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A Comparison Between Epidural and IM Tramadol for Painless Labor

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Abstract: **The pain of childbirth is arguably one of the most severe types of pain a woman will experience in her lifetime. For labor analgesia several non-pharmacologic and pharmacologic methods are adopted of which regional analgesia is considered the gold standard. In our study 50 patients ASA grade 2 were allotted in two groups, group 1 was epidural group and group 2 was tramadol group. Epidural group received 10ml bolus of 0.125% ropivacaine plus 2ugm/ml fentany1 after sitting the epidural catheter when the mother was in true labour pains. Tramadol group received 1mg/kg tramadol intramuscular when the laboring woman was in true labour pains and repeated every 3-4 hrs and the duration of 1st stage, 2nd stage, pain relief was measured using the visual analogue scale, fetal outcome using the APGAR score, mode of delivery, and maternal satisfaction as regards to pain relief was observed and compared in either group. The duration of 1st and 2nd stage were found to be shorter in the epidural group than tramadol group and the pain relief was better in epidural group and statistically highly significant with P value of <0.001. Epidural labour analgesia provides clinically highly significant pain relief in laboring women and it has no adverse effect on the maternal or fetal outcome when low dose of local anesthetic and opoid is used.**

Keywords: **Epidural labour analgesia, Ropivacaine, tramadol injection, Visual analogue scale.**

I. INTRODUCTION

Labour pain is one of the most severe pains experienced. Labour epidural analgesia still remains the "Gold Standard" of obstetric pain management, until now, there has been no single drug to overcome the superiority of neuraxial analgesia in obstetrics. Neuraxial analgesia with low dose spinal –epidural regimens provide efficacious analgesia, stable maternal haemodynamics and few tolerable side effects.[1]

As medical and religions debate subsided the use of analgesia for labor, gradually became more common, largely as a result of popular demand by 1860, anaesthesia for child had become part of medical practice by public acclaim.[2]

Nevertheless even today, misconceptions and confusions still exist among the public, physicians, nurses & midwives regarding pain relief during labor. There is continued debate among some obstetricians, over the use of analgesia and anaesthesia for labor and delivery, especially regarding epidural neuraxial blockade. Does it prolong 2nd stage of labor, or increase the rate of instrumental delivery and caesarean section (C.S.). Although recent metaanalysis suggest, that epidural analgesia, does not improve the rate of C.S[3,] others still believe that it does so[4]. Despite all controversy, there is no doubt that for most women, child birth is associated with severe pain often exceeding all expectations.[5]

Pain is not a necessary accompaniment of child birth although pain serves the important biological function of indicating the commencement of labor to the parturient, it should be effectively relieved, once it has fulfilled this task. Persistent severe pain has harmful effects on the mother and fetus sometimes.[6]

Morgan et al, showed that among these mothers experiencing, what was judged at the time to be severe pain, more than 90% viewed the experience with satisfaction in retrospect. Therefore, effective pain relief in labor is not provided in order to incur lasting gratitude, but rather to treat distress with compassion at the time and to minimize the resulting stress for mother and baby.[7]

II. MATERIALS AND METHODS

The study titled "A Comparison between Epidural and IM Tramadol for Painless Labor'' was conducted in the Department of Obstetrics & Gynecology of Yenepoya Medical College Hospital, Deralakatte, Mangalore during two years period.A total of 50 women included in the study group.

Inclusion criteria –

- Healthy primi or multiparou
- ASA grade 2.
- Aged between 18-40 yrs.
- In active labour with a singleton fetus at term will participate in the study after giving written informed consent.

Exclusion Criteria –

- Breech presentation.
- Contraindication to epidural analgesia due to hemodynamic, infectious, allergic, neurological, or hematological reasons.
- Multiple pregnancies, preeclampsia.
- Any fetal abnormality.
- Ante partum hemorrhage.
- Patient refusal.

After obtaining written informed consent from the patients, preanesthetic evaluation will be done, procedure will be explained to the patient, premedication with 50mg ranitidine hydrochloride IV & 10mg metoclopramide will be administered. Patients will be allocated in two groups,

Group E – lumbar epidural analgesia will be administered.

