comparative study between 0.2% Ropivacaine with 0.5 mcg/ ml Dexmedetomidine and 2 mcg/ ml Fentanyl with 0.2%Ropivacaine in Labor Epidural Analgesiafor the onset and duration of sensory block.

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Abstract:

Background:
Labor epidural analgesia is an effective method of reducing pain during labor. For labour epidural, opioid sparing analgesia is gaining popularity.Opioidsparing drugs like dexmedetomidinehas been as an adjuvant to local anaesthetics with fewer side effects in various techniques and its less explored in labor epidural analgesia.

Objective:
To compare analgesic effects of dexmedetomidine and fentanyl when added to ropivacaine for labor epidural analgesia.

Materials and methods:
An observational comparative study was done after obtaining approval from ethicalcommittee(IEC/NMCH/15/02/2022_7), 60 nulliparous parturients were divided into 2 groups to receive either dexmedetomidine 0.5mcg/ ml with 0.2% ropivacaine (10 ml) or fentanyl 2mcg /ml with 0.2%ropivacaine 10ml.Onset and duration of sensory blockade was noted after giving first bolus.

Results:
The mean onset time of sensory-block in fentanyl group is higher thandexmedetomidine group. The duration of the sensory blockade showed a statisticallysignificant difference between the two study groups ($p<0.05$).There was significant alteration seen in hemodynamics between the study groups. No side effects were encountered in either group.

Conclusion:
Dexmedetomidineis superior to fentanyl as an adjuvant to ropivacainefor opioid sparing analgesia in labor epidural by providing longer duration of sensory blockade without any side effects.

Key words: labor epidural, epidural analgesia, ropivacaine, dexmedetomidine, fentanyl, opioid sparing labor analgesia.

INTRODUCTION:

Parturients suffer greatly from labour pain, both physically and psychologically[1]. Labor analgesia, which is used more frequently in obstetrics, is the term for the use of a variety of techniques to lessen or eliminate maternal labour pain. Maternal and foetal safety, a quick onset, a good analgesic effect, and a low incidence of side effects are characteristics of the ideal labour analgesia[2].

With a safer cardiac profile than bupivacaine, ropivacaine[3] is a long-acting amide local anaesthetic (LA). Which has the advantage of more prediction for sensory blockade as well as decreased risk of systemic toxicity.

Opioids like fentanyl is commonly used opioid in for labor analgesia and other non-obstreticsurgeries to reduce the dose requirements of epidural local anaesthetic agents, specifically intended to minimize the side effect of an epidural blockade, including maternal motor block and hypotension[4]. Recently opioid sparing analgesia is being used with drugs like dexmedetomidine.

Dexmedetomidine[5], an extremely selective α2-adrenoceptor agonist, has an anxiolytic, sedative, and analgesic properties without causing respiratory depression. Furthermore, dexmedetomidine coupled with local anaesthetics has been successfully used for epidural labor with fewer side effects.It does not cross placenta[6] and fetal effects are less.

In our study we compared dexmedetomidine with fentanyl as an adjuvant to ropivacaine for labour analgesia with respect to onset and duration of sensory block.

MATERILAS AND METHODS:

Anobservationalsingle blinded study was conducted from MARCH 2022 to FEB 2022. After receiving informed written consent, the present investigation was carried out on 60 parturientsat Narayana Medical College and Hospital in Nellore. After receiving clearance from the institutional ethical committee(IEC/NMCH/15/02/2022_7), this study was carried out with the participation of all patients who provided written informed consent.

Sample size: 60 patients (Two groups of 30 each).

$$n = \frac{2[(a+b)^2\sigma^2]}{(\mu_1 - \mu_2)^2}$$

Fig.1. sample size formla.

Using the above formula, sample size was determined while maintaining two-sided alpha error at 5% and power at 80%. Each group needed at least 23 individuals, but for greater validation, 30 patients were chosen for each group.

