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Comparison of Labour Outcome with and Without Epidural Analgesia

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Abstract
Background:
Pain during child birth is an unpleasant and emotional experience. Adequate analgesia during labour is beneficial to mother and foetus and had positive influence on course of labour.An ideal analgesic should be easy to give ,produce good pain relief ,should not be toxic , impair consciousness of mother ,or delay the labour .Though epidural analgesia has been popular ,because of lack of awareness ,trained staff and monitoring facilities ,its use is limited .The present study was done in Rural Development Trust hospital to compare the labour outcome and maternal satisfaction of parturient with and without epidural analgesia.
Materials and Methods :
Primigravida with low risk and term pregnancies (37weeks -40weeks) coming to labour room in Rural development Trust hospital .Anantapur ,during period of 2years from 2016 to 2018 .
Using simple randomisation techniques ,divided in to 2groups
Group I :100parturients who are given epidural analgesia at 3-4cms of cervical dilatation
Group II:100parturients who are given tramadol analgesia at 3-4cms of cervical dilatation
Main outcomes were measured
1. *Duration of labour*
2. *Mode of delivery*
3. *Foetal outcome (APGAR scores , NICU admissions)*
4. *Adverse reactions and complications*
5. *Maternal satisfaction and pain relief*

RESULTS
Epidural analgesia has no effect on duration of 2nd stage of labour ,as most of the previous studies had prolonged 2nd stage .there is no significant difference in the mode of delivery between two groups foetal outcome was good in both groups .degree of pain relief and maternal satisfaction was more in epidural group compared to tramadol group .no major adverse reactions or maternal complications were observed in both the groups .
Keywords: *Epidural analgesia , Tramadol hydrochloride ,Labour analgesia .*

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I. Introduction

Pain during child birth is an unpleasant and emotional experience. Adequate analgesia during labour is of benefit to the mother and foetus and had positive influence on course of labour thus making obstetrical analgesia an essential part of modern obstetrics. The satisfaction of birth experience is greater with neuraxialtechniques, Epidural blockade is an effective means of providing analgesia during labour.[1]The need for analgesia to overcome pain in labour is highly requested by women these days and various methods of analgesia like systemic opioids, regional nerve blockade are used.[2]An ideal analgesic should be easy to administer, produce good pain relief, not be toxic to mother and foetus and should not impair the consciousness of mother. It should not have tocolytic action and should not delay the labour.[3]Though epidural analgesia has been popularly used for pain relief because of lack of awareness, trained staff and to need for monitoring facilities, its use is limited and opioids like tramadol are used even though it may not produce effective pain relief.[4] The present study was done in our hospital to compare the labour outcome and maternal satisfaction of parturient with and without epidural analgesia.

II. Materials And Methods

This prospective observational study was carried out in Department of Obstetrics and Gynaecology at Rural Development Trust Hospital, Bathalapalli,Anantapur,AndhraPradesh from August 2016-February 2018.

Study Design : Prospective Observational Study .

Study Location : This study was done in Department of Obstetrics and Gynaecology,Rural Development Trust Hospital ,Anantapur ,AndhraPradesh.

Study Duration :2years from August 2016-February 2018.

Sample size : 200 parturients

Inclusion criteria :

1. Primigravidae.
2. Full term pregnant women (37-40wks) willing for epidural or tramadol as labour analgesia .
3. Singleton pregnancy with vertex presentation with good foetal heart rate .
4. Parturient in active labour

Exclusion criteria :

1. Abnormal presentation
2. Cephalopelvic disproportion
3. Coagulation disorders (patients on anticoagulants)
4. Foetal distress
5. Spinal deformity
6. Known case of sensitivity to local anaesthetic agent or opioids
7. Any medical disorder complicating pregnancy
8. IUGR SGA and abnormal doppler foetus
9. Local sepsis at the site of puncture and systemic sepsis

Sample Size calculation : based on two proportion –Hypothesis testing. The sample size was arrived with Master Software version 2.0 by applying following details in this formula.

