Original Research Article

A prospective comparative study of effect of addition of dexmedetomidine 0.5 mcg/ml with 0.2% ropivacaine and 0.2% ropivacaine alone in epidural labour analgesia

Deepak Tugave[1*], Mukaram[2], Amruta[3]

[1]Assistant Professor, Department of Anesthesia, Bidar Institute of Medical Sciences, Bidar, Karnataka, India
[2]Associate Professor, Department of Anaesthesiology, Gulbarga Institute of Medical Sciences, Gulbarga, Karnataka, India
[3]Assistant Professor, Department of OBG, Gadag Institute of Medical Sciences, Gadag, Karnataka, India

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Abstract

Introduction: The pain of childbirth is the most painful experience for many women and maternal request is a sufficient indication for providing her pain relief during labour. The McGill pain questionnaire ranks labour pain scale between cancer pain and amputation of a digit.[1] Labour pain is associated with maternal physiological responses, which are not necessarily beneficial to the foetal well-being. **Materials and Methods:** This prospective, comparative study was going to be conducted at Department of anesthesia, Bidar Institute of Medical Sciences, Bidar during the period of November 2021 to April 2022. The sample size obtained was 38 for each group which was rounded up to 60 for each group. So final sample size estimated was 120. Reference article for sample size calculation is made based on the study conducted by Zhao Y et al. Total of 120 parturients of age group 20-35 yrs., Heights in cm: >150 cms, full term singleton vertex presentation, previous normal vaginal delivery, consented for the study, Primigravida and multigravida of physical status ASA grade I&II, foetus having normal heart rate pattern before induction of Epidural, Cervical dilatation of 3-5 cms were included in group and divided in 2 group using computer generated randomization technique. **Results:** The highest sensory level in both groups was observed at T6 (p=0.190). Total drug requirement in both groups was calculated. All the subjects 60 (100%) in both the groups required first and second dose of bolus. While third bolus was required only for 50 (83.3%) subjects of RD groups compared to 60 (100%) of RS group. Fourth bolus was required only for 34 (56.7%) subjects of RD groups compared to 50 (83.3%) of RS group. Fifth bolus was required only for 2 (3.3%) subjects of RD groups compared to 12 (20.0%) of RS group. There was statistically significant difference between the two groups for third (p=0.020), fourth (p=0.024) and fifth bolus (p=0.044). The total drug requirement for RS group (32.27+- 4.91) was significantly higher than the RD group (27.46 +or- 6.53), p value of 0.021. **Conclusion:** Epidural labour analgesia is considered to be a gold standard for pain management during labour, when ropivacaine along with dexmedetomidine is used. Many studies have been conducted to prove the use of dexmedetomidine in obstetric anesthesia in optimal doses. This wonder drug provides excellent maternal satisfaction and good progress of labour with minimal side effects to mother and foetus.

Key Words: childbirth, dexmedetomidine, Epidural labour analgesia, foetus.

Introduction

The pain of childbirth is the most painful experience for many women and maternal request is a sufficient indication for providing her pain relief during labour. The McGill pain questionnaire ranks labour pain scale between cancer pain and amputation of a digit[1]. Labour pain is associated with maternal physiological responses, which are not necessarily beneficial to the foetal well-being. Maternal hyperventilation causes an increase in oxygen consumption, plasma catecholamine concentrations, hypertension and tachycardia[2]. In addition, maternal hyperventilation may reduce foetal oxygenation, resulting in abnormal foetal heart rate patterns and an increased operative delivery[3].

Superficially, obstetric anaesthesia appears to be a simple field with a limited range of interest, but it is a deceptively demanding subspecialty. The dynamic events of normal labour require that the muscles concerned with delivery retain their power and coordination to the full[4]. Attempts to alleviate pain during labour have been made by different researcher & scientists that ranged from psychological, pharmacological, physical or combination of these techniques but all with limited success. In mid-nineteenth century labour analgesia was popularized across Europe and America after John snow administered Chloroform to Queen Victoria for birth of her 8th child, Prince Leopold (1853). Several methods have been practiced & developed since then for labour analgesia[5].

