Research Article

A Comparative Study on The Safety and Efficacy Of Intrathecal 0.5% Hyperbaric Bupivacaine Alone Versus Bupivacaine Along With Adjuvant Dexmedetomidine In Parturient Undergoing Cesarean Section – A Prospective Observational Study

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ABSTRACT: **AIM:** The aim of this study is to assess the efficacy and safety of 0.5% hyperbaric bupivacaine administered alone versus when given along with adjuvant dexmedetomidine in parturients undergoing LSCS.
METHOD: A hundred parturients of ASA grade II & III undergoing LSCS under spinal anaesthesia were randomly assigned into two groups of 50 each: group B received 0.5% hyperbaric bupivacaine (2ml) and group BD received 0.5% hyperbaric bupivacaine (1.9ml) with 10 mcg of dexmedetomidine (0.1ml). The onset and duration of sensory & motor block, intraoperative hemodynamic changes, and duration of analgesia were documented. No. of rescue analgesics given in the first 24 hrs were also noted.
RESULT: There was no significant difference between the onset of sensory and motor block. The mean duration of motor blockade in Group B was 107 ± 13.55 mins and in Group BD was 351 ± 57.36 mins. The mean duration of sensory blockade in Group B was 156.82 ± 24.75 mins and in Group BD was 415.94 ± 55.16 mins. The mean duration of analgesia in Group B was 182.86 ± 24.06 mins and in Group BD was 489.24 ± 64.76 mins. The no. of rescue analgesics consumed in group BD was less in 1st 24 hrs.
CONCLUSION: The findings of this study indicate that 10 mcg dexmedetomidine is more beneficial when used in conjunction with 0.5% hyperbaric bupivacaine compared to 0.5% hyperbaric bupivacaine used alone in parturients undergoing C-section under spinal anesthesia.
Keywords: Bupivacaine, Dexmedetomidine, LSCS, Spinal anesthesia.

INTRODUCTION:

The use of spinal anesthesia for cesarean delivery is preferred over general anesthesia, not only because it avoids the risks associated with general anesthesia, such as failed intubation, but also because it enables more effective pain control, early ambulation, and a faster return to daily activities for newly delivered mothers, thus improving their quality of life.[1]

Bupivacaine is an amide local anesthetic that produces significant sensory and motor blockade. Despite its advantages, bupivacaine can cause side effects. A disadvantage of using hyperbaric bupivacaine alone is its relatively short duration of action, which necessitates early analgesic intervention in the postoperative period.[2]

Postoperative pain management in cesarean cases is essential in order to

avoid adverse effects of pain on the mother. In addition, it facilitates the early recovery of the mother and the nursing of her newborn. Therefore, adding adjuvants to local anesthetic agents in spinal anesthesia is a sensible concept and choice.[3]

Dexmedetomidine is an $\alpha_2$receptoragonist, known to maintain hemodynamic stability, and provide good quality intraoperative and prolonged postoperative analgesia with minimal side effects when given along with hyperbaric bupivacaine. Also, dexmedetomidine has been widely used in different types of nerve blockade.[3]

MATERIALS AND METHODOLOGY:

A prospective observational study was carried out in Seth Mohandas Tulsidas Maternity Hospital, Mysuru for a period of 6 months from April 2022 to September 2022.

100 parturients undergoing Cesarean section were enrolled in the study after obtaining informed consent and were randomly divided into two groups of 50 each: **Group B** received 2 ml of 0.5% hyperbaric Bupivacaine alone for spinal anesthesia. **Group BD** received 1.9 ml of 0.5% hyperbaric Bupivacaine along with 0.1 ml of Dexmedetomidine as an adjuvant intrathecally.

Inclusion criteria:

- Women willing to participate in the study
- Women undergoing LSCS
- Age group between 18 to 40 years
- Parturients with Hb level > 10g/dl
- Parturient with singleton, without any complication
- Parturients of ASA physical status II, and III

After shifting the parturient to the operation theatre, standard monitors like NIBP, PR, MAP, and SpO_2 were connected and basal readings were noted. With the parturient in either a sitting position or left lateral position, spinal anesthesia was performed by using a 25G or 26G Spinal needle at L_2—L_3/ L_3—L_4 L4—L_5 intravertebral space by the anesthetist under aseptic circumspection.