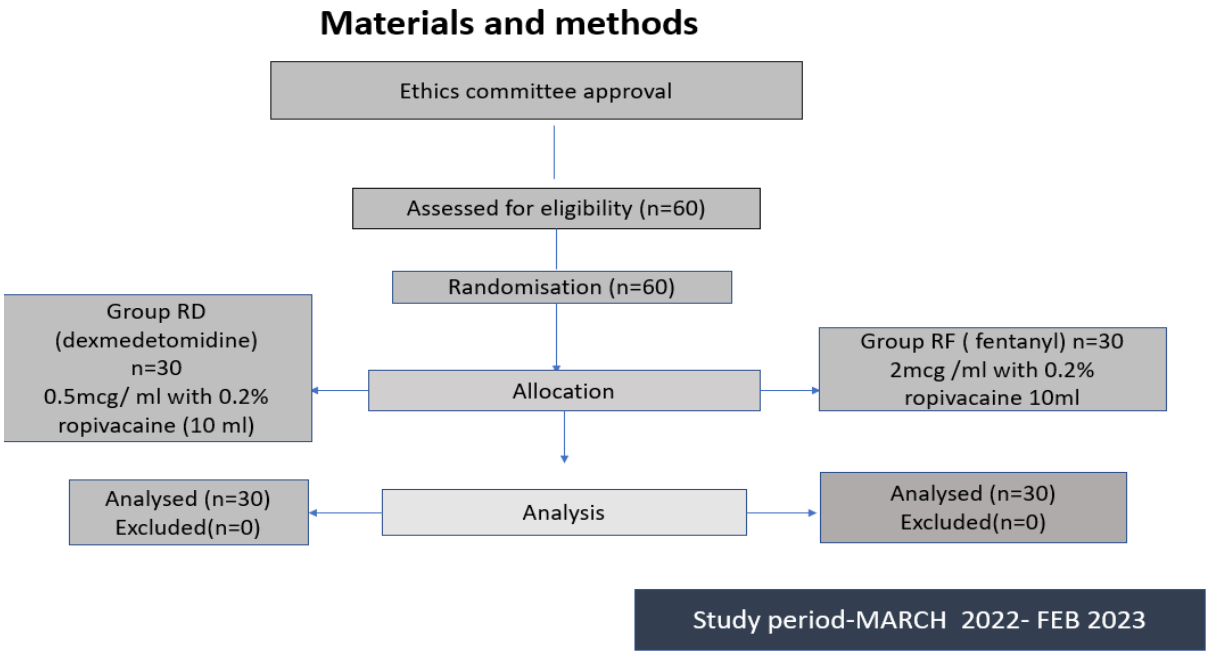
Inclusion criteria:

1. Pregnant patients without any coagulation abnormality
2. ASA-II

Exclusion criteria:

1. Patient refusal
2. Patients with spine abnormality
3. Parturients with heart defects
4. Fetal abnormalities
5. OBESE PARTURIENTS

Fig.2.consort flow chart



METHODOLOGY:

After randomly dividing the patients into two groups of 30 each:

Group RD: Patients in group RD received 0.5mcg/ ml dexmedetomidine with 0.2% ropivacaine (10 ml).

Group RF: Patients in group RF received 2mcg /ml fentanyl with 0.2%ropivacaine (10ml).

All parturients were thoroughly assessed and investigated for routine blood counts,blood sugar, urea, creatinine. The treating obstetrician monitored the uterine contractions and cervical dilatation and effacement every half an hour or when deemed necessary and informed us for the institution of labour analgesia. With the onset of first stage of labour (having regular painful contractions in latent phase) with cervical dilatation of 3-4 cm epidural analgesia was institutedor on maternal's request.

The patient was transferred to the operating room where a 20 G cannula was inserted and started on appropriate intravenous fluid. Standard monitoring with pulse oximetry, non-invasive blood pressure monitoring and ECG was applied. After recording baseline blood pressure, oxygen saturation and heart rate, parturients in both the groups were placed in the left lateral position and following strict aseptic techniques, a local infiltration of 1% lignocaine HCl was infiltrated into the intervertebral space at either L3-4 or L4-5 level and epidural space was identified using a "loss of resistance technique to air" with an 18G Tuohy needle. After locating the epidural space, an 20-G multiorifice catheter was threaded through the cranially directed tip of the epidural needle to a depth of 5 cm into the epidural space and

negative aspiration of blood or cerebrospinal fluid was confirmed. If there were no signs of an intravascular or intrathecal placement of the catheter, the catheter was secured and the woman was placed in the supine position with left uterine displacement.

Test dose (2 ml of 1.5% lignocaine with adrenaline) to confirm position of catheter. Study drug was given In study groups and parameters were measured.

Assessment of sensory block: Sensory block onset: The time period for, onset of sensory block was calculated as the time from the administration of the local anaesthetic solution to the cessation of pinprick feeling. The sensory onset was tested by using spirit swab.