Formula

$H_0 : P_1 = P_2 ; \qquad H_A : P_1 \neq P_2$

$$n = \frac{\left\{ Z_{1-\frac{\alpha}{2}} \sqrt{2\,\bar{P}(1-\bar{P})} + Z_{1-\beta} \sqrt{P_1(1-P_1) + P_2(1-P_2)} \right\}^2}{(P_1 - P_2)^2}$$

Where,

$$\bar{P} = \frac{P_1 + P_2}{2}$$

P_1 : Proportion in the first group

P_2 : Proportion in the second group

α : Significance level

$1-\beta$: Power

Two proportion –Hypothesis testing	
Proportion in group I	0.546
Proportion in group II	0.226
Estimated risk difference	0.32
Power (1- beta) %	95
Alpha error (%)	5
1 or 2 sided	2
Required sample size for each arm	57

Subjects and Selection method : The study population are the parturient who come to labor in active stage of labor .Simple randomization technique was used to divide into two groups. Out of 200 sample size, 100parturients are included in the epidural analgesia group and 100 in non-epidural group who received tramadol as analgesia.

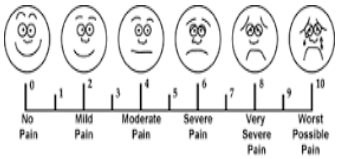
Statistical Analysis:

The collected data wasanalyzed with IBM.SPSS statistics software 23.0 Version. To describe about the data descriptive statistics frequency analysis, percentage analysis was used for categorical variables and for continuous variables the mean and S.D will be used.To find the association of significance in categorical data the Chi-Square test and Fisher's exact test was used. In both, the above statistical tools the probability value .05 is considered as significant level.

Procedure Methodology:

After obtaining ethical committee approval a written consent was obtained. A detailed examination of the patient was done and following parameters were recorded: Demographic data, parity, gestational age, vital parameters and foetal heart rate.

Two hundred primigravida women with 37-40 weeks of pregnancy were selected, who were in established active stage of labour (uterine contractions 3per10 minutes, lasting for 30 to 40 seconds, cervical dilation more than 3cms and cervical effacement more than or equal to 60%) with singleton foetus with vertex presentation and consent for analgesia givenAll enrolled women provided written informed consent for participation. Patients were divided into two groups Epidural group who received epidural 0.025% bupivacaine with fentanyl 5mcg and Tramadol group received 1mg/kg intramuscularly as bolus in the beginning, then 100mg in 500ml of ringer s lactate drip at rate of 8-24 drops/min.Continuous epidural analgesia is adjusted to least analgesic dose (10-15ml/hr) then top up doses weregiven according to a segment regression and continued till birth.500ml of Ringers lactate solution was given to every parturient before they were subjected to epidural analgesia to diminish the incidence of maternal hypotension and foetal heart rate abnormalities.Pain relief was assessed by visual analogue scale.(VAS score,0-10) with 0 representing no pain and 10 as the worst pain.VAS graded into (0-4 mild, 4-6 moderate, 7-10 severe pain). Assessment was done before and after the administration of the drug every 15minutes in the first one hour then hourly till delivery.



VISUAL ANALOGUE SCALE

Intrapatrum monitoring was done according to the standard labour ward protocol using the partogram.The time interval between drug administration and delivery was recorded,mode of delivery and side effects of analgesia either maternal or foetal were recorded. Neonatal evaluation was done by the neonatologist who was informed about the type of analgesia given to the mother using APGAR score.Neonatal Outcome was assessed by :Condition at Birth-Apgar Score, Need for NICU Admission.Patient satisfactionwas subjectively assessed as: Excellent, Good, Average or Poor. The outcome of both groups were compared and analysed.

III. Results

The collected data were analysed with IBM.SPSS statistics software 23.0 Version.To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. To find the significant difference between the bivariate samples in Independent groups the Unpaired sample t-test was used.To find the significance in categorical data Chi-Square test was used similarly if the expected cell frequency is less than 5 in 2×2 tables then the Fisher's Exact was used. In all the above statistical tools the probability value .05 is considered as significant level.

Table 1: Analysis of Maternal characteristics of two groups

ANALGESIA		Mean
Age (years)	Epidural	24.25
	Tramadol	24.44
Ht(cms)	Epidural	162.42
	Tramadol	163.18
Wt(kgs)	Epidural	58.10
	Tramadol	58.42

Maternal characteristics between two groups analysed and it was statisticallyinsignificant.(P value >0.05).

