

Comparative Study of Induction of Labour in Term Prelabour Rupture of Membrane by Dinoprostone Gel, Vaginal Misoprostol with Spontaneous Onset of Labour and Its Maternal and Foetal Outcome.

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Abstract: Labor induction is a clinical intervention that has the potential to confer major benefits to the mother and newborn when continuation of pregnancy poses a risk or danger to the outcome of pregnancy. PROM occurs in approximately 5–10 % of all pregnancies, of which approximately 80 % occur at term (term PROM)¹. Diagnosis and proper management is very important as it is implicated for various fetal and maternal complications generally due to infection. To avoid such a complication, labor is usually induced, once PROM is confirmed. This study was conducted at the department of Obstetrics and Gynecology, RIMS, RANCHI where 150 patients were studied who presented to labour emergency. Group A, B, C respectively consisted of 50 patients who were induced with dinoprostone gel, vaginal tablet misoprostol and rest for expectant management. Induction with DINOPROSTONE GEL proved to be the best. Expectant management only be followed at TERM PROM in absence of medical or obstretical complications. Delay in induction exposes mother and infants to septic work up and infection. (Wagner et al 1989). Use of prophylactic antibiotics, proper antenatal monitoring, minimal vaginal examination examination under proper aseptical conditions, screening of lower genital infections and its adequate treatment are important to prevent PROM and fetomaternal complication.

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I. Introduction

Premature rupture of membranes (PROM) refers to the loss of integrity of membranes before onset of labor, with resulting leakage of amniotic fluid and establishment of communication between the amniotic cavity and the endocervical canal and vagina². Indian studies [Bhalerao and Desai, 2000; Bhide, 2001] report an incidence of PROM in 7-12% of all labours. PROM occurs when intrauterine pressure overcomes membrane resistance. The longer the time interval between rupture of membranes and onset of labor the greater the risk of ascending infection and chorioamnionitis. The comprehensive guidelines of this prospective project is approach based with simple measures to study the labor inductions in term prelabour rupture of membrane covering the characteristics of the active and expectant management group, methods and protocols for induction, outcome of labor with the boons and bans of induction for the mother and the foetus evolving.

II. Materials And Methods

SOURCE OF DATA

This study will be carried out in the department of Obstetrics and Gynaecology, Rajendra Institute Of Medical Sciences, RANCHI. The number of cases which are admitted with clinically the provisional diagnosis as prelabour rupture of membranes > 37 weeks of gestation. All these cases were admitted in our hospital for further management and outcome.

Study Design : Comparative study

Study Period : 18 Months (DEC 2014 to MAY 2016)

Sample size calculation: The sample size was estimated on the basis of a single proportion design. We assumed confidence level of 95%. The sample size actually obtained for this study

STUDY METHODOLOGY : After written informed consent was obtained a well designed questionnaire was used to collect data of recruited patients. Questionnaire included history taking, obstretical examination (inspection, obstretical grips, auscultation of FHS), examination of genitalia (P/S examination: colour of liquor, state of cervix, any cord prolapse, litmustest, fern test), P/V examination (pelvic capacity, bishop's score, membrane present or not, colour of liquor) basic investigations (Hb%, Random blood sugar, Abo/Rh, VDRL, HIV,

HBsAg, thyroid profile, swab from gram's stain for C/S,CRP,R/E urine,C/S urine,1st trimester scan). All the patients irrespective of duration of PROM were given injectable Ampicillin 500 mg 6 hourly and injectable Gentamycin 80 mg 12 hourly by parenteral route till delivery.

BISHOP'S SCORING DONE and induction is proceeded after assessing cervical status.
score<6(a) GROUP A Cervical priming with prostaglandins mainly dinoprostone gel 0.5 mg intracervically/intravaginally.
(b)GROUP B Cervical priming with tab misoprost 25µg every 4 hours maximum Of 6 to 8 doses can be given.
The improvement of the bishop score to >6 with a favourable cervix would then advocate an oxytocin infusion in active phase of labour.

EXPECTANT GROUP/GROUP C

Patients allowed to progress with spontaneous labour.Those who showed no signs of progress after 12 hours labour was augmented with Oxytocin infusion with 2.5 units in 500 ml of normal saline.

IN FIRST STAGE OF LABOUR ALL THE THREE GROUPS HAD THE FOLLOWING (a) Monitoring of Maternal vitals.(b)Monitoring of Fetal heart rate (c)PARTOGRAPHIC CHARTING to assess progress of labour.

At the IInd stage of labor documentation done regarding

(a) mode of delivery
(b) details of the fetus being born- maturity, sex, weight, time, date of birth, Apgar score at 1 and 5 minutes with basic suctioning.

The III stage of labor documentation regarding

(a) The exact timing of placental delivery
(b) Weight of placenta
(c) Observation of post partumhaemorrhage with repair of episiotomy or any extended tears and post delivery medications necessary.

