 12, 18, 24 hours after surgery in group BD (3.21±0.83) compared to group B (2.81±0.91) up to 24 hours. Similar results were observed with study done by Ahmed, et al. [11] who compared the antinociceptive effect of dexmedetomidine or meperidine with bupivacaine to bupivacaine alone. Bakhamees, et al. [12] evaluated the patients who received dexmedetomidine and found that they had less VAS score as compared to placebo in the postoperative period.

5. Rescue Analgesia in bupivacaine and bupivacaine with dexmedetomidine study group

Rescue analgesia were also recorded from 10 min to 24 hours respectively in both groups. This data found that both Bupivacaine and Bupivacaine with Dexmedetomidine study group are equally effective. This showed that Bupivacaine provided adequate analgesia for the first 1 to 2 hours when compared to Bupivacaine+Dexmed, which provided adequate analgesia for about 4 to 6 hours and also the time taken for need for first rescue analgesia and also the number of rescue analgesia needed is reduced in Group BD than in Group B.

. Similarly, Mraovic [13] and co-worker's used 0.5% of Bupivacaine intra peritoneally after CO2 insufflation and after the dissection. They provided excellent analgesia up to 8 hours with less analgesic consumption. Hernandes et al [14] and his co-worker's added an adjuvant with local anaesthetics to study the efficacy. They compared 0.25% Bupivacaine with 2mg intra peritoneal morphine and 0.25% Bupivacaine with 2mg i.v morphine. Rescue analgesic (Metamizol) requirement were lower in Bupivacaine with intraperitoneal morphine group(2025± 1044mg) when compared with Bupivacaine with i.v morphine (4125± 1276mg) during the first 6hours. So adding an adjuvant with lesser concentration of local anaesthetics will provide analgesia similar to the higher concentration of anaesthetics.

CONCLUSION: We concluded that the administration of the intraperitoneal local anaesthetic agent, Bupivacaine in combination with dexmedetomidine can effectively reduce the need for

prescribing postoperative analgesic drugs as well as decrease postoperative pain severity in minimal surgery.

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