Table 2: Cervical dilatation at initiation of analgesia

ANALGESIA		Mean
Mean cervical dilatation (cms)	Epidural	3.47
	Tramadol	3.62

Mean cervical dilatation at initiation of analgesia in epidural group is 3.47cms and in tramadol group is 3.62cms .P value is not statistically significant ,(P value >0.05)

Table 3: Gestational age distribution at which analgesia given

			ANALGESIA	
			Epidural	**Tramadol**
GA(wks)	< 38 Weeks	Count	7	8
		%	7.0%	8.0%
	38 to 38+6	Count	25	31
		%	25.0%	31.0%
	39 to 39+6	Count	44	35
		%	44.0%	35.0%
	=40 Weeks	Count	24	26
		%	24.0%	26.0%
Total		Count	100	100
		%	100.0%	100.0%

In epidural and tramadol group maximum number of parturients received analgesia at 39 to 39+6 weeks of gestational age.

Figure 1: Gestational age distribution at which analgesia given

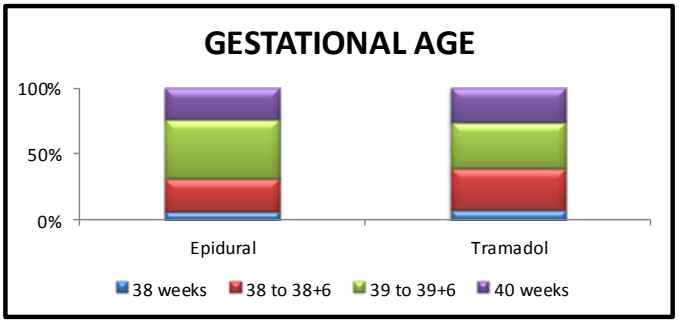


Table 4: Comparision of maternal Pulse rate , BP

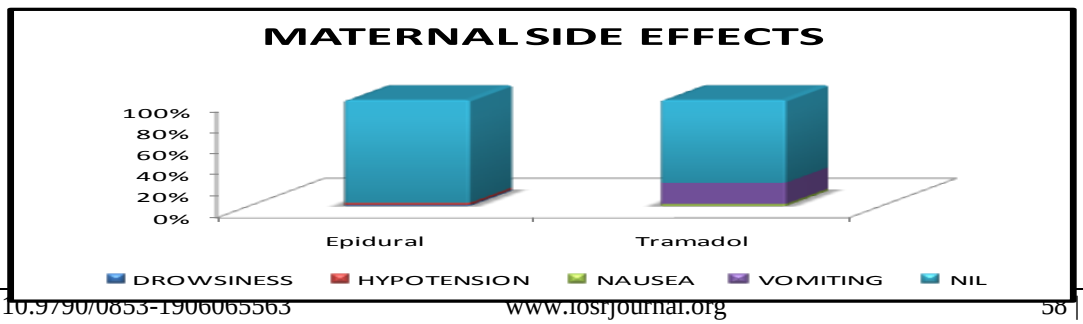
Maternal pulse rate and blood pressure	Epidural	Tramadol
Mean pulse rate (bpm)	80.0	80.5
Mean blood pressure (SBP/DBP) (mm Hg)	116.0/71.0	118.0/74.4

Mean pulse rate in epidural group is 80 bpm and in tramadol group is 80.5. Mean BP in epidural group is 116/70 mmHg and in tramadol group is 118/74.4mm Hg.

Table 5: Comparison of maternal side effects

			ANALGESIA	
			Epidural	**Tramadol**
Maternal side Effects	Drowsiness	Count	1	0
		%	1.0%	0.0%
	Hypotension	Count	2	0
		%	2%	0.0%
	Nausea	Count	0	2
		%	0.0%	2.0%
	Nil	Count	97	78
		%	97.0%	78.0%
	Vomiting	Count	0	20
		%	0.0%	20.0%
Total		Count	100	100
		%	100.0%	100.0%

Figure 2: Maternal side effects of epidural and tramadol analgesia



Hypotension is noted in 2patients in epidural group and vomiting noted in 20 patients and nausea in 2 patients in tramadol group ..P value is stastistically significant.(P value <0.05).Vomiting as side effect noted in 20% in tramadol group and absent in epidural group .P value is statistically significant .