After spinal anesthesia, the sensory blockade was measured every minute at the T10 dermatome. This is checked in the midaxillary line and considered ready for surgery after a loss of sensation to cold swabs. Every 3 minutes, the level of sensory blockade was assessed and the time from the completion of injection to the maximum level of sensory blockade was recorded.

The onset time of motor blockade (the interval from the process of injecting the drug to the occurrence of Modified Bromage scale 1 motor blockade) was noted using the Modified Bromage scale.

Hemodynamics such as NIBP, PR, MAP, and SpO2 were recorded intraoperatively at baseline, 1 minute after SAB, every 3 minutes for the first 15 minutes, every 5 minutes for the next 15 minutes, and every 10 minutes until the end of surgery.

The baby's delivery time, weight of the baby and neonatal outcome (APGAR score at 1 and 5 min) was recorded.

Intraoperatively, Bradycardia (R <60/min) was treated with Inj. Atropine 0.6 mg IV and Hypotension (MAP less than 20% of the baseline) were treated with Inj. Mephentermine 6 mg IV.

Postoperatively, all parturients were assessed by the investigators for the duration of motor blockade (from the time of injection of the drug till the patient regained complete motor power) and duration of sensory blockade (from the time of injection of the drug till the patient regained sensation at S2 dermatome) and duration of analgesia (from the time of injection of drug till the patient complain of pain at the incision site).

Inj. Diclofenac 75mg was given intramuscularly to the patient who complain of pain at the incision site with a VAS score $\geq$ 3. And the total consumption of analgesia within the first 24 hrs was noted.

All parturients were monitored post-operatively at 2 hrs, 4 hrs, 6 hrs, 12 hrs, and 24 hrs for vitals and post-operative pain (through the VAS scale). The time of the first rescue analgesic given is noted, and side effects were directly monitored by the investigators.

Then incidence of side effects was postoperatively recorded to check the efficacy and safety of spinal anesthesia in both groups.

Inj. Glycopyrrolate was given IV to treat post-operative Bradycardia; Inj. Tramadol and Inj. Chlorpheniramine maleate was given IM to treat post-operative shivering.

STATISTICAL ANALYSIS:

Statistical analysis was performed by using Microsoft Office Excel 2019 for the evaluation of data.

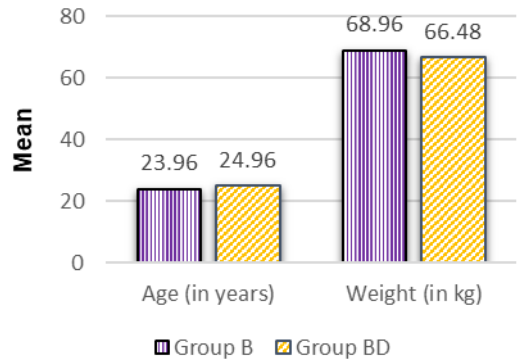
For nominal data Student t-test and categorical data chi-square test was used. The data were expressed as mean ± SD.

For categorical values, descriptive statistics were presented in the form of frequencies and percentages.
p-value < 0.05 was considered statistically significant.

OBSERVATION AND RESULTS:

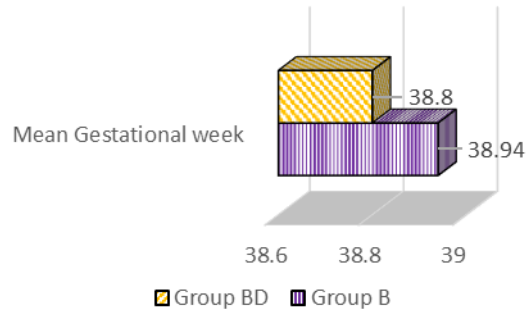
The mean age in group B was 23.96 ± 3.64 years and in group BD was 24.96 ± 3.71 years with a p-value of 0.177. The mean weight in group B was 68.96 ± 11.69 kg and in group BD was 66.48 ± 10.81 kg with a p-value of 0.273. Hence there were no statistically significant changes between the age and weight of parturients between the two groups. (Fig 1)

Fig 1: Age & Weight distribution between two groups



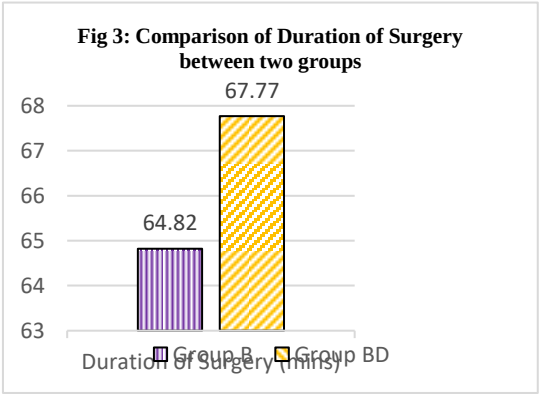
The mean gestational week in group B was 38.94 ± 1.11 weeks and in group BD was 38.8 ± 1.01 weeks with a p-value of 0.511. Therefore, the result was found to be statistically insignificant.