Postpartum stay in the hospital observed for mother and baby with the normal protocols for postpartum care and management of the complications. . In puerperium, all patients were followed clinically and investigated for evidence of infection. Neonatal morbidity was considered in cases of neonatal septicemia, convulsions, or with birth asphyxia. The following are noted

MATERNAL MORBIDITY

- POSTPARTUM HAEMORRHAGE
- PUERPERAL PYREXIA
- ENDOMETRITIS
- CHORIOAMNIOTIS

FETAL OUTCOME

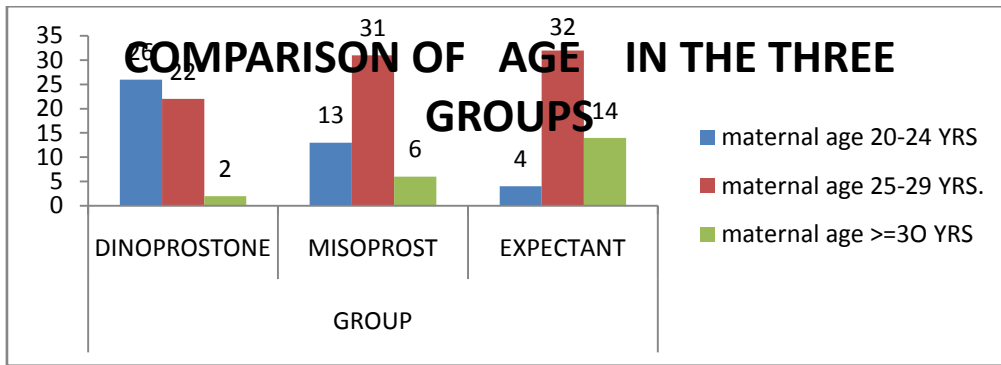
- Moderate birth asphyxia/severe birth asphyxia
- Pneumonia
- RESPIRATORY DISTRESS SYNDROME.
- MECONIUM ASPIRATION SYNDROME
- NEONATAL SEPTICEMIA
- HYPOTHERMIA

Statistical Analysis: Appropriate statistical methods proposed for the study will be applied with SPSS software version. Chi-square and ANOVA were performed to test for differences in proportions of categorical variables between two or more groups. The level $P < 0.05$ was considered as the cutoff value or significance.

III. Results

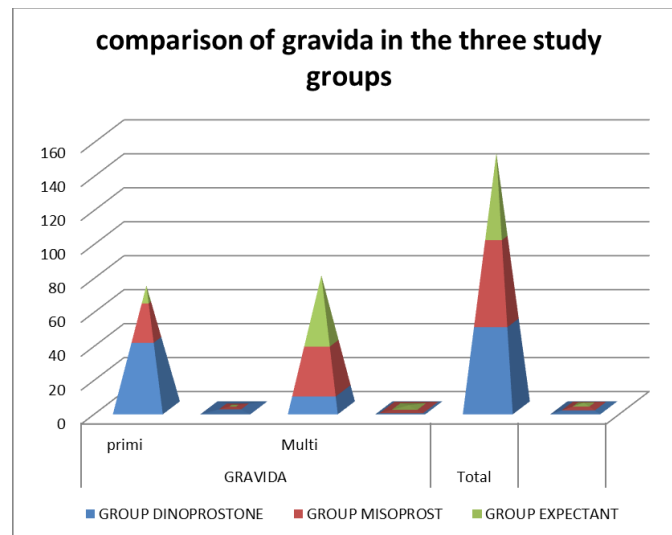
The present study was undertaken to compare induction in TERM PRELABOUR RUPTURE OF MEMBRANE with dinoprostone gel, misoprostol tablet with spontaneous onset of labour and its fetomaternal outcome. Total 150 cases were studied.

1. Incidence of PROM – Total No. of deliveries in my study period was 7,770 out of which 591 cases were of TERM PROM. Therefore incidence PROM was 7.6% in the present study.
2. Maximum number of cases belong to age group 25 – 29 years (56.7%), which was the peak age group during period of my study. .

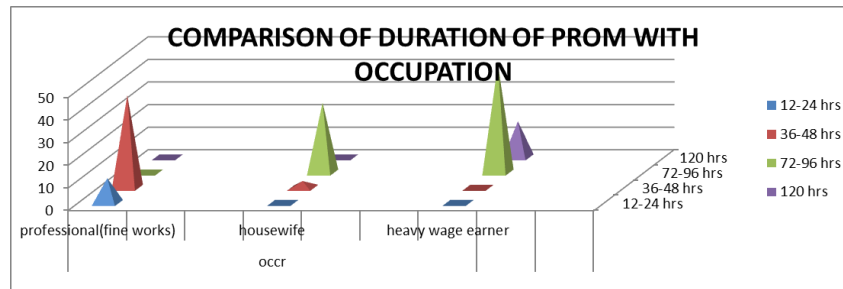


3. Total number of primigravidas in my study was 72 and multigravida 78 .Out of 72 primigravidas 40 were induced by Dinoprostone gel, 22 by Tab. Misoprostol and 10 were present in group with expectant management. Formultigravida 10 were induced with Dinoprostone gel, 28 with tab Misoprostol and expectant management in rest 40.(TABLE 2).