Table 6: Duration of labour after labour analgesia

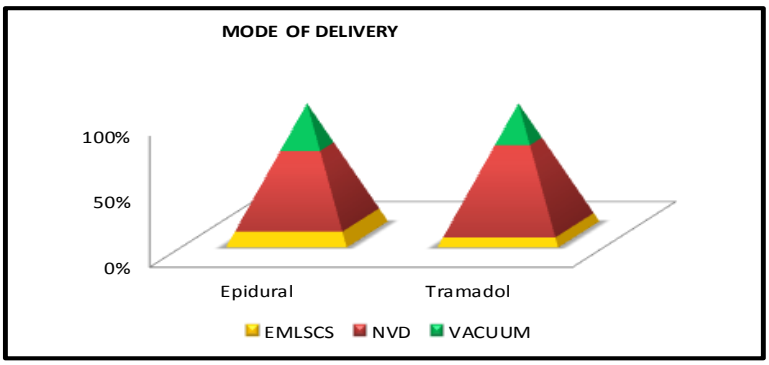
ANALGESIA		Mean
Mean duration of labour after analgesia(hrs)till full dilatation.	Epidural	6.2
	Tramadol	6.0
Mean duration of second stage(min)	Epidural	64
	Tramadol	60
Mean duration of third stage(min)	Epidural	7.2
	Tramadol	7.1

Mean duration of labour after giving analgesia till full dilatation is 6.2hrs in epidural group and 6hrs in tramadol group .Mean duration of second stage of labour is 64min in epidural group and 60min in tramadol group,and duration of third stage is 7.2 minutes in epidural and 7.1 min in tramadol group. P value is not stastically significant.(P value >0.05)

Table 7: Mode of delivery compared between two groups

			ANALGESIA	
			Epidural	**Tramadol**
MODE OF DELIVERY	EMLSCS	Count	11	7
		%	11.0%	7.0%
	NVD	Count	56	64
		%	56.0%	64.0%
	VACUUM	Count	33	29
		%	33.0%	29.0%
Total		Count	100	100
		%	100.0%	100.0%

Figure 3: Mode of delivery compared between two groups



In epidural group – 11% EMLSCS, 56% NVD's and 33% of instrumental deliveries.In tramadol group - 7% EMLSCS, 64% NVD's and 29% of instrumental deliveries.There is no significant difference between mode of delivery in both the groups(P value >0.05).

Table 8: Indications for instrumental and caesarean delivery

			ANALGESIA	
			Epidural	**Tramadol**
Indication for Caesarean delivery	ABNORMAL CTG	Count	6	2
		%	6.0%	2.0%
	NPOL	Count	0	1
		%	0.0%	1.0%
	FD	Count	3	2
		%	3.0%	2.0%
	GRADE3MSL	Count	2	2
		%	2.0%	2.0%
Indication for Instrumental delivery	MSL TO CUT SHORT 2ND STAGE	Count	9	8
		%	9.0%	8.0%
	FD	Count	5	4

		%	5.0%	4.0%
	PME	Count	8	6
		%	8.0%	6.0%
	ABNORMAL CTG	Count	4.0	6.0
		%	4.0%	6.0%
	Nil	Count	56.0	64.0
		%	56.0%	64.0%
	PROLONGED 2ND STAGE	Count	7	5
		%	7.0%	5.0%
Total		Count	100	100
		%	100.0%	100.0%

11% parturients in epidural group and 7 % in tramadol group underwent caesarean section .33% parturients in epidural group and 29 % in tramadol group underwent instrumental deliveries.

Table 9: Comparison of foetal outcome

			ANALGESIA	
			Epidural	**Tramadol**
FOETAL OUTCOME	GOOD	Count	100	99
		%	100.0%	99.0%
	POOR	Count	0	1
		%	0.0%	1.0%
Total		Count	100	100
		%	100.0%	100.0%

Foetal outcome was good in both the groups .There was no statisticallysignificant difference .(P value >0.05).Good foetal outcome means APGAR > 7 at 5 minutes .

Table 10: Comparison ofbirth weight and APGAR score.

ANALGESIA		Mean Value
Mean birth weight(kgs)	Epidural	2.99
	Tramadol	2.89
APGAR 1MIN	Epidural	7.90
	Tramadol	7.94
APGAR 5MIN	Epidural	8.92
	Tramadol	8.96

Foetal outcome was good in both the groups .APGAR score for epidural group is 7.92 at 1min and 8.9 at 5min , and in tramadol group is 7.94 and 8.96 .Mean birth weight in epidural group is 2.99 kgs and 2.89kgs in tramadol group.No statistically significance. (Pvalue>0.05) between two groups in APGAR Score and birth weight.