Fig 2: Comparison of gestational week between two groups



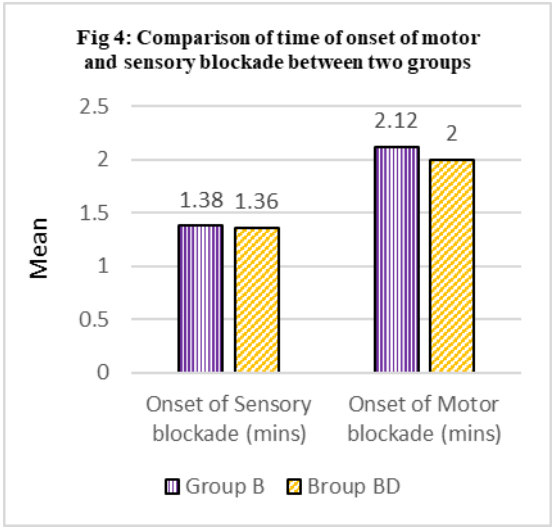
The mean duration of surgery in Group B was 64.82 ± 10.30 mins and in Group BD was 67.77 ± 15.52 mins with a p-value of 0.283. There was no significant difference in the duration of surgery between the two groups. (Fig 3)

Fig 3: Comparison of Duration of Surgery between two groups



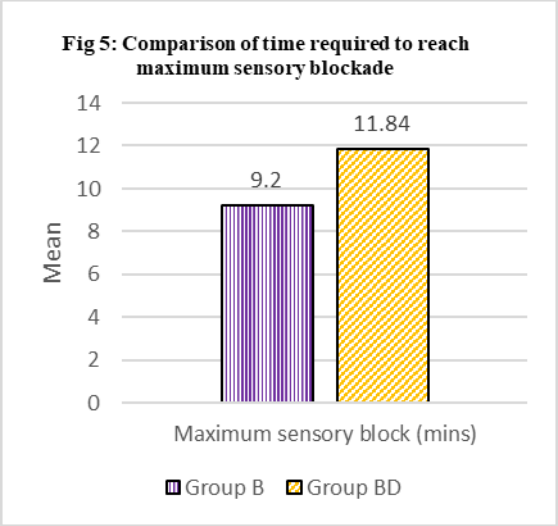
The mean onset of sensory blockade in Group B was 1.38 ± 0.49 mins and in Group BD was 1.36 ± 0.48 mins with p-value of 0.837. The mean onset time of motor blockade in Group B was 2.12 ± 0.52 mins and in Group BD was 2 ± 0.20 mins with a p-value of 0.131. Hence, there was no significant difference between onset of sensory blockade and motor blockade between two groups. (Fig 4)

Fig 4: Comparison of time of onset of motor and sensory blockade between two groups

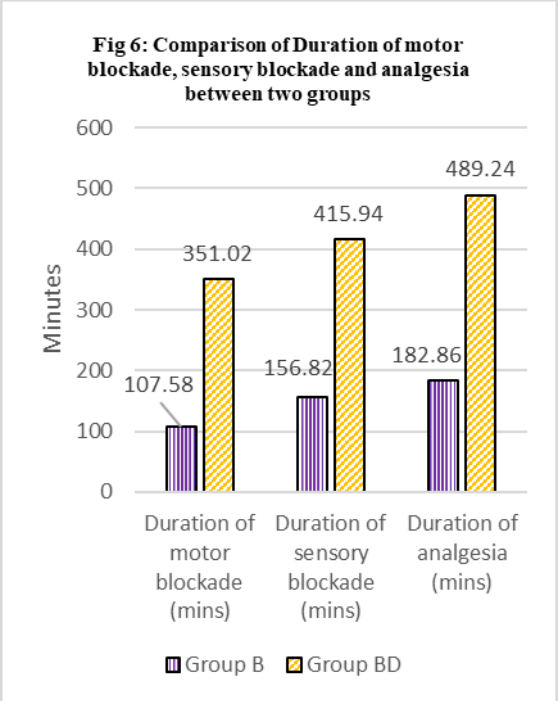


14 participants in Group B had T4 (28%) and 36 had T6 (72%) level of sensory block, where as in group BD all participants had a T4 (100%) level of sensory block with p-value < 0.0001 which was statistically significant.