		GROUP			Total	Chi Square	P value
		DINOPROSTONE	MISOPROSTOL	EXPECTANT			
GRAVIDA	primi	40 80.0%	22 44.0%	10 20.0%	72 48.0%	36.538 Df=2	0.000*
	Multi	10 20.0%	28 56.0%	40 80.0%	78 52.0%		
Total		50 100.0%	50 100.0%	50 100.0%	150 100.0%		



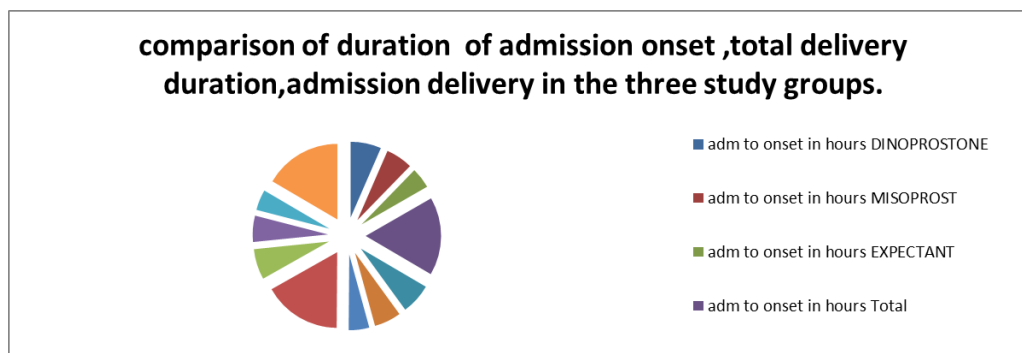
4. Out of 78 Multigravidas 60 patient had previous history of PRE TERM PROM.
5. The current study included PROM cases at TERM (37 weeks and onwards).
6. Out of 150 cases 76 were unbooked, majority belonging to low social economic class { KUPPUSWAMY CLASSIFICATION class IV 30.7% }and among heavy wage earners (42%). (nutritional deficiency in patients of PROM in my study).



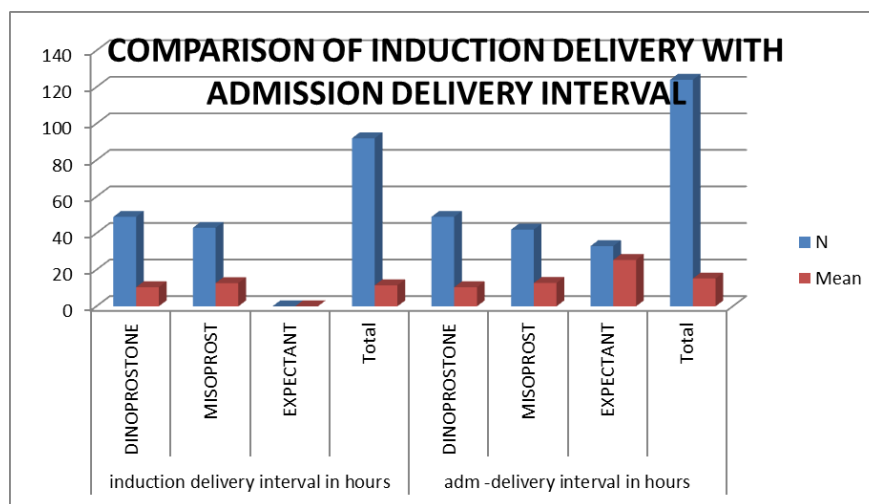
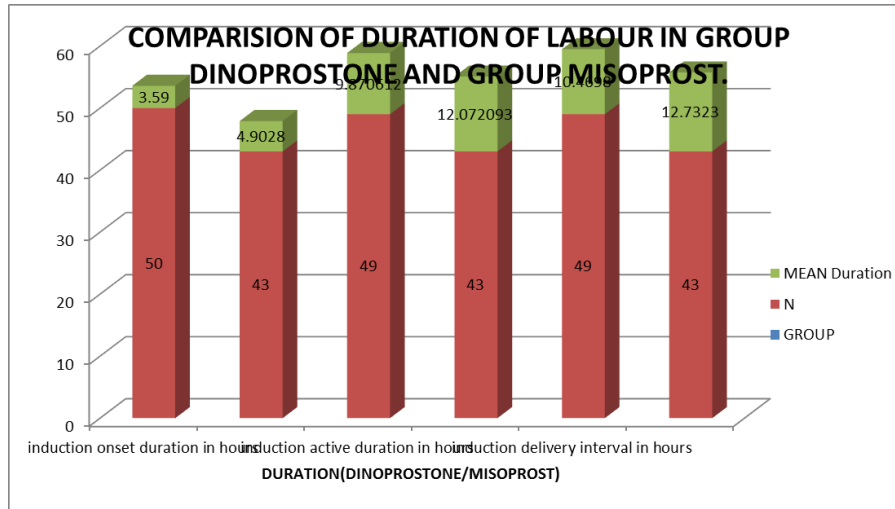
7. Admission - Onset, total duration of labour and admission delivery interval in group A was respectively 3.58 hours, 6.89 hours, 10.47 hours whereas in expectant group it was 13.69 hours, 11.62 hours, 25.39 hours. For the group induced with tab Misoprostol, it was 4.87 hours, 7.67 hours and 12.79 hours respectively. Following conclusion were deduced.

