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Original Research Article

A comparative study of 25µg versus 50µg vaginal misoprostol for induction of labour at term premature rupture of membrane

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ABSTRACT

Background: At term, infection remains the most serious complication associated with PROM for the mother and the neonate Induction of labour significantly reduces the risk of maternal and foetal infection. This randomized comparative study has been done to compare the effectiveness and safety of low and high dosage (25 mcg and 50mcg) regimen of vaginal misoprostol for induction in term PROM patients.
Methods: At term, infection remains the most serious complication associated with PROM for the mother and the neonate Induction of labour significantly reduces the risk of maternal and foetal infection. This randomized comparative study has been done to compare the effectiveness and safety of low and high dosage (25 mcg and 50mcg) regimen of vaginal misoprostol for induction in term PROM patients.
Results: PROM to delivery interval was significantly shorter with 50mcg vaginal misoprostol as compared to 25 mcg vaginal misoprostol (15.71±3.29 hours vs. 18.23±3.23 hours, (p value = 0.0023) Number of doses required was less with 50mcg vaginal misoprostol group as compared to 25mcg vaginal misoprostol (1.22±0.42 vs. 1.91±0.80, p value <0.05). 83.6% women in group A and 69.09% women in group B underwent spontaneous vaginal delivery within 24 hours. 3.64% women in group A and 7.27% in group B had instrumental delivery. Caesarean section was performed in 12.27% cases in group A and 23.64% cases in group B. The complication rate was comparable.
Conclusions: 50mcg vaginal misoprostol is more effective and safe for induction of labour at term PROM as compared to 25 mcg vaginal misoprostol

Keywords: Misoprostol, PROM

INTRODUCTION

In approximately 8 to 10% of pregnancies the membranes ruptures before the onset of labour. Premature rupture of membrane (PROM) is defined as spontaneous rupture of membranes anytime beyond 28th week of pregnancy but before the onset of labour. When membrane rupture occurs beyond 37 weeks but before term, it is called Term PROM and when it occurs before 37 completed weeks it called preterm PROM.[1] The short term risks of PROM include cord prolapse, cord compression and placental abruption. Whereas the long term risks include maternal infection (such as chorioamnionitis, postpartum endometritis, and sepsis) and more seriously, neonatal infection.[2]

Spontaneous labour follows term PROM at 24, 48, and 96 hours in 70%, 85% and 95% of women, respectively. Thus, an important proportion of women have significant latency from PROM to delivery if managed expectantly, particularly in nulliparous women.[3] The risk of intrauterine infection increases with the duration of PROM. The risk of chorioamnionitis with term PROM has been reported to be less than 10% and to increase to 40% after 24 hours of PROM.[4] The risk of intrauterine infection increases with duration of labour. Evidence supports the idea that

induction of labour, as opposed to expectant management, decreases the risk of chorioamnionitis without increasing the caesarean delivery rate. Early delivery is safer for the mother and for the foetus than allowing the pregnancy to continue its natural course. Various methods are used for cervical ripening and labour induction in PROM like oxytocin, misoprostol (oral, vaginal and sublingual) etc. Among these misoprostol is promising agent in cervical ripening and induction of labour. The ideal dose and frequency of administration of misoprostol are still under clinical investigation.

The pharmacokinetics of misoprostol suggests that it is more bio available when administered vaginally as compared with oral misoprostol. Most studies suggest that vaginal misoprostol results in shorter induction to delivery interval and a decreased need for oxytocin augmentation as compared to oral misoprostol. Presently many regimens are in use but optimal dose of vaginally administered misoprostol is still to be determined.

This randomized comparative study has been done to investigate the effectiveness and safety of low and high dosage (25 mcg and 50mcg) regimen of vaginal misoprostol for cervical ripening and induction of labour in term PROM patient's unfavourable cervix with respect to following objectives

- Time interval from induction to delivery.
- Rate of caesarean section.

METHODS

This study is undertaken in the department of Obstetrics and Gynaecology at Tata Main Hospital Jamshedpur, Jharkhand, INDIA from: 1st July 2014 to 31st January 2016. Approval from the Institutional Ethics committee (IEC) was taken.

Inclusion criteria

Pregnant women presenting with term PROM, nulliparous, singleton pregnancy, cephalicpresentation, Bishop score<5, clinically adequate pelvis.

