Effect of the Use of Dexmedetomidine as a Local Anesthesia Adjuvant to Bupivacaine 0.1% in Epidural Labor Analgesia

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Abstract

Objective: Objectives of this study are to study the effectiveness of adding dexmedetomidine in labor epidurals with 0.1% bupivacaine in females undergoing normal vaginal delivery.

Material and Methods: This study was proposed for the pregnant females in active labor in obstetrical and gynecological department of Hameed Latif Hospital who request epidural analgesia for pain relief during normal vaginal delivery. Sample size is calculated using G power software. One hundred thirty three (134) women were included in study and it was assured that they all met inclusion. All participants were divided into Control and study groups. Patients in control group (67 women) were given 0.1% bupivacaine 10ml diluted in normal saline. Study group (67 patients) was also given 0.1% bupivacaine diluted in normal saline 10 ml along with 50 microgram dexmedetomidine. After giving loading dose and epidural activation 0.1% 10ml bupivacaine at a rate of 10ml/hr was started in both groups. Modified bromage scale was used to describe the Level of motor block. Side effects were reported and managed. The time elapsed from start of labor till complete cervical dilation, timing of each stage of labor, and either spontaneous vaginal, instrumental delivery or caesarean section being done or not is noted for each patient. 6 hours post Delivery, maternal satisfaction was evaluated with the five-point Likert's scale as follows: 1 for poor, 2 for fair,3 for good, 4 for very good, and 5 for excellent satisfaction. Onset of analgesia was the primary outcome, while the secondary outcomes included the duration of analgesia, hemodynamic variations, progress of labor, mode of delivery and complications to mother after getting dexmedetomidine in epidural.

Results: Dexmedetomidine group showed a remarkably early onset of analgesia as compared to bupivacaine group. (6.90±1.42 vs 11.66±1.68) $p<0.001$. VAS in dexmedetomidine group remained ≤3 for 209.24±67.032 mins vs 104.18±23.65 mins in control group; $p<0.001$.

Conclusion: Duration of Analgesia is prolonged and onset of analgesia is shortened after adding dexmedetomidine with bupivacaine without any significant side effects.

Keywords: Labor Analgesia, pregnant, Epidural Anaesthesia.

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Introduction

Females who have experienced normal labor for child birth have claimed it to be most difficult and distressing moments of their life due to excruciating and unbearable pain.[1] Provision of effective and satisfactory labor analgesia to the parturient helps in achieving greater degree of well-being for both mother and child.[2] Several medical and non-medical pain relief methods are used since ages for pain relief

during childbirth. Epidural anesthesia and intravenous opioids (pethidine) are most commonly offered to the mothers for relieving labor pain.[3] So far, Epidural is considered gold standard in attaining maternal satisfaction for pain free deliveries. lt can be modified for individual parturient in order to achieve highest level of comfort and pain relief. To attain better and prolonged analgesia several additives have been used with local anesthetists and their effects are studied.[4] Epidural opioids are conventionally being used as adjuvants, however associated side effects (nausea, vomiting, and pruritus) may limit their uses.[5] An alpha 2 adrenoceptor agonist, dexmedetomidine, has been effectively used and studied in labor epidurals and provided better analgesia without significant side effects.[6] Hameed Latif Hospital is one of the largest tertiary care private setup offering painless deliveries in Lahore. It is need of the hour to modify and improve our clinical practice in order to achieve highest level of patient satisfaction and provision of best possible maternal and fetal outcome. This study is proposed to investigate and elaborate the effect of adding dexmedetomidine to bupivacaine in labor epidurals and to study possible side-effects associated with its use.

Material and Methods

This study was proposed for the pregnant females in active labor in obstetrical and gynecological department of Hameed Latif Hospital who request epidural analgesia for pain relief during normal vaginal delivery. This study is registered at clinicaltrials.gov as a randomized clinical trial. Trial registry number is NCT 06550414 Sample size is calculated using G power software. Keeping Alpha error 0.05 and power of study 80% the total sample size is calculated to be 134 It is equally divided in 2 groups. Study design is Prospective double blinded randomized control trial. Some operational definitions are Time required to attain a VAS of less than or equal to 3 after giving loading dose is onset of analgesia. Time after loading dose till the VAS >3 or break- through pain reported by the mother is duration of analgesia. Side effects are hypotension that is, Systolic blood pressure less than 100 mmHg or a decrease in mean arterial pressure (MAP) greater than 30% from the baseline. Bradycardia, heart rate less than 60 and Nausea / Vomiting. Sampling technique used is Non probability purposive sampling. All Patients were assigned an envelope and they were randomly divided into 2 groups using a computer generated method.