Group T – inj. Tramadol will be administered IM.

Once the patient is in established active phase of labour, vital signs are recorded and the pain scores are noted before administering the drug.Inj. Tramadol 1mg/kg is given IM.Pulse rate, blood pressure, pain intensity will be assessed using V A S.Vitals and analgesia will be recorded at time T0 – when analgesia is administered, T0 + 15min, T0+30min and then every hourly till the baby is delivered

In the epidural group, before performing the block the patient will be preloaded with 10ml/kg of Ringers lactate, NIBP and pulse oximetry will be recorded. Fetal heart rate and uterine activity will be monitored throughout labour. Maintenance fluid therapy is with ringers lactate 3ml/kg/hr.With the patient in left lateral position, skin is disinfected using sterile precautions, after identifying the level skin is infiltrated with 0.5% lignocaine. The epidural space will be identified at a lumbar interspace using the loss of resistance air with a 18G Touhys needle. Epidural multihole catheter will be advanced 3-5cm into the epidural space and fixed with an adhesive plaster. 3ml of test dose will be given with 2% lignocaine with adrenaline, if no signs of inadvertent block are present then, initial bolus dose of 8ml 0.125% ropivacaine with2mcg/ml fentanyl will be injected through the epidural catheter.

A pain score of <4/10 on a visual analogue scale will be considered to represent onset of analgesia. If analgesia is not achieved within 30 min then additional bolus of 5ml will be given and if still analgesia is not achieved then additional 5 ml of the solution will be given and if VAS score is consistently >4/10 the parturient will be excluded from the study.

After the bolus the analgesia will be maintained with continuous infusion with 0.125% ropivacaine +2 mcg/ml fentanyl as required. The start of epidural infusion will be recorded as T0, the clinical status of the parturient will be assessed at T0+ 15min, then T0+30min and then every half hourly until the outcome of labour.At each of these points pain will be assessed using the visual analogue scale from 0-10cm.Motor block will be evaluated throughout the labour according to the Breen's modified Bromage scale. The mode of delivery (vaginal or C.S.) and the use of instrumentation during extraction will be noted. After delivery total volume of local anaesthetic solution administered by the investigator will be recorded.H.R., B.P., motor blockade will be recorded at regular intervals till the patient recovers from the drug.