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	
					Lower Bound	Upper Bound			
adm to onset in hours	DINOPROSTONE	49	3.5816	1.18738	.16963	3.2406	3.9227	2.00	8.00
	MISOPROSTOL	43	4.8795	.90498	.13801	4.6010	5.1580	3.00	6.00
	EXPECTANT	33	13.6970	2.65147	.46156	12.7568	14.6371	10.00	16.00
	Total	125	6.6986	4.54514	.40653	5.8939	7.5032	2.00	16.00
total duration of labour in hours	DINOPROSTONE	49	6.891020	1.0470280	.1495754	6.590279	7.191762	4.7500	7.8300
	MISOPROSTOL	43	7.678605	1.2257118	.1869193	7.301386	8.055823	6.0000	9.3000
	EXPECTANT	33	11.623333	3.6368639	.6330967	10.333757	12.912909	6.0000	18.5000
	Total	125	8.411280	2.8621261	.2559963	7.904592	8.917968	4.7500	18.5000
adm -delivery interval in hours	DINOPROSTONE	49	10.47	1.877	.268	9.93	11.01	7	16
	MISOPROSTOL	42	12.79	2.012	.310	12.17	13.42	10	17
	EXPECTANT	33	25.39	5.362	.933	23.49	27.30	17	35
	Total	124	15.23	6.998	.628	13.98	16.47	7	35

DINOPROSTONE WAS FOUND TO BE BETTER INDUCING AGENT THAN MISOPROSTOL AS INDUCTION-ONSET, INDUCTION-ACTIVE AND INDUCTION –DELIVERY INTERVAL WERE LESS AS COMPARED TO TAB MISOPROSTOL.



a) Dinoprostone gel was found to be a better inducing agent and shortens duration of labour.

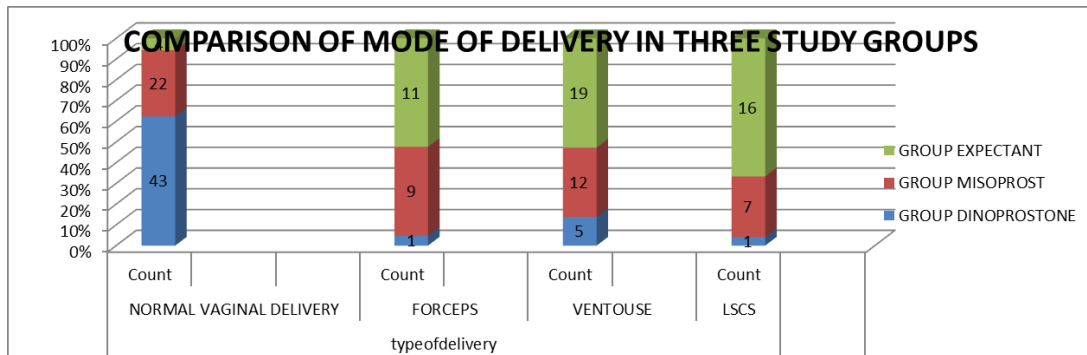


8. Comparison of Induction in group A and B : Induction - onset , Induction -active, induction - delivery interval was less in group A induced by Dinoprostone than in group B induced by Tab Misoprostol . Hence Dinoprostone gel. was found to be better inducing agent in this study than tab Misoprostol .
COMPARISON OF INDUCTION ONSET,INDUCTION ACTIVE AND INDUCTION DELIVERY INTERVAL IN GROUP DINOPROSTONE AND MISOPROSTOL.