Exclusion criteria

Associated with fever ≥38°C or obvious chorioamnionitis, any contraindication of vaginal birth,Meconium stained amniotic fluid. . Non reassuring foetal CTG. Sample sizewas calculated based on statistics and previous study done by Bharathi A et al.[5] The following formula was applied to calculate the adequate sample size for the present study.[6,7]

$$N= c \times [p1 (1-p1) + p2 (1-p2)]/ (p1 – p2)^2$$

N= size per group, C=10.5 for 90% power, P1 = 0.61 with 25 mcg vaginal misoprostol 61% delivered in <12hrs, P2 = 0.32 (with 50 mcg vaginal misoprostol 32% delivered in <12hrs)

$$N = 10.5 \times [0.619(1-0.61) + 0.32(1-0.32)]/(0.61-0.32)^2$$

N = 56, Therefore 55 patients were included in both the groups thus making a sample size of 110.

For all pregnant women presenting with history of leaking per vagina at term, per speculum and per vaginal examination was done under all aseptic precautions. High vaginal swab was taken and Bishop's score was recorded. Following this admission CTG was done. Informed consent was taken from all participant. Antibiotic started. All participants were randomly divided in two groups.

- Group A (25 mcg vaginal misoprostol): In this group 25 mcg misoprostol kept in posterior fornix under aseptic precautions.
- Group B (50 mcg vaginal misoprostol): In this group 50 mcg misoprostol kept in posterior fornix under aseptic precautions.

Dose was repeated till adequate uterine contraction (3-4 contraction lasting for more than 40 seconds in 10 minutes' period) or bishop score improves (>6). Dose was repeated every four hours to maximum 5 doses. Oxytocin was used for labour augmentation. It was started after 6 hours of last dose. CTG was done before each dose of misoprostol and in every 2 hours in active labour. Progress of labour was monitored on a partograph. Active intervention was done at appearance of foetal distress, meconium stained liquor, uterine hyper stimulation or non-progress of labour. A vigilant watch was maintained to detect sings of chorioamnionitis.

Statistical analysis

All data were calculated as be as mean with standard deviation or proportions and percentage. MedCalc software was used for calculation. Mean, median, standard deviation and variance would be calculated and following statistical significance tests would be applied.

- Student's paired T-test will be used as the statistical tool to test for significance of observed mean differences.
- Statistical analysis would be done using Chi-square Test. A p value <0.05 will be considered significant.
- Student t-test will be employed to compare for difference between two means. A p value <0.05 will be considered significant.
- Test of Significance for Difference of Proportions. A p value <0.05 will be considered significant.
- Neonatal outcomes in term of Apgar score and NICU admission. $\chi^2_{cal} = 1.107$ (at 95% confidence limit, with degree of freedom (n1 – 1). (n2 – 1) = 3, $\chi^2_{tab} = 7.815$) $\chi^2_{cal} < \chi^2_{tab}$ {1.107<7.815} at 5% level of significance 0.05}variables.

RESULTS

Mean age the mean age of patients was similar in both groups, 24.38 years in group A and 24.45 years in group B. The maximum number of patients with PROM was in the age group of 21 -25 years.

Percentage distribution of age between two groups is shown in Table 1The mean gestational age of the patients presented with term PROM was 272.9 days in group A and 272.35days in group B.

Table 1: Age distribution among the two study group labour.

Age (in year)	Misoprostol (25µg) (n=55)		Misoprostol (50µg) (n=55)		Total	
	No.	Percentage	No.	Percentage	No.	Percentage
≤ 20 y	4	7.27	7	12.72	11	10
21 – 25 y	33	60	29	52.73	62	56.36
26 - 30 y	16	29.09	17	30.91	33	30
31 – 35 y	2	3.64	2	3.64	4	3.64
Total	55	100	55	100	110	100
Mean±S.D	24.38±3.22		24.45±3.14		24.42±3.17	

Table 2: Percentage distribution of gestational age at time of delivery (in weeks).