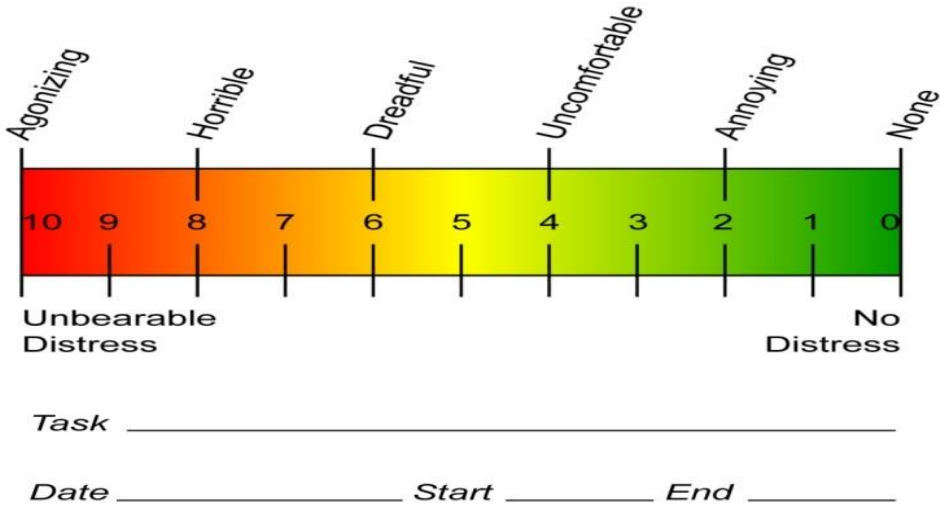


FIGURE –1 – VISUAL ANALOGUE SCALE

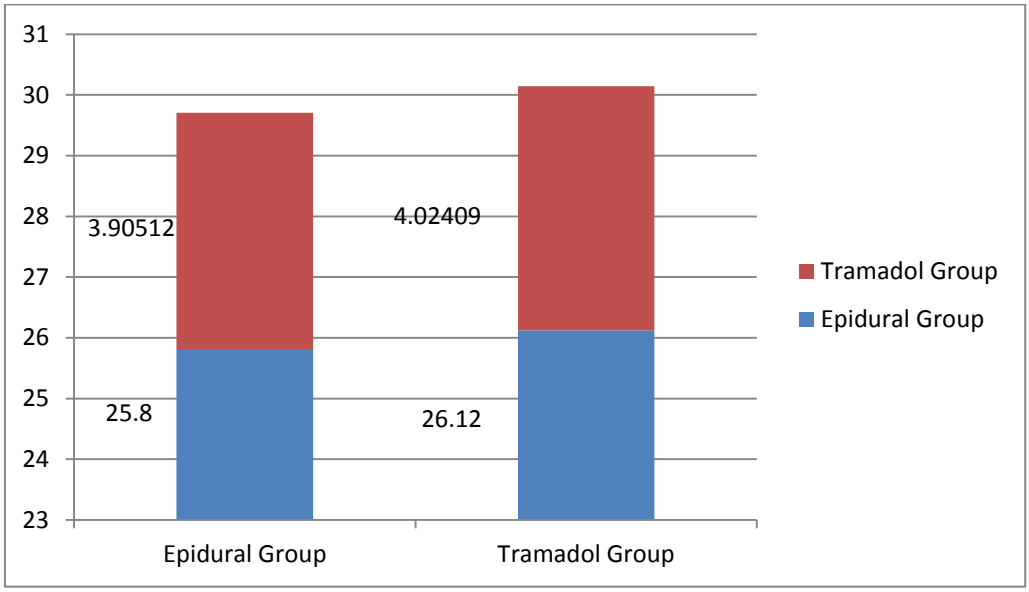
III. RESULTS

TABLE 1: COMPARISON OF AGE

GROUP	N	Mean	Std. Deviation
EPIDURAL GROUP	25	25.8000	3.90512
TRAMADOL GROUP	25	26.1200	4.02409

P valure 0.777

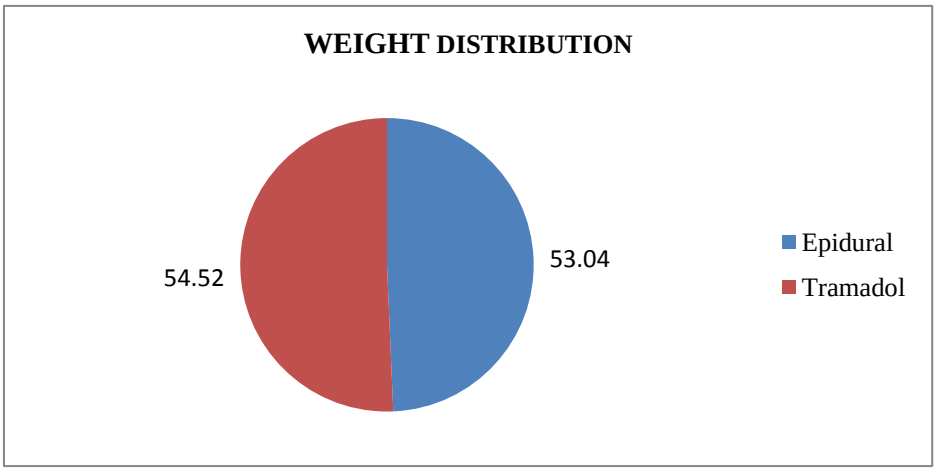
AGE DISTRIBUTION



Both the groups are comparable with respect to age with p value of 0.777.