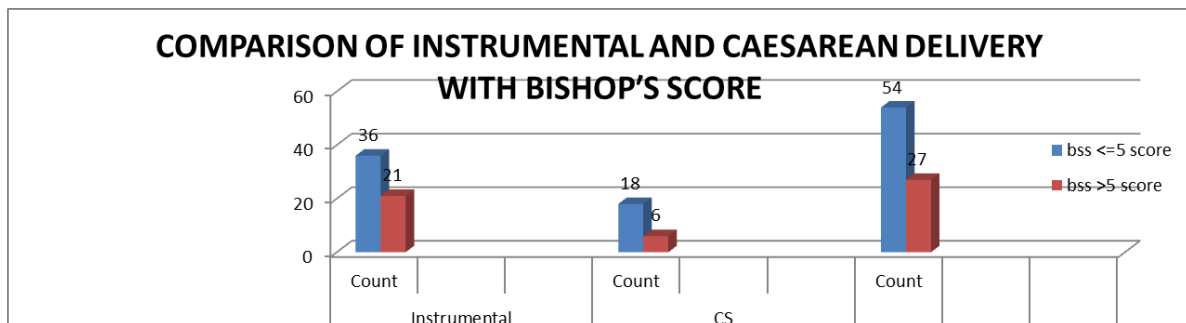
Group Statistics

GROUP	N	Mean	Std. Deviation	Std. Error Mean	't value	P value	
induction onset duration in hours	DINOPROSTONE	50	3.5900	1.17669	.16641	5.978	0.000
	MISOPROSTOL	43	4.9028	.89463	.13643		
induction active duration in hours	DINOPROSTONE	49	9.870612	1.7509241	.2501320	5.942	0.000
	MISOPROSTOL	43	12.072093	1.7979771	.2741889		
induction delivery interval in hours	DINOPROSTONE	49	10.4698	1.87670	.26810	5.556	0.000
	MISOPROSTOL	43	12.7323	2.02812	.30929		

9. Mode of Delivery:



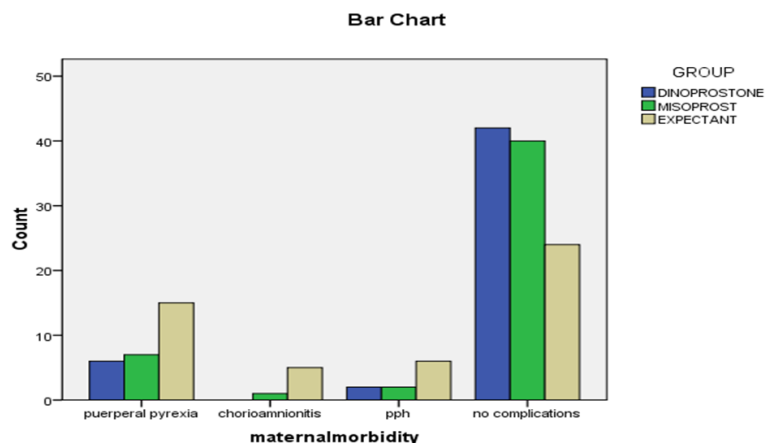
- a) Total number of normal delivery was 46%, forceps delivery 14%, Ventouse 24%, LSCS 16%.
 - b) Normal delivery was present in 43 patients induced with Dinoprostone gel 22 in patients with Tab Misoprostol and 4 in expectant group.
 - c) 6 instrumental delivery in Group A, 21 in Group B and 30 in Group C. There was only 1 LSCS in group A, 7 in Group B and 16 in Group C. Instrumental delivery and LSCS was more in expectant group.
10. When comparing with BISHOP'S SCORE more incidences of instrumental delivery (63%) and LSCS (75%) were found with BISHOP'S SCORE ≤ 5 .



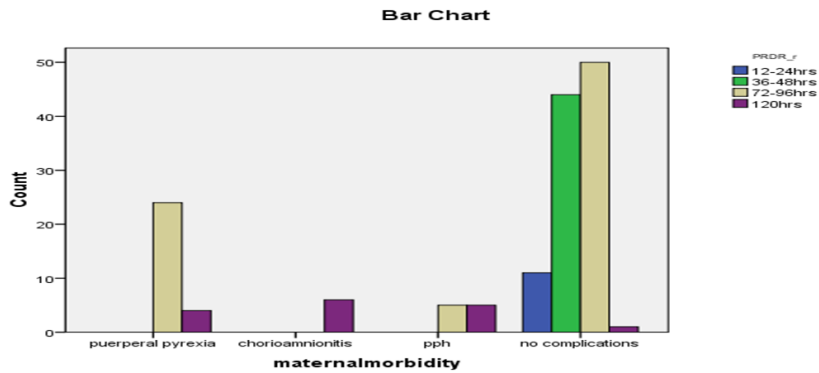
- 11. No correlation was found between duration of PROM with admission-onset, total delivery interval and admission delivery interval.
- 12. Maternal Morbidity

(i) Comparison with study groups

a. Group A induced with dinoprostone gel had the least maternal morbidity (8 cases only). Most common was puerperal pyrexia (6 cases) followed by PPH (2 cases).



b.Total number of morbidity in Group B was 10.Puerperal pyrexia was present in 7 cases ,chorioamnionitis in 1 case,PPH in 2 cases, and no complications in the rest 40 cases.



c.Expectant group had the maximum morbidity (26 cases).Puerperal pyrexia was present in 15 cases,5 cases of chorioamnionitis and 6 cases of PPH.

