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Pre-labour Rapture of Membrane at Term in Patients with an Unfavorable Cervix: Active verses Conservative Management

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ABSTRACT

Objective: The present quasi-experimental (comparative clinical trial) study was conducted to compare the outcome of active versus conservative management in patients with prelabour rupture of membrane (PROM) at term with an unfavourable cervix.

Materials & Methods: The study was carried out at Gynae & Obstetrics Department, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka over a period of 12 months from July 2009 to June 2010. Women admitted in the Obstetrics & Gynaecology Ward of BSMMU with pre-mature rupture of membrane (PROM) at term with unfavourable cervix was the study population. A total of 86 women with rupture of membranes at > 37 weeks of gestation with a single foetus in a cephalic presentation, Bishop's score below 6, absence of active labour, no history of previous uterine surgery, no contraindication to vaginal delivery, a normal cardiotocogram and an adequate pelvis on clinical pelvimetry were included in the study and divided into two groups – study group (who received 25 µg of misoprostol every 6 hours in the posterior fornix of the vagina to a maximum of 4 doses) and control (who received conservative treatment for 24 hours).

Result: The result shows that the study and control groups were almost identical in terms of age (p = 0.058), parity (p = 0.812), H/O past abortion (p = 0.366). Majority (94.3%) of the patients in case group and 64.4% in control group took 24 or < 24 hours to deliver their babies. The mean interval between PROM and uterine contraction and that between ROM and delivery were significantly less in the study group than those in the control group (p < 0.001 and p < 0.001 respectively). About 63% of study group experienced significant uterine contractions after 1st dose, 23.3% after 2nd dose, 9.3% after 3rd dose and 4.7% after 4th dose of misoprostol, while none of the patients in control group experienced significant contraction during the same period (p < 0.001). Twenty two (50.6%) of controls needed oxytocin for induction as opposed to none in the study group. The need for oxytocin during labour in study group were significantly less (37.2%) than that in control (80.5%) (p= 0.024). The incidence of failed induction was even less in study group (11.6%) than that in control (44.2 %) (p = 0.001). Two (4.7%) patients in the study group developed uterine hyperstimulation, 2.3% uterine tachysystole and another 2.3% nausea/vomiting while none of patients in control group developed the same complications. One (2.3%) of the patients in study group experienced chorioamnionitis and 9.3% exhibited group-B streptococci in high vaginal swab culture. In contrast, 18.6% of the controls developed chorioamnionitis and 14% showed the presence of group-B streptococci in high vaginal swab. In terms of mode of delivery, normal vaginal delivery (NVD) occurred in 88.4% study group as compared to 53.5% of control group (p<0.001). There was no significant difference between the groups in terms of foetal distress (p= 0.747) and neonatal sepsis (p = 0.121). Over half of the patients in the both groups had a history of less than 4 vaginal examinations during labour. There was no significant differences between the groups with respect to Apgar score at 1 minute of birth, neonatal sepsis and foetal distress (p=0.063, p=0.121 and p=0.747 respectively).

Conclusion: The study concluded that management of premature rupture of membrane with unfavourable cervix using vaginal misoprostol increases the rate of normal delivery thereby reducing the risk of caesarean section, while conservative management of premature rupture of membrane usually fails to augment normal delivery. So it is safer to give induction to women presenting with premature rupture of membrane with unfavourable cervix using vaginal misoprostol.

Key words: Induction of labour, active management, conservative management, prelabour rupture of membrane (PROM) at term and unfavourable cervix.

ORIGINAL ARTICLE

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INTRODUCTION

Pre-labour rupture of membrane (PROM) occurs in about 8% of pregnancies;[1] about 80% of which are term pregnancies.[2] If labour is not induced, over 60% of these pregnant women begins labour spontaneously within 24 hours and over 95% within 72 hours. As the time between the rupture of the membranes and the onset of labour increases, so does increase the risk of maternal and foetal infection. For these reasons, many physicians recommend that labour be induced if the pregnancy is at term and labour does not begin spontaneously shortly after the membrane's rupture. Others believe that waiting for labour to begin spontaneously is preferable for mothers, if there is no evidence of foetal or maternal compromise. However, there is limited information about which approach is better.[3] The most serious complications of PROM at term is maternal and neonatal infection and the risk of complication increases as the duration of PROM prolongs.[3-5] Therefore, the goal of management of PROM at term is to deliver the infant as early as possible. The management of term pregnancy with PROM with unfavourable cervix remains controversial. Active induction of labor soon after PROM reduces the risks of maternal and foetal sepsis[4] compared with conservative management, and is associated with a shorter interval from PROM to significant uterine contractions and delivery.[6]