TABLE 2 – WEIGHT DISTRIBUTION

GROUP	N	Mean	Std. Deviation
Epidural	25	53.0400	4.15812
Tramadol	25	54.5200	4.80555



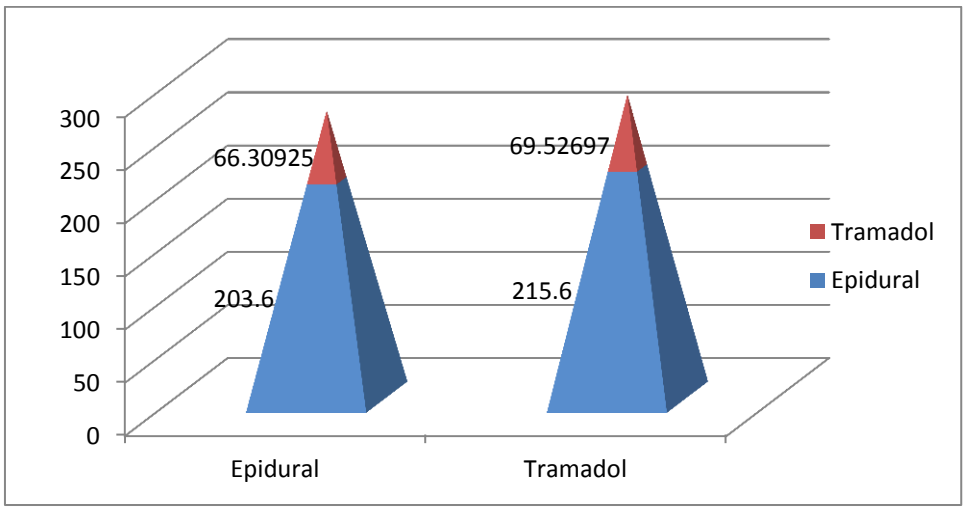
Either group were comparable with respect to weight with P value of 0.25

TABLE 3 – COMPARING THE DURATION OF 1ST STAGE

GROUP	N	Mean	Std. Deviation
Epidural	25	203.6000	66.30925
Tramadol	25	215.6000	69.52697

P value 0.535

DURATION OF 1ST STAGE



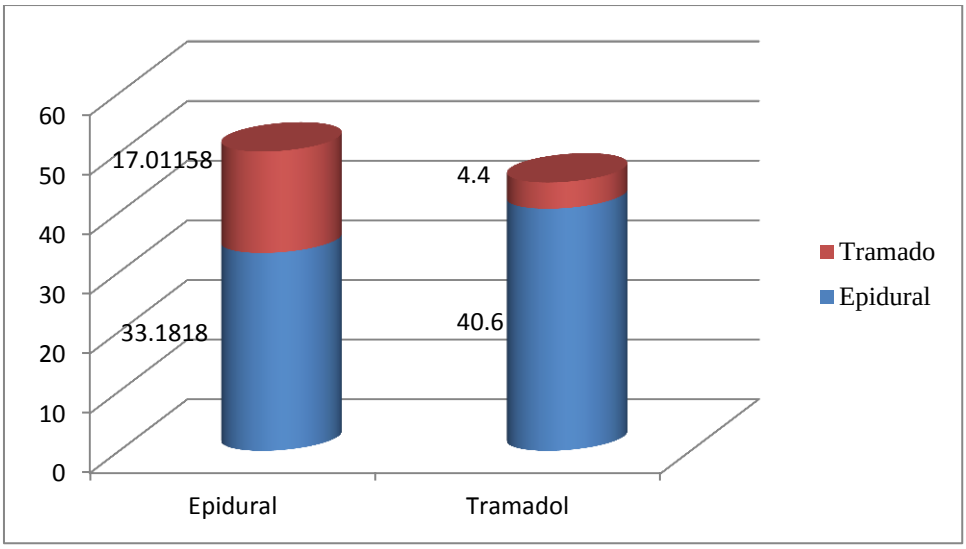
Statistically significant difference was found between epidural and Tramadol group with duration of 1st stage being shorter in the epidural group.