Gestational age	Misoprostol (25µg) (n=55)		Misoprostol (50µg) (n=55)		Total	
	No. of patients	Percentage	No. of patients	Percentage	No.	Percentage
$37 – 38^{+6}$	24	43.64	26	47.27	50	45.45
$39 – 40^{+6}$	31	56.36	29	52.73	60	54.55
Mean ± S.D	272.90 ± 6.73		272.35 ± 7.33		272.44 ± 7.16	

Patients presenting with term PROM were divided into two groups one is early term (37 0/7 weeks through 38 6/7 weeks), and second is full term (39 0/7 weeks through 40 6/7 weeks). The data is tabulated and graphically depicted in Table 2. Majority of the patient had bishop score either 3 or 4 and the difference noted between the two study groups was statistically not significant (p value >0.05).
Mean number of doses required for induction of labour in term PROM was significantly less with group B (50mcg vaginal misoprostol) than group B (25mcg vaginal misoprostol), p value < 0.05.

Table 3: Comparison of number of doses between the two groups.

Number of doses	Misoprostol (25µg) (n=55)		Misoprostol (50µg) (n=55)	
	No.	Percentage	No.	Percentage
1 – 2	47	85.45	55	100
3 – 4	7	12.73	0	0
5	1	1.82	0	0

For Test of Significance, Chi – square Distribution (χ^2-Test) χ^2_{cal}= 8.627 (at 95% confidence limit ,with degree of freedom =2, χ^2_{tab}=5.991 $\chi^2_{cal}>\chi^2_{tab}$ {8.627>5.991} at 5% level of significance

Table 3 show comparison of number of doses between two groups. The overall mean induction to delivery time interval statistically less in patients who received 50mcg vaginal misoprostol (group B) in comparison to group A [11 hours 26 minutes versus 12 hours 38 minutes, p value =0.0289 (p < 0.05)].

Table 4: Comparison of induction to delivery time interval.

IDL (in hour)	Misoprostol (25µg) (group A)		Misoprostol (50µg) (group B)	
	No	Percentage	No	Percentage
>4-8 h	4	7.27	5	9.09
>8-12 h	21	38.18	30	54.55
>12-16h	24	43.64	18	32.73
>16-20h	5	9.09	2	3.64
>20-24h	1	1.82	0	0

For Test of Significance, Chi-square Distribution (χ^2-Test) χ^2_{cal} = 16.610 (at 95% confidence limit, with degree of freedom =4, χ^2_{tab}= 9.488), Hence, Misoprostol (50µg) group is statistically significant than Misoprostol (25µg) group, according to their PROM to delivery time interval, with p – value = 0.0023{ p <0.05}.

Table 5: Comparison of PROM to delivery time interval.

PDL interval (in hour)	Misoprostol (25µg) (n=55)		Misoprostol (50µg) (n=55)	
	No.	Percentage	No.	Percentage
>8 – 12 h	2	3.64	5	9.09
>12 – 16h	12	21.82	30	54.55
>16 – 20h	28	50.91	14	25.45
>20 – 24h	9	16.36	5	9.09
>24 h	4	7.27%	1	1.82

For Test of Significance, Chi-square Distribution (χ^2-Test) χ^2_{cal} =16.610 (at 95% confidence limit, with degree of freedom =4,

χ^2_{tab}=9.488), Hence, Misoprostol (50µg) group is statistically significant than Misoprostol (25µg) group, according to their PROM to delivery time interval, with p – value = 0.0023{ p <0.05}.

However, in both groups maximum number of patients is delivered within 16 hours of induction. In group B more number of patients delivered within 12 hours than group A (63.64% vs. 45.45%). In present study mean PROM to delivery interval was significantly less in 50mcg vaginal misoprostol group (group B) as comparison to group A (Table 5).

In present study oxytocin required for augmentation for labour was 27.27% of patients with group A (25 mcg vaginal misoprostol) and 23.64% of patients with group B (50 mcg vaginal misoprostol), which was not statistically significant p value 0.8267 (p>0.05) (Table 6).

Table 6: Comparison of augmentation with oxytocin.

Augmentation	Misoprostol (25µg) (n=55)		Misoprostol (50µg) (n=55)	
	No.	Percentage	No.	Percentage
Yes	15	27.27	13	23.64
No	40	72.73	42	76.36

Percentage of vaginal delivery in group A was 83.64% and group B was 69.09%, (p value 0.4450), cesarean section in group A was 12.72% and group B was 23.64% (p value 0.2636) and instrumental delivery in group A was 3.64% and group B 7.27% (p value 0.6831). There was no significant statistical difference in mode of delivery between two groups (Table 7).