The contemporary goal of providing maternal labour analgesia is the relief of the suffering and the pain of labour and delivery, while minimizing effects on maternal safety, awareness, motor functions, progress of labour and foetal well-being. Regional anaesthetic techniques are especially well suited for achieving this goal[6]. Over the past ten years there have been remarkable changes in the field of obstetric anaesthesia. Not only newer techniques such as combined spinal-epidural, continuous epidural infusions, walking epidurals and patient controlled epidural analgesia (PCEA) are now available, Epidural analgesia for labour was maintained either by intermittent boluses or by continuous infusion of the local anaesthetics[7,8]. Each technique had its own advantages and disadvantages though the purpose remains the same: a painless labour and a healthy neonate.

Of all labour analgesia techniques, epidural analgesia is the most effective form of analgesia and has become the “gold standard” in obstetric care. Ropivacaine has been used commonly for epidural labor analgesia, because of less motor block and stable haemodynamics[9]. dexmedetomidine, an alpha 2- agonist for alpha 2-adrenergic receptors, possesses properties of analgesia and sedation without any respiratory depression effect and enhances their effects without increasing the incidence of side effects when added to local anesthetic agents. It has a opioid sparing effect and hence included in labour analgesia to reduce the side effects caused by opioid when added to local anaesthetics[10].

*Correspondence
Dr. Deepak Tugave
Assistant Professor, Department of Anesthesia, Bidar Institute of Medical Sciences, Bidar, Karnataka, India.
E-mail: Dr.deepaktugave21@gmail.com

Aims and objectives

We wanted to compare efficacy, safety, quality of analgesia, total drug requirement, effect on the course and duration of labour, neonatal outcome, maternal satisfaction and adverse events if any, of ropivacaine 0.2% + 0.5 mcg/mL of dexmedetomidine with that of 0.2% of ropivacaine alone, for epidural labour analgesia.

Materials and methods

This prospective, comparative study was going to be conducted at Department of anesthesia, Bidar Institute of Medical Sciences, Bidar during the period of November 2021 to April 2022.

The sample size obtained was 38 for each group which was rounded up to 60 for each group. So final sample size estimated was 120. Reference article for sample size calculation is made based on the study conducted by Zhao Y et al. Total of 120 parturients of age group 20-35 yrs., Heights in cm: >150 cms, full term singleton vertex presentation, previous normal vaginal delivery, consented for the study, Primigravida and multigravida of physical status ASA grade I&II, foetus having normal heart rate pattern before induction of Epidural, Cervical dilatation of 3-5 cms were included in group and divided in 2 group using computer generated randomization technique.

Group RS received 0.2% ropivacaine epidurally as bolus dose of 8 mL followed by intermittent top ups as and when required.

Group RD received 0.2% ropivacaine with 0.5 mcg/mL of dexmedetomidine epidurally 8 mL as bolus dose followed by intermittent top ups as and when required.

A complete history of each patient was obtained, and clinical examination was done. Routine investigations along with coagulation profile was obtained and noted. All baseline parameters like Heart Rate, Blood Pressure, ECG, SpO2, Foetal Heart Rate were recorded. Lignocaine sensitivity test was done. Intravenous access was achieved with 18G intravenous cannula. Preloading was done with ringer lactate solution 10 mL/Kg. With Patient in sitting position, her back was cleaned, painted and draped, to achieve and maintain asepsis. A 2 mL Lignocaine 2% of solution was injected locally in L3-L4 space into the skin and subcutaneous tissue. An 18G epidural needle was advanced up to interspinous ligament. A 10cc loss of resistance syringe with 2mL of air in it was attached at the hub of the needle after removing the stylet. The needle was then advanced slowly until loss of resistance felt. Epidural space was confirmed with hanging drop technique. An 18G epidural catheter was threaded through the needle and secured in the epidural space with 5 cms of length into the epidural space. Following this, needle was removed, and catheter strapped firmLy to the back of the patient with an adhesive tape. Distal end of the catheter was covered with a sterile gauge piece and a cover. During this whole procedure care was taken not to advance either the needle or the catheter during contractions as chance of piercing the dura or a blood vessel is maximum during contractions.

After fixing the catheter patient was made to lie down with a wedge placed on her left side to avoid aortocaval compression. After negative aspiration for blood and CSF a test dose of 3 mL of 2% Lignocaine with adrenaline was administered to confirm epidural placement of the catheter. Maternal heart rate every 5 mins in initial half an hour after the drug was administered and thereafter every 30 minutes. Maternal hypotension was considered if fall in blood pressure was 20% or more in comparison to baseline value and it was treated with increased rate of intravenous fluids and if needed injection ephedrine 6 mg bolus. Bradycardia (less than 50 beats/minute).6 It was treated with atropine given in bolus of 0.6 mg. The intensity of pain was assessed using a 10 cm visual analogue scale. All patients were made familiar with VAS scoring system earlier. The patient was asked to point to the position on the line between 1-10 cm to indicate how much pain they were currently feeling. The far-left end indicates 'NO PAIN' and the far-right end indicates 'WORST PAIN'. 0- no pain, 1-3-mild pain, 4-7 moderate pain, 8- 10 severe pain.