TABLE 4 – COMPARISON 2ND STAGE

GROUP	N	Mean	Std. Deviation
Epidural	22	33.1818	17.01158
Tramadol	23	40.6000	17.81385

P value 0.153

DURATION OF 2ND STAGE



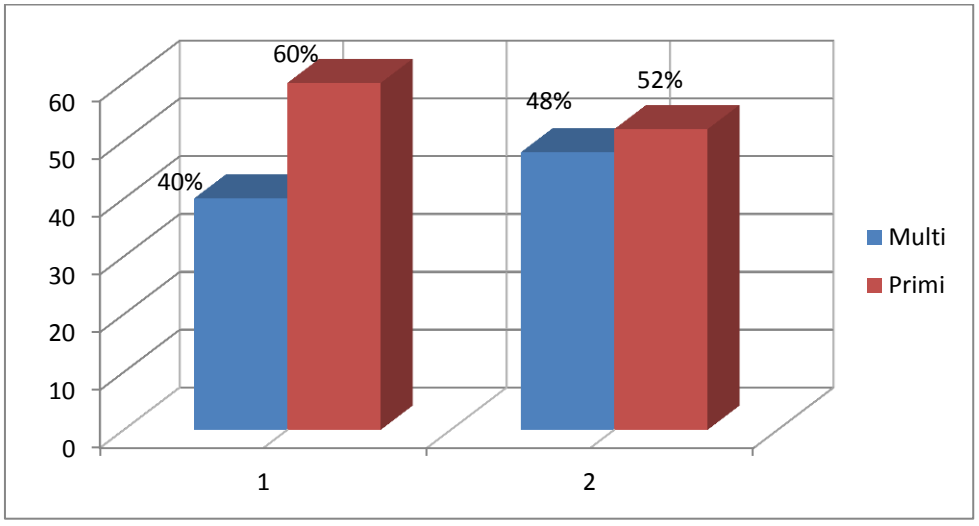
Duration of second stage was found to be shorter in the epidural group, however 3 patients in the epidural group and 2 patients in tramadol group went in for LSCS dure to obstetric indications.

TABLE 5 – DISTRIBUTION OF PRIMIGRAVIDA AND MULTIPARA

	GROUP		TOTAL
	EPIDURAL	TRAMADOL	
Multi Count	10	12	22
%	40.0%	48.0%	44.0%
Primi Count	15	13	28
%	60.0%	52.0%	56.0%
Total Count	**25**	**25**	**50**
%	**100.0%**	**100.0%**	**100.0%**

X2=0.325 P value =0.569 ns

Distribution of primigravida and multipara

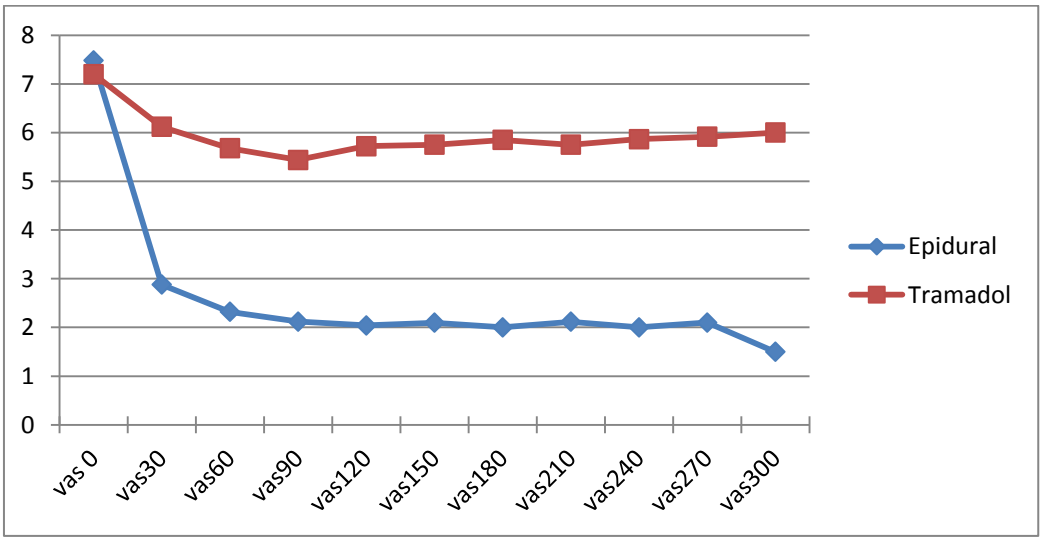


The two groups showed no statistically significant difference with respect to distribution of primigravida and multipara.