Patients in 37 or more weeks of pregnancy, having a single pregnancy with cephalic presentation, without any significant systemic disease was included in the study. Patients with breech or lateral presentation, multiple pregnancies, eclampsia or preeclampsia, hypertension, diabetes, bleeding abnormalities, obesity (morbid or severe) or known allergic to any used drug were omitted from trial. All patients who met inclusion criteria were explained the associated risks of epidural analgesia and the use of dexmedetomidine in epidural block. Written informed consent was taken from all females. All participants were divided into Control and study groups. Patients in control group (67 women) were given 0.1% bupivacaine 10ml diluted in normal saline. Study group (67 patients) was also given 0.1% bupivacaine diluted in normal saline 10 ml alongwith 50 microgram dexmedetomidine. After giving loading dose and epidural activation, infusion was started in both groups. 0.1% 10ml bupivacaine at a rate of 10ml/hr was started in both groups. The infusions were prepared by a resident anesthesiologist who was not included in the study. Furthurmore, anesthesiologist providing epidural analgesia and resident involved in following labor progress and pain scores were blinded. Ringer's lactate 500ml bolus was given to all the women who were 3 to 5 cm dilated (cervical) and were in active 2nd stage of labor; afterwards routine monitoring was started in all the patients including noninvasive blood pressure monitoring, electrocardiography, and pulse oximetry. All patients were explained the way of reporting their pain according to visual analog scale (Vas). VAS is from 1 to 10. (0 for no pain perceived at all to 10 for the worst pain ever experienced). Patients were then made to sit on a couch with a pillow to make proper position. Under complete aseptic techniques local anesthetic was infiltrated into L 3- 4 and L 4-5 intervertebral disc by xylocaine 2%.The epidural space was approached via an 18-gauge touhy needle. Loss of resistance to air was used to ensure proper epidural space. Catheter was placed in epidural space and it was fixed at a depth of 4.5 cm. Aspiration was done to rule out intrathecal or intravascular placement. Next injection of 3ml 2% xylocaine with 5microgram/ml adrenaline was given as a test dose. Patient was observed for tachycardia or tinnitis.

After properly securing the catheter woman were placed into left lateral position in order to avoid inferior vena caval compression by gravid uterus. Drug in epidural catheter was given only during uterine contraction to decrease the risk of over spread of drug into epidural space. In case of VAS greater than 3 and breakthrough pain l, then a top up dose of bupivacaine 0.1% 10ml was given. Total number of top up doses was noted down. Modified bromage scale was used to define the level of motor block. Readings of bromage scale was taken before installing epidural catheter, then after every 15 minute during the 1st hour and then after every 30 minutes till delivery. If bromage scale greater than 2 was recorded, bupivacaine infusion was either decreased or stopped until bromage scale decreased to less than 1. Side effects were reported and managed. Heart rate and blood pressure both systolic and diastolic were monitored and recorded before activating epidural catheter and at 5, 15, 30, 45 and 60 mins after epidural activation and then every hour till the end of delivery. Hypotension, if happened, was treated by Phenylephrine (bolus of 50 micrograms) along with intravenous fluids. Bradycardia was treated by intravenous

0.5 mg atropine. Cardiotocography was used for fetal heart rate monitoring.in case of abnormalities in CTG mother was given bolus of IV fluid and her position was changed to left lateral. The time needed for cervical dilatation, the duration of each stage of labor, and the mode of delivery was recorded. maternal satisfaction was evaluated 6 hours post-delivery with the five- point Likert's scale as follows: 1 for poor, 2 for fair,3 for good, 4 for very good, and 5 for excellent satisfaction. Onset of analgesia was the primary outcome, while the secondary outcomes included the duration of analgesia, hemodynamic changes, labor progress, and maternal complications. Data was analyzed, entered and tabulated using SPSS version 26. Frequencies, percentages, mean values and standard deviation (SD), or median and range were used to describe baseline characteristics in Data entering process. Qualitative data was compared using Chi-Square test (or Fisher's exact test) Besides, Mann-Whitney U test and independent- samples test were used to compare two groups of non-parametric and parametric quantitative data respectively. P values <0.05 was considered statistically significant for all of the used statistical tests.