Table11: **NICUadmission ofnewborns in both the groups**

			ANALGESIA	
			Epidural	**Tramadol**
NICU ADMISSION	NORMAL	Count	98	99
		%	98.0%	99.0%
	ADMITTED	Count	2	1
		%	2.0%	1.0%
Total		Count	100	100
		%	100.0%	100.0%

Only two babies in epidural group and one baby in tramadol group was in NICU admission for observation.

Table12: Indications for NICUadmission of newborns of two groups

			ANALGESIA	
			Epidural	**Tramadol**
INDICATION	NO	Count	98	99
		%	98.0%	99.0%
	RESPDISTRESS	Count	1	0
		%	1.0%	0.0%

	SEC APNOEA	Count	0	1
		%	0.0%	1.0%
	TACHYPNOEA	Count	1	0
		%	1.0%	0.0%
Total		Count	100	100
		%	100.0%	100.0%

Only 2 babies in epidural group and 1 baby in tramadol group admitted in NICU for observation for indications of respiratory distress ,tachypnoea in epidural group and for secondary apnoea in tramadol group.

Table 13: comparison of degree of painrelief between two groups

			ANALGESIA	
			Epidural	**Tramadol**
DEGREE OF PAIN RELIEF	MILD	Count	42	26
		%	42.0%	26.0%
	MODERATE	Count	7	59
		%	7.0%	59.0%
	NO PAIN	Count	51	15
		%	51.0%	15.0%
Total		Count	100	100
		%	100.0%	100.0%

Degree of pain relief between two groups was compared and was statistically significant(P value < 0.05) .51%of women in epidural group had no pain compared to 15 % in tramadol group .only 2 parturients required single top up dose in epidural group.

Figure 4: Comparisonof degree of painrelief between two groups

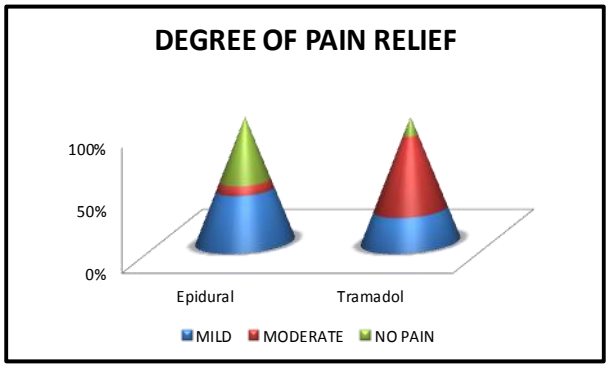
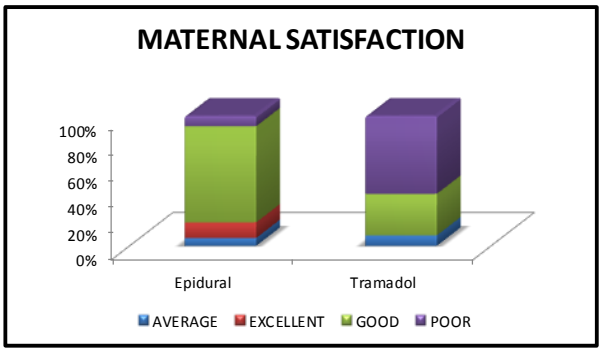


Table 14: Comparison of maternal satisfaction between two groups

			ANALGESIA	
			Epidural	**Tramadol**
MATERNAL SATISFACTION	AVERAGE	Count	6	8
		%	6.0%	8.0%
	EXCELLENT	Count	12	0
		%	12.0%	0.0%
	GOOD	Count	74	32
		%	74.0%	32.0%
	POOR	Count	8	60
		%	8.0%	60.0%
Total		Count	100	100
		%	100.0%	100.0%

Maternal satisfaction compared between two groups and is statistically significant with P value <0.01. Satisfaction was good in 74% women with epidural group and 32%in tramadol group and excellent in 12% in epidural group.