TABLE – 6 COMPARISON OF PAIN RELIEF USING THE VISUAL ANALOGUE SCALE

Time	Group	N	Mean	Std. Deviation	T
vas0	epidural tramadol	25 25	7.4800 7.2000	.65320 .40825	1.81800 p=.075ns
vas30	epidural tramadol	25 25	2.8800 6.1200	.83267 .88129	13.36200 p <0.001 vhs
vas60	epidural tramadol	25 25	2.3200 5.6800	.85245 .80208	14.35300 p <0.001 vhs
vas90	epidural tramadol	25 25	2.1200 5.4400	.60000 .50662	21.13900 p <0.001 vhs
vas120	epidural tramadol	25 25	2.0400 5.7200	.67577 .61373	20.15600 p <0.001 vhs
vas150	epidural tramadol	21 24	2.0952 5.7500	.76842 .67566	16.98100 p <0.001 vhs
vas180	epidural tramadol	20 20	2.0000 5.8500	.72548 .58714	18.44800 p <0.001 vhs
Vas210	epidural tramadol	17 16	2.1176 5.7500	.78121 .68313	14.18100 p <0.001 vhs
Vas240	epidural tramadol	12 15	2.0000 5.8667	.85280 .74322	12.58500 p <0.001 vhs
Vas270	epidural tramadol	10 12	2.1000 5.9167	.87560 .51493	12.72300 p <0.001 vhs
Vas300	epidural tramadol	4 1	1.5000 6.0000	.57735 .	

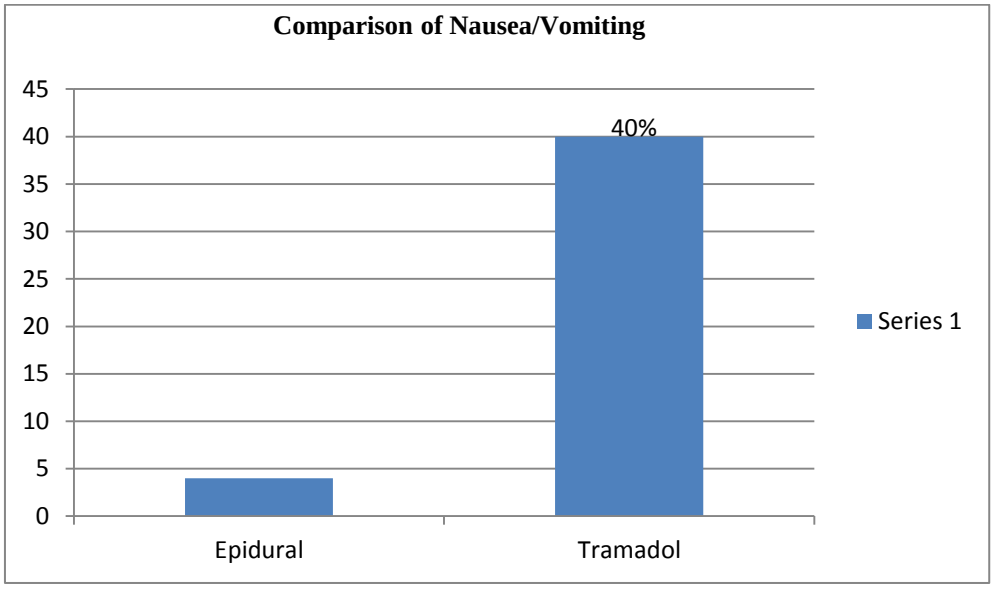
Comparison of pain relief in either group using visual analogue scale



A statistically significant difference was found between either group with respect to pain relief. The P value at the start of the procedure is 0.075 which is comparable, but after 30 min of starting the procedure P value is 0.001 which is statistically significant showing epidural analgesia to give significantly better analgesia compared to tramadol injection.