Results

Total 134 females were enrolled in the study. They all met the inclusion criteria. They were allocated into 2 equal groups. Patient's characteristics, cervical dilation at time of epidural analgesia and total duration of epidural anesthesia is shown in **Table-1**. The dexmedetomidine group showed a remarkably early onset of analgesia as compared to bupivacaine group. (6.90±1.42 vs 11.66±1.68) p<0.001. Simultaneously the duration of analgesia after loading dose of bupivacaine in both groups was significantly different. VAS in dexmedetomidine group remained ≤3 for 209.24±67.032 mins vs 104.18±23.65 mins in control group; p<0.001. **Fig-1** showed total number of top ups required by patients in both the groups after activation of epidural till delivery. After loading dose 3 patients out of 67 delivered after only 1 top-up dose in dexmedetomidine group. 22 patients delivered after 2 top-ups whereas 28 and 11 females demanded a 3rd and 4rth bolus respectively. Only 2 patient's required 5th bolus and 0 patient needed a 6th one. Whereas in control group none of the female delivered after a single top-up. 4 females took 2nd top-up before delivery.14 and 24 ladies received 3rd and 4th top up respectively, whereas 15 patients received 5th top-up and finally 8 ladies delivered after 6th bolus in control group When it comes to maternal complications , no significant difference was detected between both groups. 10 patients in dexmedetomidine group whereas 5 patients in control group experienced hypotension and 1 patient in dexmedetomidine underwent bradycardia. No patient in either group developed respiratory depression. p-value is 0.078, showing that complications are not statistically significant among groups. The dexmedetomidine group had significantly improved maternal satisfaction (3.26±0.56 vs 4.45±0.56) and sedation scores as compared to control groups. (3.59±0.67 vs 2.34±0.50) No significant difference was noted among groups regarding bromage scale which was recorded at 15, 30, 45 and 60 minutes post epidural activation in both groups. Heart rate, systolic and diastolic blood pressure were recorded before giving dose in epidural catheter in both the groups. There was no significant difference

among groups regarding (p-value ≥0.05). Then baseline variables (H.R, SBP, and DSP) were recorded at 15mins, 30mins. 40 and 60 mins after giving loading dose in epidural catheter in both groups. Mean heart rate and blood pressure was recorded using independent sample t test in both the groups and following results were obtained.

Factors to study	Group	Number of patients	Mean	P value
Age (years)	Bupivacaine	67	28.44	0.134
	Dexmedetomidine	67	29.62	
Weight(kg)	Bupivacaine	67	89.41	0.024
	Dexmedetomidine	67	86.53	
Cervical dialation(cm)	Bupivacaine	67	3.51	0.113
	Dexmedetomidine	67	3.37	
Duration till delivery(mins)	Bupivacaine	67	315.4	0.007
	Dexmedetomidine	67	359.2	