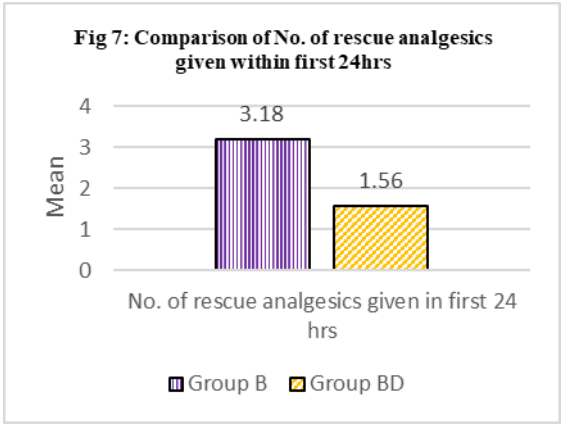
The mean time required for peak block height (maximum sensory blockade) in group B was 9.2 ± 1.42 mins and in Group BD was 11.8 ± 1.85 mins with p-value < 0.0001. Hence, the time required for maximum sensory blockade was statistically significant in both groups. (Fig 5)



The mean duration of motor blockade in Group B was 107 ± 13.55 mins and in Group BD was 351 ± 57.36 mins with p-value < 0.0001. The mean duration of sensory blockade in Group B was 156.82 ± 24.75 mins and in Group BD was 415.94 ± 55.16 mins with p-value < 0.0001. The mean duration of analgesia in Group B was 182.86 ± 24.06 mins and in Group BD was 489.24 ± 64.76 mins with p-value < 0.0001. Hence, the duration of motor blockade, sensory blockade, and analgesia were statistically significant. In Group B the mean no. of rescue analgesics consumed was 3.18 ± 0.48 and in Group BD was 1.56 ± 0.50 with p-value < 0.0001 which was statistically significant. (Fig 6)



In Group B the mean no. of rescue analgesics consumed was 3.18 ± 0.48 and in Group BD was 1.56 ± 0.50 with p-value < 0.0001 which was statistically significant. (Fig 7)



VAS score in group B was 2.42 ± 1.51, 1.88 ± 1.09, 2.88 ± 1.85, and in group BD was 0, 0, 0.38 ± 0.83 with p-value <0.001 which was statistically significant. At 12 hrs VAS score in group B was 2.48 ± 1.31 and in group BD was 2.44 ± 0.54, with a p-value of 0.842 which was statistically not significant. At 24 hrs VAS score in group B was 2.06 ± 1.47 and in group BD was 2.8 ± 0.90, with a p-value of 0.003 which was statistically significant. (Fig 8)

APGAR score was calculated to evaluate the health of new-born. There was no significant difference between the two groups in 1 minute and 5minute APGAR score. (Fig 9)

We observed shivering in 46% of participants in group B and 30% in group BD, Bradycardia in 2% of participants in group B and 10% of participants in group BD, hypotension in 4% of participants in group B, nausea was more frequent in group B (26%) than group BD (6%), vomiting was prevalent in group B, while headaches were reported by 22% in group B and 2% in group BD. There was no statistical difference between the two groups in terms of post-operative side effects. (Fig 10)