TABLE – 7 COMPARISON OF NAUSEA/VOMITING

Nausea/vomiting	GROUP		TOTAL
	EPIDURAL	TRAMADOL	
absent Count %	24 96.0%	15 60.0%	39 78.0%
Present Count %	1 4.0%	10 40.0%	11 22.0%
Total Count %	**25 100.0%**	**25 100.0%**	**50 100.0%**

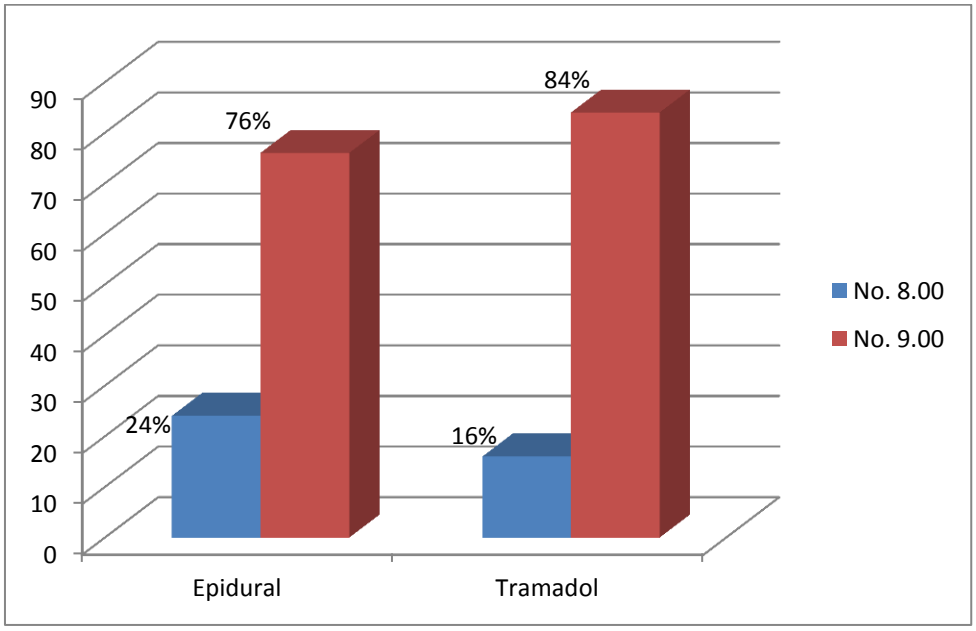


About 40% of patients experienced nausea/vomiting in the tramadol group as compared to epidural analgesia group where only one patient experienced nausea/vomiting. The patients were treated with inj. Ondansetron 4mg.

TABLE – 8 COMPARISON OF FETAL OUTCOME USING APGAR AT 1 MIN

Apgar score at 1 min.		**GROUP**		**Total**
		EPIDURAL	**TRAMADOL**	
8.00	Count	6	4	10
	%	24.0%	16.0%	20.0%
9.00	Count	19	21	40
	%	76.0%	84.0%	80.0%
Total	**Count**	**25**	**25**	**50**
	%	**100.0%**	**100.0%**	**100.0%**