Assessment of motor blockwas done by using modified bromage scale (tab.1)

The adequacy of analgesia was assessed with a 10-cm linear visual analog scale (VAS), where 0 refers to no pain and a score of 10 refers to worst imaginable pain, immediately before epidural placement and at 5, 10, 20, 40, 60, 80 and 100 min after injection of the study drug. Onset of analgesia was considered as time to achieve VAS <3. Duration of analgesia was taken as time between T = 0 and breakthrough pain, which was defined as VAS >3, or request for additional analgesia and was treated in a similar way in both groups by a bolus of 6 ml of ropivacaine 0.1%.

Haemodynamic parameters of the parturient—heart rate, systolic and diastolic blood pressure, were recorded every 5 min for the first 30 min, then every 30 min until study was completed.

STATISTICAL ANALYSIS:

Data were entered in MS excel and analysis was done using SPSS 21.0 version. Data were presented as Mean and Standard deviation for continuous variables and as percentages for categorical variables. A Chi-square test was done to find out any association between categorical variables. Independent sample t test was compared when applied to quantitative variables (Age, weight, onset and the duration of Motor and sensory, duration of rescue analgesia, HR, SBP, DBP, MAP) between the groups (RD, RF). A p value of less than or equal to 0.05 was considered significant.

RESULTS:

Demographic data (age, weight, dilation etc.) of parturients in both the groups were comparable.

At the initiation of labor analgesia, the mean VAS score was 5.3 in group RD and 5.13 in group RF ($P = 0.79$).

The mean time of onset of sensory block (VAS ≤3) was significantly faster in group RD as compared to group RF respectively [mean 5.03± 2.13 minsin group RD] vs [mean 7.36± 0.99 mins in groupRF],($P < 0.05$).

The mean duration of analgesia of bolus dose, defined as the time until parturient request for additional analgesia, was found to be significantly more with group RD as compared to group RF (90.6± 8.82 minsvs 69.5± 8.59 mins)($P < 0.05$). This also implies that the mean first top up time was also significantly more in group RD as compared to Group RF.

There was no motor block in any parturients and therefore Modified Bromage Score was 0 in all the patients.

There was statistically significant difference in hemodynamic variables i.e.SBP, DBP between both the groups with p value of ($P < 0.05$).

None of the participants in both the groups had any side effects like nausea, vomiting, hypotension, bradycardia, hypersensitivity reaction, pruritis, respiratory depression, urinary retention.

The distribution of the subjects according to the Ramsay sedation scale is depicted in the graph above. No sedative effect was noticed in either group. There was no discernible difference between the two groups. Mean RSS in group RD was 1.76 0.43, while it was 1.93 0.57 in group RF**(Fig 5)**.

DISCUSSION:

Labor analgesia is right of every mother. The optimal labor analgesia not only provides adequate analgesia to parturients but also reduces opioid intake without causing adverse effects, allowing for rapid neonatal or maternal postpartum recovery. Opioid sparing analgesia such as dexmedetomidine has a low risk of motor block, vomiting, nausea, pruritus, when compared to fentanyl.

Fentanyl like opioids are commonly used adjuvants for labor analgesia, drugs like these crosses placenta and may cause respiratory depression and other side effects on fetus.

Dexmedetomidine[5] is an alpha 2 agonist, which is a good alternative for opioid adjuvants and its gaining good popularity among opioid sparing analgesia. It does not cross placenta[6] and fetal effects are less.

Gao. et al[7].in their study they studied dexmedetomidine in comparison with sufentanyl.in their research, duration of first epidural infusions in dexmedetomidine was significantly longer than sufentanyl (median value:115 vs 68 min, $P < 0.01$).

In the research work done by **Atienzar et al[4]** shows that epidural infusion of 0.1% ropivacaine with fentanyl 2/μgmLat 10 mL/h provided adequate analgesia in the first stage of labour. In contrast to our study they have used two concentrations of ropivacaine that is 0.1% & 0.2% long with fentanyl. But there was no statistical significance between two groups in terms of sensory blockade.

There was significant difference was seen in haemodynamic parameters among both the groups.

Limitations of study:

In our research we studied the analgesic effects after the first bolus, not till the delivery and we did not measured the top up doses and total drug consumed. This will be done in the future studies.

Conclusion:

From our study , We conclude that dexmedetomidine is a better alternative than fentanyl as an adjuvant to local anaesthetic in labour epidural for opioid sparing analgesia.