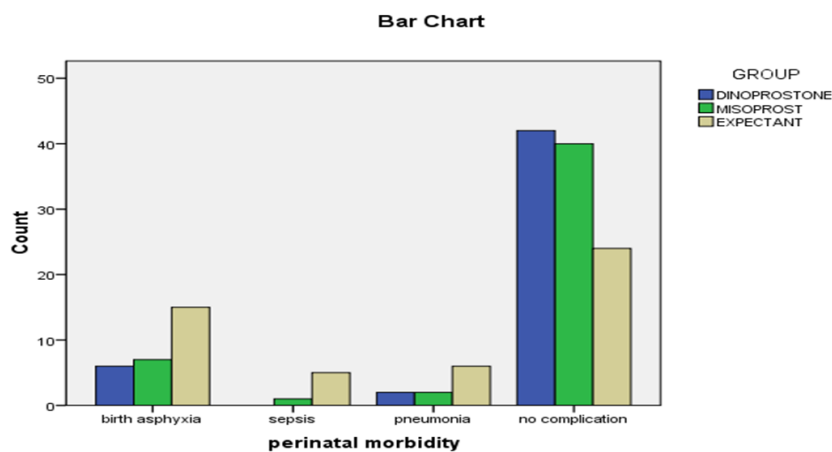
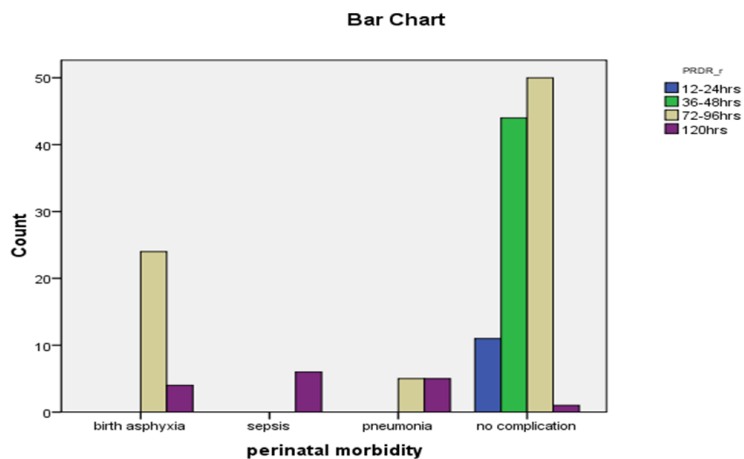
(ii)Comparison with duration of PROM

a.In 12-24 hr and 36-48hr duration of PROM no morbidity was present.

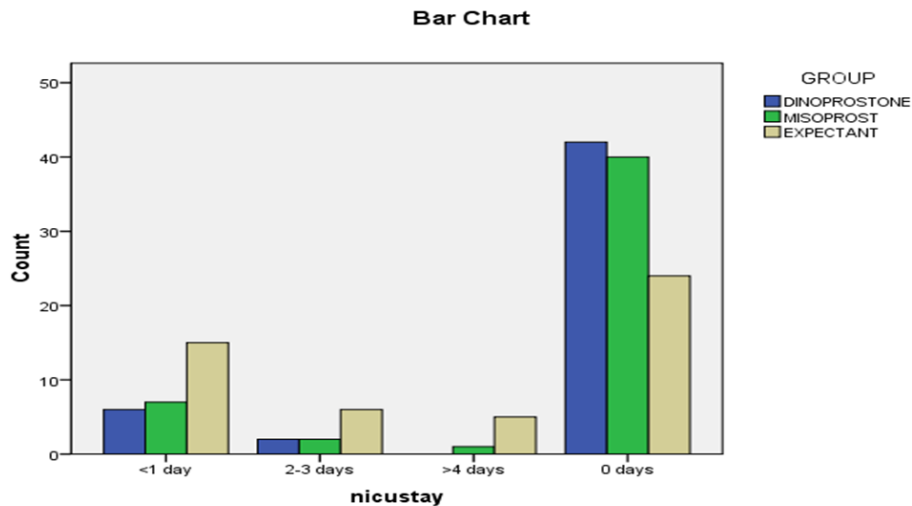
b.In 72-96hr PROM duration 29 patients had morbidity (24 cases of puerperal pyrexia and 5 cases of PPH).

c.In 120hr PROM duration there were 4 cases of puerperal pyrexia,6 cases of chorioamnionitis, 5 cases of PPH and no morbidity in just one case.