Table-1: *Demographic data of both groups*

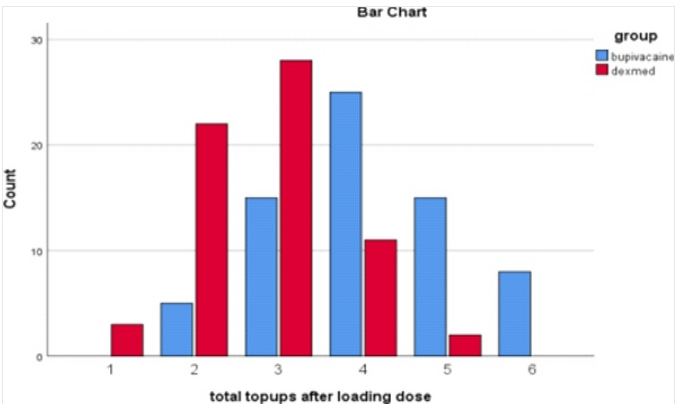

Figure 1: *Comparison of top-ups among groups*

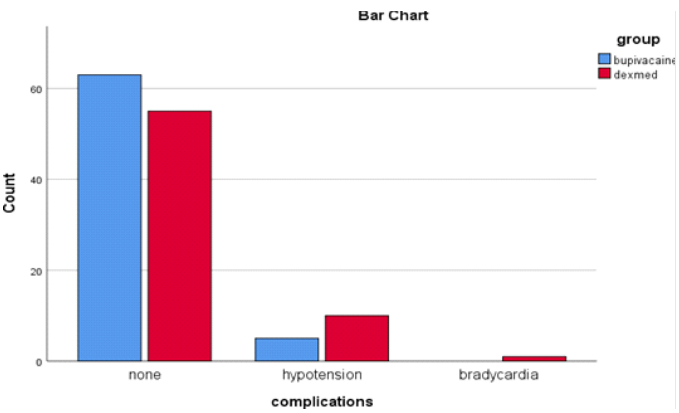

Figure 2: *Comparison of complications in both groups*

Group	Time	Parameter	Mean Value	P Value
Bupivacaine	15 mins	H. R	74.48	.001
Dexmed			69.53	0.001
	30 mins	H. R	77.91	.001
			71.39	0.001
	45 mins		77.75	.001
			72.27	.001
	60 mins		78.39	0.185
			80.34	0.187
Bupivacaine	15 mins	S. BP	110.5	0.003
Dexmed			110.25	
	30 mins		109.25	0.012
			107.83	
	45 mins		111.52	0.012
			107.56	
	60 mins		113.48	.001
			107.54	
Bupivacaine	15 mins	DBP	70.98	.001
Dexmed			56.43	.001
	30 mins		69.84	.00
			61.93	0
	45 mins		70.22	.33
			68.74	0.34
	60 mins		69.14	0.14
			71/9	0.14

Table-2: *Hemodynamic changes (H.R, SBP, DBP) in both groups*

Discussion

Effective pain relief during labor and delivery is cornerstone of recent advances in care of obstetric patients. According to recent meta-analysis Labor epidurals are proved to be most efficacious and reliable method of pain relief in laboring patients.[7]

Opioid free labor analgesia is superior to conventional labor epidurals with opioids used as adjuvants due to undesirable effects of opioids on mother as well as on neonate.[8]

Non opioid labor analgesic adjuvants are studied recently in order to reduce the dose of local anesthetics agents and to find a netter replacement of opioid analgesics. Alpha 2 agonist, dexmedetom-

idine, has been shown to reduce the dose of local anesthetics, have opioid sparing analgesic properties and provide better analgesia when used as adjuvants with bupivacaine in labor epidurals.[9] Hameed Lateef hospital is well known tertiary care hospital in Lahore and is famous due to its labor provision services. This study was conducted to ascertain the efficacy and proficiency of adding dexmedetomidine as a supplement to local anesthetic in labor epidurals for normal labor. As we have limited experience with the drug we used a fixed loading dose (50 microgram) once in all patients regardless of their weight. Commonly used concentrations of dexmedetomidine in labor analgesia are 0.5µg/ml, 0.5µg/kg, 1µg/kg and 1µg/ml.[10]

In the present study the dexmedetomidine group established early analgesia in comparison to control group (6.90 vs 11.66 mins p<0.001) and duration of analgesia (VAS<3) after loading dose was also significantly prolonged in dexmedetomidine group. (209 mins vs 104 mins) p value <0.001. Zhang et al. did a meta-analysis and concluded that by adding dexmedetomidne onset and duration of analgesia is hastened and prolonged respectively. This was in concurrence to our results. (Zhang et al. 2023).[11] Study done by Chengyi et al. in 2023 compared different doses of dexmedetomidine with bupivacaine in labor epidurals and found that maternal satisfaction was highest in the group receiving 0.2µg/ml of dexmedetomdine with bupivacaine. We compared a single dose (50µg) of dexmedetomidine with bupivacaine alone and found better maternal satisfaction with the use of dexmedetomidine. Our results are in concurrence to Chengyi et al regarding better maternal satisfaction but different in terms of dose of dexmedetomidine.[12]

Our study found that sedation scores are significantly greater in dexmedetomidine group as compared to control group. Our results are in alliance to the study performed by Minghao liu et al 2024. Above mentioned study is done on pregnant patients undergoing cesarean section under epidural block in which dexmedetomidine is added with ropivacaine. They also used Ramsey sedation score in their study. However they concluded that satisfaction with epidural was not increased significantly after adding dexmedetomidine. They used dexmedetomidine in dose of 0.5µg/kg. These results are in contradiction to our results regarding improved maternal satisfaction with the use of dexmedetomidine.[13]

Our study concluded that there is no significance difference among both groups regarding maternal complications. Similar results were recorded by Mei Fan et.al when he added dexmedetomidine with ropivacaine for labor analgesia. Our results are in coordination with his study.[14] Hemodynamics (mean arterial blood pressures and heart rate) were more controlled and on a lower side in the patients given dexmedetomidne; but these finding are not clinically significant as the readings were in the lower limit of normal and the side effects (hypotension, bradycardia) were statistically insignificant. Zhao et al. (2017) studied effects of dexmedetomidine on hemodynamics and their results were same as of our study.[15] These findings can also be attributable to better analgesia and maternal satisfaction in patients receiving dexmedetomidine.

Conflict of Interest None

Funding Source None

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Authors Contribution

SS: Conceptualization of Project

SK: Literature Search

SK: Data Collection

ZB: Statistical Analysis

AR: Drafting, Writing Manuscript

HK: Drafting, Revisions