For the labour that is induced, the timing of the induction is controversial. Indeed, the decision to induce labour often depends more on the convenience of the physicians, nurses or midwives than on the actual time that elapsed after rupture of the membranes. If labour is induced, the method of induction is usually by intravenous administration of oxytocin. More recently, prostaglandins, followed by an infusion of oxytocin, if necessary, have been used, though it is not widely established that the latter method is better.[4] Misoprostol is a prostaglandin E1 analogue which is rapidly absorbed after oral administration. Its uterotonic and cervical ripening properties have become increasingly well-known, and the wealth of information has emerged from studies investigating its potential use in obstetrics & gynaecology.[7] Misoprostol has been the drug of choice for induction of labor in developing countries, because it is cheap, stable at room temperatures, does not require refrigeration prior to use, is easy to prepare and the route of administration is convenient.[8,9] In most trials, prostaglandins have been administered vaginally, which results in a longer half-life than oral misoprostol administration. However, low dosing may have an advantage in induction of labour because of the reduced risks of uterine hyperstimulation and tachysystole.[10] The advantages of misoprostol with reference to PROM is the avoidance of repeated vaginal examination which subsequently reduces the risk of sepsis for both mother and baby.[11] The recommended dose for vagianl misoprostol for labour induction is 25 µgm every six hours.[12] There are two management options for PROM at term: treating the patient conservatively for 24 to 72 hours or active management using oxytocin or prostaglandins to accelerate cervical ripening and avoid chorioamnionitis, maternal and neonatal morbidity.[13-14] The background information so far discussed shows that the efficacy and safety of misoprostol in case of PROM at term with unfavourable cervix is disputable. The objective of the present study was to compare the outcome of active versus conservative management of patients with prelabour rupture of membrane (PROM) at term with an unfavourable cervix.

MATERIALS & METHODS

This quasi-experimental (comparative clinical trial) study was conducted over a period of 12 months from July 2009 to June 2010 in the Department of Obstetrics & Gynaecology, BSMMU Hospital, Dhaka. Women admitted in the Obstetrics & Gynaecology Ward of BSMMU with PROM at term with unfavourable cervix were study population. Pregnant women with ruptured membranes at > 37 weeks of gestation, a single foetus in cephalic presentation, Bishop's score below 6, absence of active labour, no history of previous uterine surgery, no contraindication to vaginal delivery, a normal cardiotocogram and an adequate pelvis on clinical pelvimetry were included in the study. A total of 86 such patients

were enrolled in the study. For random allocation of patients into groups, there were 2 cards – one marked "A" and another "B". The doctor on duty shuffled the cards and patients who consented for participating in the study were asked to draw a card blindly. Patients who have had cards marked "A" were allocated into active management group (study group, n=43), while patients with cards marked "B" were assigned to conservative management group (control group, n = 43). Study group received 25 µg of misoprostol every 6 hours in the posterior fornix of vaginal to a maximum of 4 doses. Control group received conservative treatment (rest in bed) for 24 hours. The primary outcome variable was mode of delivery (normal or caesarean) and secondary outcome variables were need of oxytocin for induction of labour and the complications developed. Data were processed and analysed using software SPSS (Statistical Package for Social Sciences) version 16.0. The statistics used to analyse the data were Chi-square (χ^2) and Student's t-Test. The level of significance was set at 0.05 and p-value was considered significant.

RESULTS

There was no significant difference between the groups in terms of age (p = 0.058), though patients of 30 or more than 30 years were higher in the study group compared to that in the control group. The subjects in both groups were predominantly primipara (69.8% and 72.1% respectively) with no significant difference between the groups in terms of parity (p = 0.812) and past history of abortion (p = 0.366) (Table I). Majority (94.3%) of the patients in study group and 64.4% in control group deliver their babies within 24 hours. The mean interval between ROM and uterine contraction and that between ROM and delivery were significantly less in the study group than those in control group (p < 0.001 and p < 0.001 respectively). About 63% of study group experienced significant uterine contractions after 1st dose, 23.3% after 2nd dose, 9.3% after 3rd dose and 4.7% after 4th dose of misoprostol while none of the patients in control group experienced significant contraction during the same period. Over half (50.6%) of controls needed oxytocin for induction as opposed to none in the study group. The need for oxytocin during labour in study cases were significantly less (37.2%) than that in controls (80.5%) (p=0.024). The incidence of failed induction was even less in cases (11.6%) than that in controls (44.2%) (p=0.001) (Table II).

TABLE I. Demographic characteristics between two groups

Demographic characteristics	Group		p-value
	Study (n = 43)	Control (n = 43)	
Maternal age (years)*			
<25	11(25.6)	19(44.2)	
25-30	19(44.2)	19(44.2)	
≥30	13(30.2)	5(11.6)	
Mean ± SD #	26.9 ± 3.4	25.2±3.1	0.058
Para*			
Primipara	30(69.8)	31(72.1)	0.812
Multipara	13(30.2)	12(27.9)	
H/O past abortion*	8(18.6)	5(11.6)	0.366

Figures in the parentheses indicate corresponding %;
* **Chi-squared Test** (χ^2) was done to analyze the data.
# Data were analyzed using **Unpaired t-Test** and were presented as **mean ± SD.**

Table III shows that 4.7% of patients in study group developed uterine hyperstimulation, 2.3% uterine tachysystole and another 2.3% nausea/ vomiting while none of patients in the control group developed the same complications. One (2.3%) patient in study group experienced chorioamnionitis and 9.3% exhibited group-B Streptococci in high vaginal swab culture.