Pain scale was assessed every 5 mins after the drug was given and thereafter every 30 minutes on a scale of 0-10. Sensory level was assessed by absence of sensation to pin prick. foetal heart rate was monitored by obstetrician by using Foetal Doppler. Incidence of motor blockade, hypotension, bradycardia, nausea, vomiting, motor blockade were also looked for and appropriately treated. Neonatal status was assessed by APGAR score at 1 min and 5 mins. using parameters of Heart rate, Respiratory rate, Color of the skin, muscle tone and grimace response to stimulus<7 considered signicant.7 The assessment of maternal satisfaction was done by asking the parturient about pain relief and acceptance of this technique in view of rural myths and belief.

Statistical Analysis

Statistical analysis was done using descriptive and analytical statistics. The chi square test was used to check differences in proportions. Continuous variables are expressed as mean and standard deviation. The normality of continuous data was analysed by the Shapiro-Wilk test. As the data followed normal distribution, parametric test (t-test) was used to analyse the data. The independent sample t- test was used to check mean difference. The level of significance was kept at $p<0.05$.

Results

The highest sensory level in both groups was observed at T6 (p=0.190). Total drug requirement in both groups was calculated. All the subjects 60 (100%) in both the groups required first and second dose of bolus. While third bolus was required only for 50 (83.3%) subjects of RD groups compared to 60 (100%) of RS group. Fourth bolus was required only for 34 (56.7%) subjects of RD groups compared to 50 (83.3%) of RS group. Fifth bolus was required only for 2 (3.3%) subjects of RD groups compared to 12 (20.0%) of RS group. There was statistically significant difference between the two groups for third (p=0.020), fourth (p=0.024) and fifth bolus (p=0.044). The total drug requirement for RS group (32.27+- 4.91) was significantly higher than the RD group (27.46 +or- 6.53), p value of 0.021.

The duration of labor (mins) between the two groups was compared. It was found that the mean labor time for stage I and stage II did NOT show any statistical significance difference between the two groups. The total labor duration of RD group (180.93+-21.26) was significantly lower than the RS group (199.40+-24.63), (p=0.003) (table 2) The haemodynamic parameters i.e. the mean heart rate, systolic blood pressure, mean arterial pressure, SPO2 did not show any statistical significance in both the groups. The mean VAS score between the two groups at various time intervals did NOT show any statistically significant difference for mean VAS score at 5 min (p=0.209), 30 min (p=0.447), 120 min (p=0.140) and 210 min (p=0.579) between the two groups (p>0.05).

Table 1: Details of APGAR at Baseline and 5 Mins. of the Study Population

APGAR	Group RS (N=60)		Group RD (N=60)		P-Value
	Mean	SD	Mean	SD	
1 min	8.00	0.37	8.00	0.36	1.000
5 min	8.90	0.30	8.85	0.18	0.309

Table 2: Details of Duration of Labor (Mins) among the Study Population

Variable	Group RS (N=60)		Group RD (N=60)		P-Value
	Mean	SD	Mean	SD	
Stage 1	162.95	20.6	158.05	15.25	0.294

Stage II	35.87	8.60	37.18	8.64	0.003

Table 3: Average details of age, weight and height of study population

Parameter	Group RS (N=60)	Group RD (N=60)
Age	25.9	24.65
Weight	55.92	78.75
height	105.73	84.52

Table 4: Distribution of Bolus Requirement among the Study Population

Dose	Group RS (N=60)	Group RD (N=60)
First dose	100%	100%
Second dose	100%	100%
Third dose	100%	83.30%
Fourth dose	83%	56.70%
Fifth dose	20%	3.30%

Table 5: Comparison of Mean Drug Requirement between the Two Groups

	Group RS (N=60)	Group RD (N=60)
Mean Drug Requirement	30.93	27.46

Table 6: Comparison of Maternal Satisfaction between the Two Groups

Maternal Satisfaction	Group RS (N=60)	Group RD (N=60)
Excellent	26.70%	73.30%
Good	53.30%	46.70%

Discussion

Ropivacaine has been introduced into obstetric anesthetic practice with the proposed advantage of causing less motor blockade. Previous studies proved that dexmedetomidine could extend the duration of local anesthetics when added as a adjuvant for epidural analgesia. In our study, we found that dexmedetomidine could decrease the total drug requirement when combined with ropivacaine for labor analgesia without increasing side effects[8].