Fig 8: Comparison of VAS score between two groups

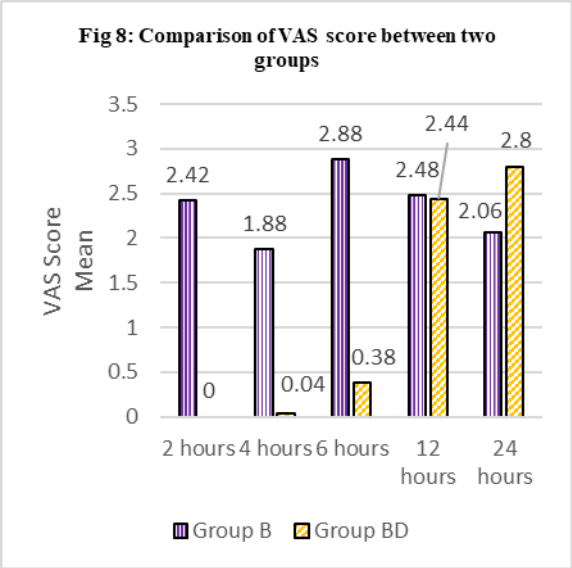
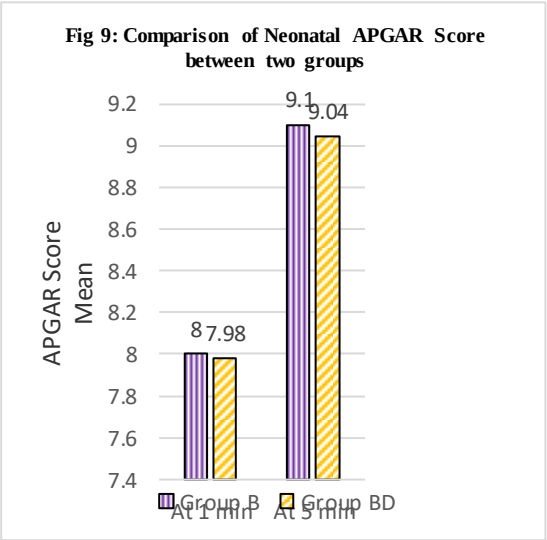


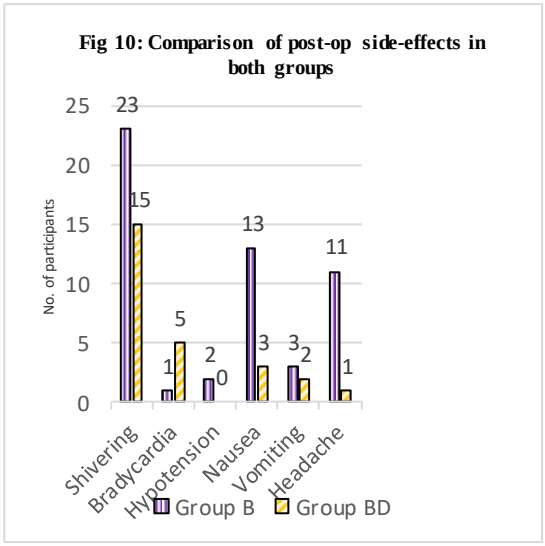
Fig 9: Comparison of Neonatal APGAR Score between two groups



DISCUSSION:

In our study, the mean onset of sensory blockade in Group B was 1.38 ± 0.49 mins and in Group BD was 1.36 ± 0.48 mins with a p-value of 0.837. The mean onset time of motor blockade in Group B was 2.12 ± 0.52 mins and in Group BD was 2 ± 0.20 mins with a p-value of 0.131. Hence, there was no significant difference between the onset of sensory block and motor block between the two groups. Thus, the time of onset of sensory block and motor block was comparable to the study conducted by M Azam et al [6].

Fig 10: Comparison of post-op side-effects in both groups



Hemodynamic changes:

Fig 11: Comparison of SBP between two groups

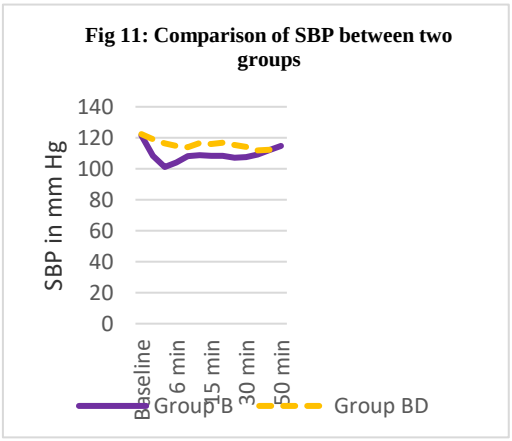
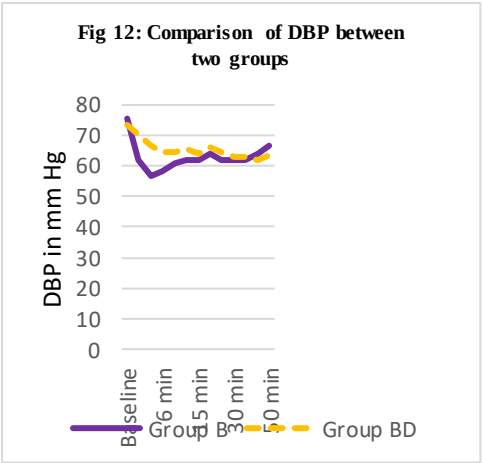
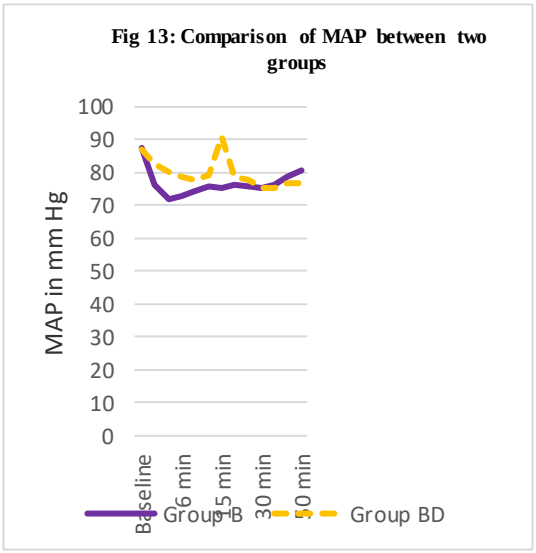
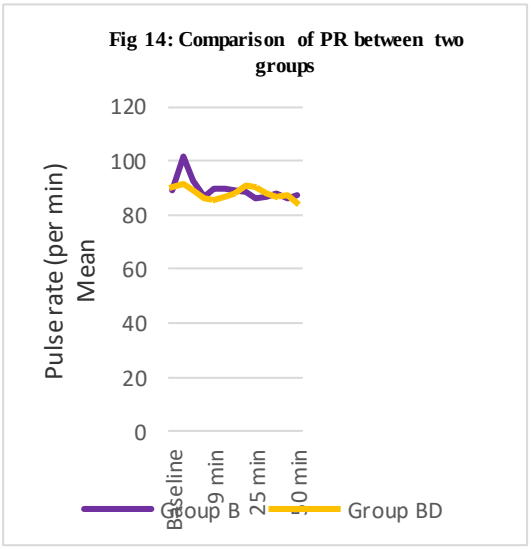


Fig 12: Comparison of DBP between two groups







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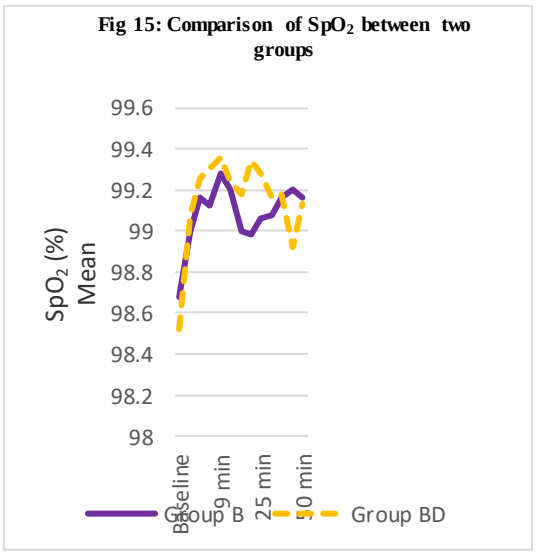

In our study, the peak sensory level achieved by group B was T_4 in 28% of participants and T_6 level in 72% which is consistent with the research result of Xiao-xiao Li et al [4] (peak sensory level at T_4 was 37% and T_6 was 61%). We found that the peak sensory level achieved by group BD in our study is T_4 in 100% of participants, this is in accordance with the study conducted by Chanda Salame et al [14].