Table 7: Comparison of Mode of delivery between the two study groups.

Mode of delivery	Misoprostol (25µg) (n=55)		Misoprostol (50µg) (n=55)		χ^2_{cal}	p-value
	No.	Percentage	No.	Percentage		
Normal vaginal delivery (NVD)	46	83.64	38	69.09	0.583	0.4450
Instrumental vaginal delivery	2	3.64	4	7.27	0.167	0.6831
Caesarean section	7	12.72	13	23.64	1.250	0.2636

For Test of Significance, Chi-square Distribution (χ^2-Test). At 95% confidence limit, with degree of freedom = 1, χ^2_{tab} = 3.841 $\chi^2_{cal}<\chi^2_{tab}$, at 5% level of significance Hence, Misoprostol (25µg) group is statistically not significant than Misoprostol (50µg) group, according to their mode of delivery

Among the indication for caesarean section most common indication was fetal distress in both groups (42.86% versus 53.84%). Prevalence of meconium stained liquor was more with 50mcg vaginal misoprostol (23.08%) as compare to group A (14.29%).

Table 8: Comparison of indication of caesarean section.

Indication for C.S.	Misoprostol (25µg) (n=7)		Misoprostol (50µg) (n=13)	
	No	Percentage	No	Percentage
Failed induction	2	28.56	0	0
Fetal distress	3	42.86	7	53.84
Meconium strained liquor	1	14.29	3	23.08
Arrest of labor/DTA	1	14.29	3	23.08
Total	n=7	100	n=13	100

There was no case of failed induction in group B. The difference of indication of caesarean section was not statistically significant among both groups. P value 0.2431 (Table8).

Prevalence of prolonged second stage and fetal distress was insignificantly more in group B in comparison to group A. In present study one patient in the group A and three patients in group had uterine hyper stimulation during labour process. The difference is not significant. With respect of Apgar score, the two study groups were comparable with no significant statistical difference. (Table 9).

Table 9: Comparison of babies APGAR score in both groups (1 min).

Apgar score	Misoprostol(25µg) (n=55)		Misoprostol (50µg) (n=55)	
	No.	Percentage	No.	Percentage
< 7/10	3	5.45	8	14.55
≥ 7/10	52	94.55	47	85.45

For Test of Significance, Chi-square Distribution (χ^2 Test) χ^2_{cal} = 1.616 (at 95% confidence limit, with degree of freedom = 1, χ^2_{tab} = 3.841). $\chi^2_{cal}<\chi^2_{tab}$ (1.616 <3.841) at 5% level of significance. Hence, Misoprostol (25µg) group is statistically not significant than Misoprostol (50µg) group, according to their Apgar score at 1 minute, with p - value = 0.2036 (p>0.05).

Table 10: Comparison of NICU admission

NICU	Misoprostol (25µg) (n=55)		Misoprostol (50µg) (n=55)	
	No.	Percentage	No.	Percentage
Yes	5	9.09	11	20
No	50	90.91	44	80

NICU admissions of babies are 9.09% in group A and 20% in group B, the difference statistically not significant. P value = 0.1763 shown in Table 10.

NICU admission was seen in 14% and 16% cases respectively in both groups (p >0.05).

DISCUSSION

This study was conducted on patient (n=110) admitted in labour room of Tata Main Hospital. In present study the two groups were comparable with respect to maternal age and maximum number of nulliparous women who presented with PROM was in age group of 21-25years. There no statistical significant difference of gestational age between two groups (P >0.05). The majority of patient in both groups presented at full term gestational (39 0/7 weeks through 40 6/7weeks). In group A 43.64% presented at early term (37 0/7weeks through 38 6/7weeks) and 56.36% at full term gestational age. In group B 47.27% presented at early term and 52.73% at full term gestational age.