Figure 5: shows comparison of maternal satisfaction between two groups



IV. Discussion

The present study was conducted at RDT Hospital, Bathalapalli from August 2016- February 2018 on"Comparison of labour outcome with and without epidural analgesia" in the department of Obstetrics and Gynaecology in RDT Hospital. Parturients were divided intotwo groups using simple randomisation technique after counselling regarding the labour analgesia. All women who participated were primigravidae who gave written consent.No technical difficulty or inadvertent dural puncture was encountered in the epidural group.

Maternal characteristics like age, height (cms), weight (in kgs) of two groups were compared . There is no statistically significant differences between the two groups.This is similar to study conducted by Salehet al[8]andJaitley anu[7]

Mean cervical dilation at initiation of analgesia is 3.47cms in epidural group compared to 3.62 cms in tramadol group,comparable to studies conducted by Saleh et al[8]andjaitley anu.[7]There is no significant difference between the two groups.

Maternal side effects of both types of analgesia were compared:

Hypotension was noted in 2 parturients of epidural group in my study and vomiting in 20% of tramadol group with p value< 0.05. In the study conducted by Saleh et al[8] there was hypotension in form of transient hypotension in epidural group compared to tramadol group with (Pvalue< 0.05) which is statistically significant.In my study,maternal hypotension is considered when blood pressure falls more than 20% of her baseline blood pressure or <90mm hg and it was managed with IV fluid administration and left lateral position.Vomiting in tramadol group managed by antiemetics .

Effect of analgesia on labour duration:

In the studies of Saleh et al [8]Philip e Hess et al [9] and Jaitleyanu[7] ,duration of second stage of labour was prolonged in epidural group compared to tramadol group and it was stasticallysignificant in their studies . In the present study there is no significant difference in the duration of second stage of epidural and tramadol group.There is no significant difference in duration of 1st and 3rd stage of labour in epidural and tramadol group in the present study which was similar to the studies of Saleh et al[8]and Jaitleyanu[7]. This shows that epidural analgesia with low dose of bupivacaine and fentanyl does not cause motor blockade and does not interfere with the descent or internal rotation of the presenting part or maternal expulsive forces.

Mode of delivery:

In the present study there is no significant difference in mode of delivery between two groups which was similar to the study of Saleh et al[8] .In the present study there is no significant difference between epidural and tramadol group in mode of delivery (P value is >0.05), Indications for instrumental and caesareandeliveries in epidural group is due to obstetric indications for grade 3 MSL and abnormal CTG, not due to epidural analgesia.

Neonatal outcome :

Mean APGAR scores at 1min and 5minutes were similar in both the groups.,and 2 babies in epidural group and 1 baby in tramadol group transfered to neonatal intensive care unit for observation but discharged back to the mother after 5-6hours ,both neonates were followed up for another 24hours and were found to be clinically active and asymptomatic.Mean birth weights are 2.99kgs in epidural group and 2.89kgs in tramadol group .There was no statistically significant differences in the foetal outcome between the two groups, and it was similar to the studies of Saleh et al and Jaitley anu.

Degree of pain relief :

There was complete pain relief in 36% of parturients in epidural group and 15% in tramadol group , and it was statistically signicant P value <0.05 .it was similar to the studies of Saleh et al[8]and jaitleyanu[7]Maternal satisfaction :

Maternal satisfaction was good in 74%of epidural group and it was 32%in tramadol group and with Pvalue<0.01 which is statistically significant and it was similar to the studies of Jaitley et al and Saleh et al which was statistically significant.In study of Jain et al[10] they reported that 90% of women found epidural to be of great benefit in terms of pain reliefand in the study by Anwer et al[6], study concluded that epidural analgesia provided excellent pain relief in majority of the patients .

V. Conclusion

- Epidural analgesia is a Safe and excellent method for painless delivery.

The present study showed following :

- There is no prolongation of duration of labour and maternal side effects are minor in epidural group when compared to Tramadol analgesia.
- There was no increase in the rate ofinstrumentaldeliveries and caesarean delivery.
- No serious maternal complications were seen in the study in both the groups.
- The neonatal outcome was good with APGAR>7 at 5minutes.
- Epidural analgesia provides excellent analgesia for parturient who opted forit compared to tramadol analgesia.
- The fear of pain,lack of awareness made many women to demand caesarean section. If the fear associated with the pain of labour can be addressed and the advantages of vaginal birthwith labour analgesia were to be explained to these women, many unnecessary caesarean deliveries can be avoided.

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