13. PERINATAL MORBIDITY

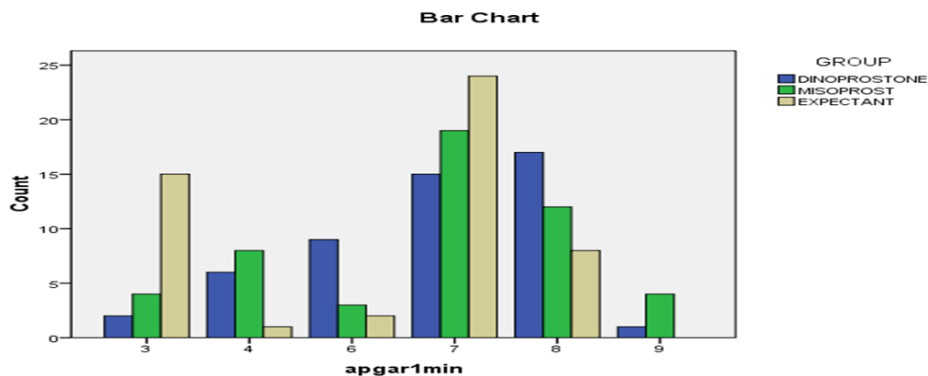


- i. Group A had least the perinatal morbidity (6 cases of birth asphyxia and 2 cases of pneumonia).
 - ii. Group B had 10 cases of perinatal morbidity (7 cases of birth asphyxia, 1 case of sepsis and 2 cases of pneumonia).
 - iii. Expectant group had the maximum morbidity (15 cases of birth asphyxia, 5 cases of sepsis, 6 cases of pneumonia).
- b. Comparison with duration of PROM
- i. No morbidity were present in 12-24hr and 36-48hr PROM duration.
 - ii. In 72-96 hr PROM duration 24 cases of birth asphyxia, 5 cases of pneumonia were present and.
 - iii. In 120 hr PROM duration there were 4 cases of birth asphyxia, 6 cases of sepsis, 5 cases of pneumonia.
- c. Comparison of NICU stay in group



- i. In Group A .There were 6 cases requiring <1 day and 2 cases requiring 2-3 days NICU stay.
 - ii. In Group B .There were 7 cases requiring <1 day NICU stay, 2 cases of 2-3 days stay and 1 case of >4 days NICU stay.
 - iii. Expectant group had maximum NICU stay. (15 cases <1 day, 6 cases had 2-3 days stay and 5 cases had >4 days NICU stay.)
- Presence of more cases of neonatal morbidity can be explained by longer rupture delivery interval in expectant group supported by LENIER, SCARBROUGH, FILLINGIN and BAKER (1965).

d. APGAR scoring

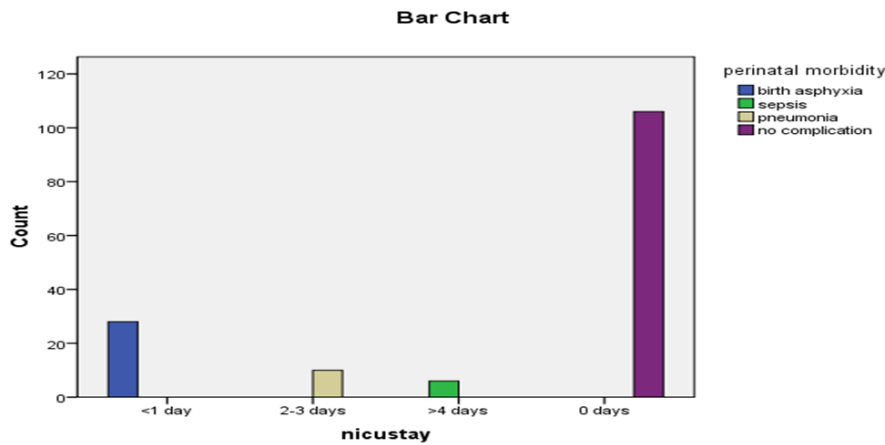


- i. In Group A , APGAR 0-3 was present in 4% cases, 4-6 in 30% cases and 7-9 in 66%.
 - ii. In Group B , APGAR 0-3 was present in 8% cases, 4-6 in 22% cases and 7-9 in 70%.
 - iii. In Group C , APGAR 0-3 was present in 30% cases, 4-6 in 6% cases and 7-9 in 64% cases.
- APGAR scoring 0-3 signifies severe depression, hence maximum cases of severe depression were seen in expectant group.

e.PERINATAL MORTALITY.

THERE WERE ONLY 4 CASES OF NEONATAL MORTALITY IN THE EXPECTANT GROUP.