The present study compared the quality of analgesia, total drug requirement, effects on course and duration of labour, neonatal outcome (APGAR Score), adverse events if any and maternal satisfaction while using intermittent epidural bolus doses of 0.2% ropivacaine and 0.2% ropivacaine plus 0.5 mcg/ml dexmedetomidine. S. Fyneface-Ogan et al, studied the role of dexmedetomidine in labour outcome when added as adjuvant with intrathecal bupivacaine in comparison with fentanyl in bupivacaine. There was no significant difference in APGAR score and umbilical venous blood pH in both the groups also foetal heart rates and maternal blood pressure were unchanged after injection of drug in both the groups[9].

Similar trends of foetal heart rate were seen in our study. Yu et al in their in vivo study evaluated role of dexmedetomidine in cesarean section under general anaesthesia and its effects on foetus, placental transfer and foetal metabolism was noted to provide a reference for the

clinical use of dexmedetomidine. The rate of placental transfer of dexmedetomidine was 0.76, as dexmedetomidine is retained in placenta and hence very negligible amount is transferable. In our study most significant findings were less total drug requirement in ropivacaine with dexmedetomidine group than in plain ropivacaine group. Tao Zang et concluded that dexmedetomidine is better than sufentanil in terms of analgesic effect and low drug requirement[10,11].

Conclusion

Epidural labour analgesia is considered to be a gold standard for pain management during labour, when ropivacaine along with dexmedetomidine is used. Many studies have been conducted to prove the use of dexmedetomidine in obstetric anesthesia in optimal doses. This wonder drug provides excellent maternal satisfaction and good progress of labour with minimal side effects to mother and foetus. Ropivacaine with dexmedetomidine requires less top up dosage compared to ropivacaine alone in labor analgesia with minimal side effects.

References

1. Khan MA, Yasin B, Zaffar M, et al. Epidural analgesia. The Professional Medical Journal 2008;15(01):101-3.
2. Sia AT, Kwek K, Yeo GS. The in vitro effects of clonidine and dexmedetomidine on human myometrium. Int J Obstet Anesth 2005;14(2):104-7.
3. Fernando R, Bonello E, Gill P, et al. Neonatal welfare and placental transfer of fentanyl and bupivacaine during ambulatory combined spinal epidural analgesia for labour. Anaesthesia 1997;52(6):517-24.
4. Anim-Somuah M, Smyth RM, Jones L. Epidural versus non-epidural or no analgesia in labour. Cochrane Database Sys Rev 2011;(12): CD000331.
5. Mousa WF, Al-Metwalli R, Mostafa M. Epidural analgesia during labor vs no analgesia: a comparative study. Saudi J Anaesth 2012;6(1):36-40.
6. Jun W, Zhengzhuang A, Li O. Analgesic efficacy of dexmedetomidine used for epidural anesthesia on labor analgesia. Biomedical Research 2018;29(3):426-30.
7. Kiran S, Jinjil K, Tandon U, et al. Evaluation of dexmedetomidine and fentanyl as additives to ropivacaine for epidural anesthesia and postoperative analgesia. J Anaesthesiol Clin Pharmacol 2018;34(1):41- 5.
8. Selim MF, Elnabtity AMA, Hasan AMA. Comparative evaluation of epidural bupivacaine–dexmedetomidine and bupivacaine-fentanyl on Doppler velocimetry of uterine and umbilical arteries during labor. J Prenat Med 2012;6(3):47-54.
9. Cousins MJ, Veering BT. Update on anatomy, physiology and pharmacology of epidural neural blockade. Pain Management and Anesthesiology 1998:277-94.
10. Naaz S, Ozair E. Dexmedetomidine in current anaesthesia practice-a review. J Clin Diagn Res 2014;8(10):GE01-4.
11. Wangping Z, Ming R. Optimal dose of epidural dexmedetomidine added to ropivacaine for epidural labor analgesia: a pilot study. Evid Based Complement Alternat Med 2017;2017;1-4.

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