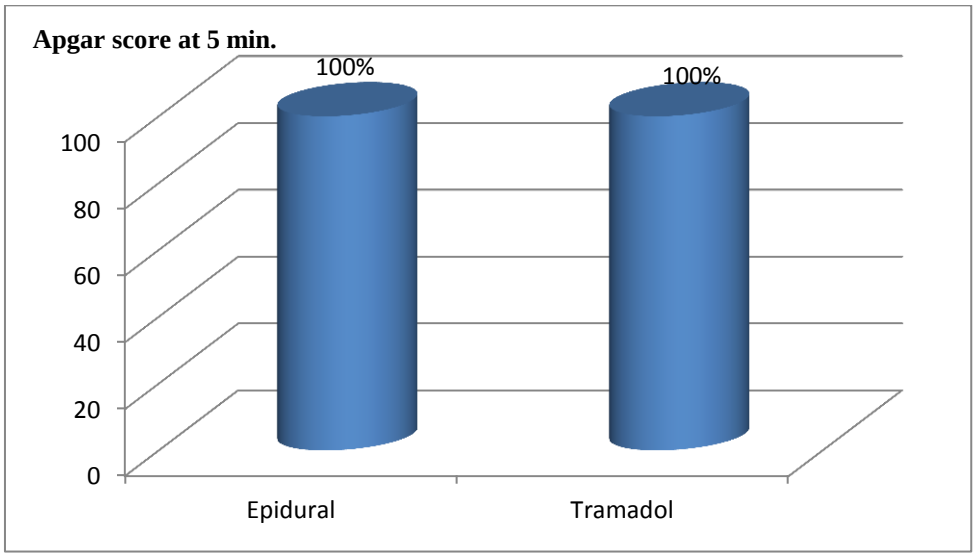
Comparison of fetal outcome using APGAR at 1 min



Apgar score was found to be either 8 or 9 in both the groups with epidural group having 24% neonates with score of 8 and 76% neonates with score 9. In tramadol group 16% patients had score 8 and 84% had score 9.

TABLE – 9 APGAR SCORE AT 5 MIN

Apgar score at 5 min		GROUP		Total
		EPIDURAL	TRAMADOL	
10.00	Count	25	25	50
	%	100.0%	100.0%	100.0%
Total	**Count**	**25**	**25**	**50**
	%	**100.0%**	**100.0%**	**100.0%**



Apgar score was 10 in both the groups at 5 min.

IV. DISCUSSION

For labour analgesia several non-pharmacologic and pharmacologic methods are adopted of which regional analgesia is considered the gold standard, among pharmacological techniques, pethidine, morphine have been used, inhalation agents like entonox, sevonox which is a combination of sevoflurane and oxygen have also been used.

Intramuscular opioids have been used in the past for labour analgesia, but do not provide effective pain relief compared to other techniques. It is also associated with side effects like respiratory depression, nausea/ vomiting drowsiness. For the past two decades epidural analgesia has been successfully used for providing labour analgesia with bupivacaine with adjuvants like fentanyl, sufentanil etc.

In this prospective study 0.125% ropivacaine with 2mcg/ml fentanyl has been compared with intramuscular tramadol 1 mg/ml. Parameters analysed were analgesic efficacy using visual analogue scale, duration of 1st and 2nd stage of labour, side effects, maternal satisfaction and fetal outcome in either group.

The mean duration was found to be shorter in the epidural group in both multipara and primigravida compared to tramadol. Zhang J. Et al in their study found that the duration of 1st stage does not increase when epidural analgesia is given to the patient[8]. In our study we found that the mean duration was shorter in the 1st stage with epidural analgesia.Li Q. Al who investigated the effects of epidural ropivacaine with fentanyl & found that the duration of 1st stage of labour was shortened in the epidural analgesia group.

In our study we have used 0.125% ropivacine with 2mcg/ml fentanyl which does not produce motor block, hence the bearing down effort by the mother during 2nd stage is not affected, and hence the duration of 2nd stage of labour was found to be shorter in our study.

Jain S et al who studied the analgesic efficacy of intramuscular opioids versus epidural analgesia inlabour and concluded that the analgesic efficacy and materanal satisfaction is better with epidural analgesia than with opioids. Muir et al who compared epidural Ropivacaine with Bupivacaine and found no significant differences in the neonatal outcome in both the groups and the neonatal outcome was good.

V. CONCLUSION

We conclude from our study that epidural labour analgesia provides clinically highly significant pain relief in labouring women and it had no adverse effect on the maternal or fetal outcome. The duration of 1st and 2nd stage is also shortened in most of the cases which can be advantageous. However in patients who have a contraindication for regional analgesia injection Tramadol is a useful alternative as it is cheap and easily available and has minimal adverse effects on the mother and fetus.

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