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	Grade	Criteria

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Table.1. **modified Bromage scale for lower limb**

	Grade 0	No motor block
	Grade 1	In ability to raise extended leg; able to move knees and feet
	Grade 2	In ability to raise extended leg and move knee; able to move feet
	Grade 3	Complete block of motor limb

Parameter	**Group RD** **Mean ± SD (mins)**	**GROUP RF** **Mean ± SD (mins)**	**P VALUE**	**Statistical significance**
Onset of sensory blockade	5.03± 2.13	7.36± 0.99	<0.05	significant
Duration of sensory blockade	90.6± 8.82	69.5± 8.59	<0.05	significant

Table.2. onset And duration of sensory blockade

Table.3. HAEMODYANMIC PARAMETERS

Parameter (during study period)	**Group RD** **Mean ± SD**	**GROUP RF** **Mean± SD**	**P VALUE**	**Statistical significance**
Systolic blood pressure (mmhg)	108.8± 8.83	119.05±7.89	<0.05	significant
Diastolic blood pressure (mmhg)	75.6± 13.64	80.9± 5.121	<0.001	Significant
Pulse rate(bpm)	99.3± 7.83	100.73± 7.83	0.48	Not significant

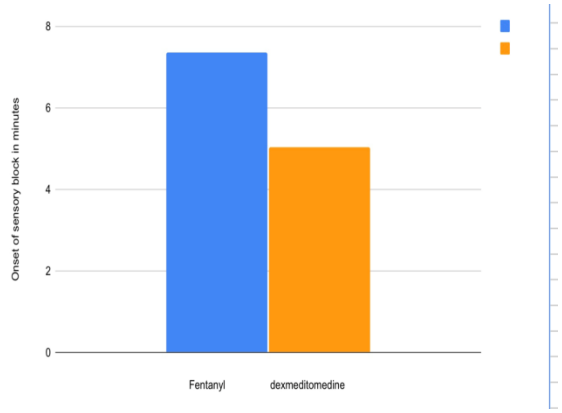

Fig.3Mean onset of sensory blockade between two groups.

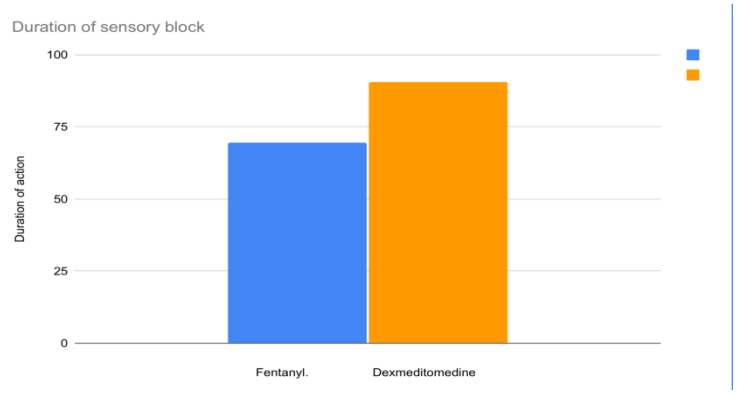

Fig.4.Mean duration of analgesia.

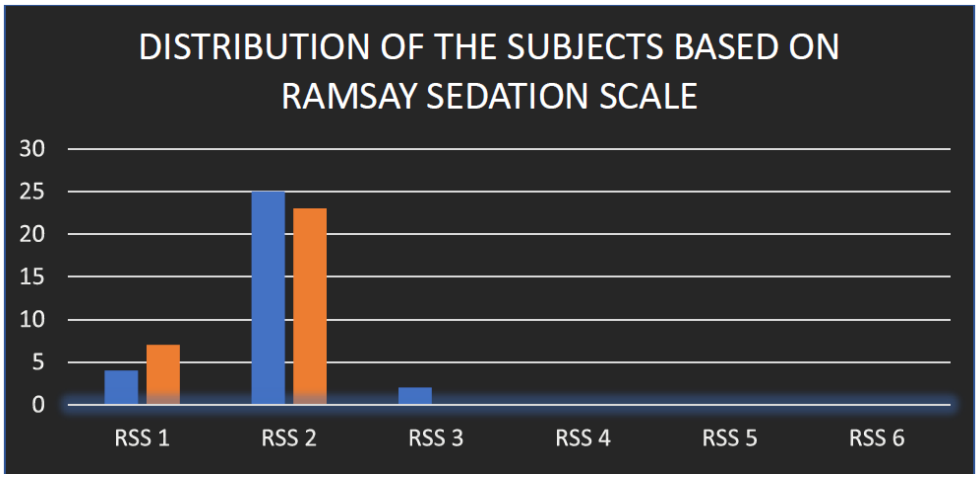

Fig 5: RAMSAY sedation scale among two groups.