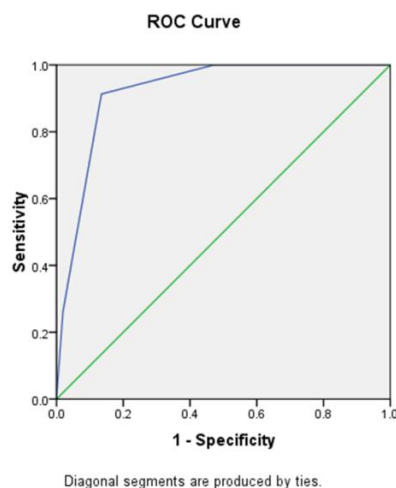
There were just 4 cases of neonatal death in the expectant group of PROM duration 120 hours



IV. Discussion

Overall PROM occurs in approximately 10% of pregnant patients with the range falling between 2.7% and 17%. In this present study there were about 7770 deliveries of which 591 cases belonged to TERM PROM(7.6%) of approximately 38 weeks gestational age..VARNER AND GALASH³ have reported mean age group as 25 yrs in PROM .In my study 56.7% patients belonged to 25-29yrs .KODKANY AND TELANG⁴, SEMEZUEK SIKORA⁵ et al and CHAUDHARI SNEHAMAY⁶ et al found maximum PROM cases to be primigravidas. (72 out of 150 in this study). Out of 150 cases 76 were unbooked, majority belonging to low social economic class { KUPPUSWAMY CLASSIFICATION class IV 30.7% }and among heavy wage earners (42%)(nutritional deficiency in patients of PROM in my study). RUSSELL AND ANDERSON⁷ (1962) used an aggressive approach to management of PROM and were able to demonstrate improved maternal and foetal outcome than previous nonaggressive approaches .In the current study cases were distributed into three groups- Group A induced with Dinoprostone gel, Group B induced with tab Misoprostol , Group C belonging to expectant management. Admission-onset, total duration of labour ,admission delivery interval was minimum in the group induced with Dinoprostone gel and maximum in expectant group. The risk of developing chorioamnionitis increase proportionately with increase in length of latent period. Therefore by induction not only is labour expedited but maternal and foetal morbidity is also curtailed. KAPPY⁸ et al (1979) suggested that fostering aggressive management with increased use of labour inductions led to increased rates of failed inductions necessitating caesarean section . In the present study Instrumental and caesarean delivery was more in expectant group(30 instrumental and 16 LSCS .) . Normal vaginal delivery was maximum in Group A(Dinoprostone gel 43) and minimum in expectant group(4) More incidences of caesarean delivery (75%) was present with poor bishop's score (≤ 5)in the present study, which is in accordance with KAPPY et al that poor bishop was related to increased rates of induction failure. Maternal risk in TERM PROM is related to infection . Prolonged latency periods at TERM are associated with an increased risk of endometritis (DAIKOKU⁹ et al ,1981). WEBB¹⁰ (1967) demonstrated that the risk of maternal mortality is approximately 1 death for each 5451 cases of PROM. In the present study GROUP A (Dinoprostone gel) had the least maternal morbidity . Maximum morbidity was present in expectant group with prolonged latent period ..Greater severity of maternal morbidity was present in 120hr duration of PROM . Patients in expectant management were frequently monitored for evidence of chorioamnionitis and aggressive antibiotic regimes were administered to prevent morbidity (JOHNSON ¹¹ et al 1981). Maternal CRP estimation is a reliable test for early detection of chorioamnionitis. . In the present study CRP levels were estimated in all cases and significantly raised levels were found in PROM duration 96 hrs onwards (≥ 10 mg/l). Regarding Perinatal morbidity Group A (Dinoprostone) had least perinatal morbidity , Group B(Misoprostol) had intermediate morbidity, Group C (Expectant) had maximum morbidity(15 cases birth asphyxia,5 cases of sepsis,6 cases pneumonia). PROM duration of 12-24hr and 36-48 hr was free from perinatal morbidity of any sort. PROM duration of 120 hr was associated with maximum morbidity (4 cases of birth asphyxia ,6 cases of sepsis, 5 cases of pneumonia .) Regarding comparison of perinatal morbidity with NICU stay Group A needed least NICU stay (<1 day in 6 cases,2-3 days in 2 case).Expectant group had maximum NICU stay(15 cases <1 day NICU stay,6 cases with 2-3 days and 5 cases had >4days NICU stay). (explained by longer rupture interval in expectant group supported by LENIER, SCARBROUGH, FILLINGIN and BAKER¹² (1965). APGAR score 0-3 signifies severe

depression and maximum cases were present in expectant group. The pathogenesis of perinatal septicemia is related primarily to maternal factors ,i.echorioamnionitis. Hence an ROC curve has been plotted in this study whether maternal CRP is of any value to predict neonatal sepsis in patients with TERM PROM13,14. ROC curve was constructed and used to select cut off value to dichotomise serum CRP as being increased or not (AUC:0.921, SE 0.022, P<0.001). A cut off of 10 mg/l for serum CRP appeared to represent reasonable compromise between sensitivity and specificity for prediction of neonatal sepsis and hence prevent useless treatment of infants due to presumed infection.



V. Conclusion

In nulliparous women induction with DINOPROSTONE GEL proved to be the best..Expectant management only be followed at TERM PROM in absence of medical or obstretical complications.). A cut off of 10 mg/l for serum CRP appeared to represent reasonable compromise between sensitivity and specificity for prediction of neonatal sepsis.

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