In our study, the mean duration of motor block is found to be increased in group BD compared to group B (351 ± 57.36 mins **vs** 107 ± 13.55 mins). The mean duration of sensory blockade in Group B was 156.82 ± 24.75 mins and in Group BD was 415.94 ± 55.16 mins with a p-value < 0.0001. Hence, the duration of motor block and sensory block were statistically significant in our study. This was in accordance with the studies conducted by Rahul Rajan et al [5]., M Azam et al [6]., Sushruth MR et al [7]., Lin Liu et al [9]., Yong-Hong Bi et al [10]., and Chanda Salame et al [14]. Nasr I. A concluded that the duration of sensory and motor block is seen longer in the group of parturients, who were given with sufentanil or dexmedetomidine with hyperbaric bupivacaine as intrathecal spinal anesthesia. [8]

The mean duration of analgesia In Group B was 182.86 ± 24.06 mins and in Group BD was 489.24 ± 64.76 mins with a p-value < 0.0001. According to Ali M.S [15] in the dexmedetomidine group the mean postoperative duration of analgesia was 270.25±23.81 minutes, while in bupivacaine, the mean was found to be 140.46±10.38 minutes. Ali M.S concluded that women undergoing elective cesarean section with standard spinal anesthesia with dexmedetomidine have longer post operative analgesia duration compared to standard spinal anesthesia given alone.

In our study, the mean no. of rescue analgesics consumed in group B was 3.18 ± 0.48 and in Group BD was 1.56 ± 0.50 with a p-value < 0.0001. In the study conducted by Chanda Salame et al., the Bupivacaine group required 2-3 doses of Diclofenac and Dexmedetomidine required 1-2 doses of Diclofenac as a rescue analgesic in the first 24 hrs. [14]

Intraoperative side-effects:

The incidence of shivering is lower in group BD (2%) compared with group B (24%) in our study. It is comparable with the results of Sushruth MR [7]

and Karim Nasseri [11] who had found a lower incidence of shivering with the use of intrathecal dexmedetomidine.

In our study, the mean MAP was found significantly higher from 1 min after SAB to 6 mins in group BD compared to group B. 10% of participants in group B and 2% of participants in group BD developed hypotension. In the study conducted by M Azam et al [6]., 36.7% with bupivacaine and 13.3% with dexmedetomidine developed hypotension which was statistically different.

The pulse rate was significantly higher at 1 min after SAB from the baseline in Group B in our study. The incidence of bradycardia was not significant in our study. None in group BD and 2% of participants in group B developed bradycardia. Karim Nasseri [11] reported 8.33% with bupivacaine and 4% with dexmedetomidine developed bradycardia.

VAS score:

With regard to VAS score our study is comparable to studies conducted by Rahul Rajan et al [5] and Chanda Salame et al [14]. In our study, the VAS score was significantly higher in group B at 2 hrs, 4 hrs, and 6 hrs compared to group BD. At 12 hrs also VAS score was lesser in group BD but was not statistically significant.

Neonatal APGAR score:

There was no significant difference between the two groups at 1-minute and 5-minute APGAR scores ($p = 0.836$, $p = 0.549$, respectively). In the study by Houman Teymourain et al., [12] and Yong-Hong Bi et al [10]., it was shown that dexmedetomidine had no adverse effects on neonatal APGAR scores and no significant difference was seen in both groups.

Postoperative side-effects:

We observed shivering in 46% of participants in group B and 30% in group BD, Bradycardia in 2% of participants in group B and 10% of participants in group BD, hypotension in 4% of participants in group B, nausea was more frequent in group B (26%) than group BD (6%), vomiting was prevalent in group B, while headaches were reported by 22% in group B and 2% in group BD. There was no statistical difference between the two groups in terms of post-operative side effects.

Xia F et al [13] in their study observed 33.33% hypotension, 15.5% nausea and vomiting, and 20% shivering cases, whereas the dexmedetomidine group had 17.7% hypotension, nausea, and vomiting cases, 15.5% shivering cases, and 2.2% PDPH case.

CONCLUSION:

According to our findings, when dexmedetomidine is combined with hyperbaric bupivacaine, the following results can be achieved:

- Prolonged duration of sensory block
- Prolonged duration of motor block
- Hemodynamics were stable throughout the LSCS, except for Bradycardia in few patients post-operatively.
- Prolonged duration of analgesia
- The incidence of post-operative shivering was less
- Consumption of no. of rescue analgesics was less
- Incidence of intra-operative and postoperative side effects was less

Hence, the findings of this study indicate that dexmedetomidine is more beneficial and safer when used in conjunction with hyperbaric bupivacaine than when used alone Intrathecally in parturients undergoing C-section under spinal anesthesia.

ACKNOWLEDGEMENT:

The authors are thankful to the Department of Anaesthesiology, Seth Mohandas Tulsidas Maternity and Child Health Hospital, Mysuru for providing all the facilities to carry out this work.

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