Present study included women with pre-induction cervical bishop score of less than 5. The mean bishop's score at the start of induction was comparable in both groups, being 3.45±0.899 in group A (25mcg misoprostol) and 3.24±0.902 in group B (50mcg misoprostol. The difference was statistically not significant (p value >0.05) This finding was consistent with study by Girija S et al.[8]They reported initial bishop score was 3.18±1.17 in 25mcg misoprostol group and 3±1.49 in 50mcg misoprostol group. Priyanka S also reported mean initial bishop score 3.55 in 25mcg misoprostol group and 3.48 in 50mcg misoprostol group (p value =0.703).[9]

Mean number of doses required in group A was 1.91 and in group B was 1.22 (1.91±0.80 vs. 1.22±0.42, p value = 0.0134). Mean number of doses required for labour induction with term PROM was significantly less with 50mcg vaginal misoprostol (group B) as compare to group A (p<0.05). The study done by Myedanli MM10comparing 25mcg and 50mcg vaginal misoprostol for labour induction beyond 41 week of gestation found that proportion of women delivered vaginally with single dose was significantly greater with 50mcg group (0/49 vs. 41/47 p <0.001) Another study by Bharathi A shows women delivering vaginally with single dose of vaginal misoprostol was high in 50mcg misoprostol group.[5]

In this study, it was found that 15 case (27.27%) of group A and 13 cases (23.64%) of group B required augmentation with oxytocin. The difference was not statistically significant, with P = 0.826. The study done by Makbib Diroet alwhere decreased rate of oxytocin augmentation with 50 mcg group (53.9% in 50mcg group versus 68% in 25 mcg group, P<0.015).[11]

A study by S priyanka9 reported oxytocin augmentation required in 60.2% cases with 25mcg group and 52.9% cases with 50 mcg misoprostol group (P=0.328) which was not statistically not significant.

The mean induction to delivery time interval in this study was found to be in group A (25 mcg vaginal misoprostol) mean was 12.38 hours with SD 2.83 and in group B (50mcg vaginal misoprostol) mean was 11.26 hours with SD 2.46.

The induction to delivery interval was statistically significantly shorter with group B as compare to group with value 0.0289. Howeve,r in both groups maximum number of patients is delivered within 16 hours of induction and in group B more number of patients delivered within 12 hours than group A (63.64% vs. 45.45%).

A double blinded randomized trail done by Makbib Diroet al reported the mean induction to delivery interval was significantly shorter in 50mcg vaginal misoprostol group as comparison to 25mcg group (933min. versus 1194min. P value < 0.013).[11]

Finding of present study was consistent with study from Has R et al shows induction to delivery interval was significantly longer with 25mcg misoprostol group as compare to 50mcg group (991.2±514.4 min. vs. 703.12±432.6 min).[12]

Sanchez Ramos L et al found similar result that the 50mcg vaginal misoprostol was associated with shorter induction to delivery interval compare to 25 mcg misoprostol.[13]

A retrospective study done by Kreft M et al for induction of labour with 25 and 50mcg misoprostol every 6 hourly found the induction to delivery interval was significantly shorter with 50mcg dosing (18.4h vs 24.6 h, P<0.001).[14] PROM was indication for induction in 20.9% of cases in their study.

In another study by GirijaS et al mean induction to delivery interval in 25mcg vaginal misoprostol group was 14.42±13.2 hours and in 50mcg group was 18.58±13.73 hours.[8] The difference was not statistically significant between both groups (p value 0.73)

A study by Priyanka S using 25mcg misoprostol 4 hourly and 50 mcg misoprostol every 8 hourly for induction of labour, reported no statistical significant difference in mean induction to delivery interval between 25 and 50mcg vaginal misoprostol groups (9.67±4.52 hours vs 9.20±4.19 hours with p value 0.472). PROM was indication for induction in 46.5% cases in their study.[9] The difference in finding from present may be due to different dosing interval and different number of doses used in different study.

In present study, with 25 mcg vaginal misoprostol (group A) 46 cases (83.6%) underwent normal vaginal delivery, 2 cases (3.64%) had instrumental delivery and 7 cases

(12.72%) delivered by caesarean section. And with 50mcg vaginal misoprostol (group B) 38 patients (69.09%) had normal vaginal delivery, 4 patients (7.27%) had instrumental delivery and 13 cases (23.64%) delivered by caesarean section.

Higher percentage of patients in group A delivered vaginally (83.64% vs 69.09%) but the difference was not statistically significant with p value 0.445. The difference of rate of caesarean section (12.72% vs. 23.64%) and instrumental delivery (3.64% vs. 7.27%) between two groups was also not statistically significant. (p >0.05).

In a study by Girijan S et al 73.33% of patients with 25 mcg vaginal misoprostol and 70% of patients with 50 mcg misoprostol delivered vaginally and no significant difference was observed between the two groups. Also rate of caesarean section and instrumental delivery in two study groups was comparable in their study.[8]

Kreft M et al found similar result, there was no significant difference between two groups in terms different mode of delivery.[14]

A comparative study by S priyanka, more patients with 25mcg vaginal misoprostol delivered vaginally as compare to 50mcg vaginal misoprostol (92% vs 79% p value 0.009).[9] The difference of caesarean section and instrumental delivery between two groups was statistically not significant in their study.

In our study the indication for caesarean delivery and indication for instrumental delivery was comparable in both groups. Foetal distress (non reassuring foetal heart rate tracing) was indication for caesarean section in 42.86% cases with 25mcg misoprostol and in 53.84% cases with 50 mcg misoprostol, which was not statistically significant (p >0.05). There were 2 cases of failed induction in group A and no cases of failed induction in group B. Meconium stained liquor was insignificantly higher in group B.

These findings were consistent with Study by Girija Set al, the indication of caesarean section was comparable in both groups (25 and 50mcg misoprostol p value 0.22).[8]

Study conducted by Has R et al[12]showsrate of caesarean sections due to non-reassuring foetal status was higher with the higher dose (28.6 vs. 10.3%; P < 0.05).

In study by S priyankathe non-assuring foetal heart rate and meconium stained liquor was significantly higher in 50mcg misoprostol group compare to 25mcg group (46.7 vs 14.3% and 46.7 vs 14.3% respectively).[9]

In present study one patient (2.86%) with 25mcg developed uterine hyper stimulation that led to caesarean section for foetal distress. With 50mcg misoprostol 3 patients (5.45%) developed uterine hyper stimulation out of which two cases had caesarean section for foetal distress. The difference was not statistically significant (p value 0.6105). Priyanka S reported 1 case with 50mcg vaginal misoprostol none of patients with 25mcg developed uterine hyper stimulation.[9]

In another study by Girija S et alreported that uterine contraction abnormalities (tachysystole, hyper stimulation) in 4% cases with 25mcg and 10% cases with 50mcg vaginal misoprostol.[8]

Has R et al and Myedanli MM reported similar results that the rate of uterine tachysystole and hyper stimulation syndrome was comparable in both groups.[10,13]

In group A (25 mcg misoprostol), 1 minute APGAR <7 was seen in 3 (5.45%) neonates and in group B (50mcg misoprostol), 1 minute APGAR <7 was seen in 8 (14.55%). The difference in APGAR is not statistically significant, P value = 0.2036.

None of the neonates with group A had APGAR score <7 at 5 minute. In group B 2 (3.64%) neonates had APGAR <7 at 5minute. (P value >0.05) In our study, 5 (9.09%) cases from group A required NICU admission and 11(20%) cases from group B required NICU admission. More number of neonates with group B required NICU admission but the difference was not statistically significant (p value =0.176).

These finding was consistent with study by Girija S et al, APGAR <7 at 1minute was 3.3% neonates with 25mcg vaginal misoprostol and in 10% neonates with 50mcg vaginal misoprostol (p >0.05).[8] None of neonates with both groups had APGAR at 5 minute <7. Neonatal outcome were comparable.

Similar to this study neonatal outcome (APGAR and NICU admission) was comparable in lower and higher dose vaginal misoprostol groups in the study by Makbib Diro et al, Ozsoy M, Meydanli MM et al and Kreft M.[10,11,14,15]

CONCLUSION

Active management of term PROM patients with induction of labour is associated with reduced maternal and neonatal infective morbidity and increased maternal satisfaction without increasing caesarean section or operative vaginal birth.

Number of doses of 50mcg vaginal misoprostol was significantly lesser compared to 25mcg misoprostol.

Induction to delivery interval was significantly shorter with 50mcg vaginal misoprostol as compared to 25 mcg misoprostol (p value 0.0289). However most of the patients with both 25mcg and 50mcg vaginal misoprostol were delivered within 16 hours.

Mode of delivery in term of NVD, caesarean section and instrumental delivery was comparable in both groups, with no statistical significant difference.5.There was no significant difference in maternal and foetal complications in both groups.

There was no significant difference in outcome of labour in both groups.

Based on our findings we conclude 50mcg vaginal misoprostol was more effective and safe for induction of labour at term PROM with comparable maternal and foetal outcomes as compared to 25 mcg vaginal misoprostol.

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