TABLE II. Comparison of induction related variables between groups

Induction related variables	Group		p-value
	Study (n = 43)	Control (n = 43)	
Interval from rupture of membrane to uterine contractions#	8.8 ± 3.4	15.0 ± 4.7	<0.001
Interval between rupture of membrane & delivery*			
≤24 hrs	41(94.3)	28(64.4)	<0.00 1
>24 hrs	2(5.7)	15(35.6)	
Mean ± SD	11.5±3.5	18.7±5.7	
Oxytocin needed*			
For induction	0(0.0)	22(50.6)	0.134
During labour	16(37.2)	35(80.5)	0.024
Induction failed*	5(11.6)	19(44.2)	0.001

Figures in the parentheses indicate corresponding %;
***Chi-squared Test** (χ^2) was done to analyze the data.
#Data were analyzed using **Unpaired t-Test** and were presented as **mean ± SD.**

In contrast, 18.6% of the controls developed chorioamnionitis and 14% showed the presence of group-B Streptococci in high vaginal swab. In terms of mode of delivery, normal vaginal delivery (NVD) occurred in 88.4% of the study group as compared to 53.5% in controls (p < 0.001).There was no significant difference between the groups in terms of foetal distress (p = 0.747) and neonatal sepsis (p = 0.121). Over half of the patients in the both groups had a history of less than 4 vaginal examinations during labour.

TABLE III. Comparison of maternal outcome between groups

Induction related variables	Group		p-value
	Case (n = 43)	Control (n = 43)	
Uterine hyperstimulation**	2(4.7)	0(0.0)	0.247
Uterine tachysystole**	1(2.3)	0(0.0)	0.500
Nausea/vomiting**	1(2.3)	0(0.0)	0.500
Chorioamnionitis**	1(2 .3)	8(18 .6)	0.015
Presence of Group-B Streptococci in vaginal culture**	4 (9.3)	6(14.0)	0.501
Mode of delivery*			
NVD	38(88.4)	23(53.5)	<0.001
Caesarean section	5(11.6)	20(46.5)	

Figures in the parentheses indicate corresponding %;
* **Chi-squared Test** (χ^2) was done to analyzed the data.
Fisher's Exact Test was done to analyzed the data.

There was no significant difference between the groups with respect to Apgar score at 1 minute of birth, neonatal sepsis and foetal distress (p=0.063, p=0.121 and p=0.747 respectively) (Table IV).

TABLE IV. Comparison of foetal and neonatal outcome between groups

Outcome	Group		p-value
	Case (n = 43)	Control (n = 43)	
Foetal distress*	5(11.6)	6(14.0)	0.747
Neonatal sepsis**	0 (0.0)	3(6.9)	0.121
Apgar score <7 at 1 minute*	5(11.6)	5(11.6)	0.063

Figures in the parentheses indicate corresponding %;
* **Chi-squared Test** (χ^2) was done to analyzed the data.
Fisher's Exact Test was done to analyzed the data.

DISCUSSION

In the present study case and control groups were almost identical in terms of maternal age, parity and history of past abortion. Shetty et al.[15] conducted a similar study, where there were no differences in maternal age between women with active and conservative management of PROM (29.2 vs. 29.2 years respectively). In our study two-thirds of the women in both active and conservative management groups were primipara. Majority (94.3%) of the patients in active management group and 64.4% in conservative group required 24 or < 24 hours to deliver their babies. The mean interval between ROM and uterine contraction and that between ROM and delivery were much less in the former group than those in later group (p < 0.001 and p < 0.001 respectively). About 63% of active group exhibited significant uterine contractions after 1st dose, 23.3% after 2nd dose, 9.3% after 3rd dose and 4.7% after 4th dose of misoprostol. Twenty two (50.6%) of conservative group needed oxytocin for induction as opposed to none of the active group. The need for oxytocin during labour in active group were significantly less (37.2%) than that in conservative group (80.5%) (p = 0.024). The incidence of failed induction was staggeringly higher in conservative group (44.2%) than that in active group (11.6%) (p = 0.001). This is similar to the observation of Ayaz et al[16] who reported 67% of the patients with significant uterine contractions after a single dose of misoprostol, while 16%, 10% and 7% had contractions after 2nd, 3rd and 4th doses respectively.

All study subjects in the active group showed significant uterine contractions within 24 hours of PROM compared to 69% in conservative group. The mean interval between PROM and the onset of significant uterine contractions was 8.8 hours in active group and 15.0 hours in conservative group (p < 0.001). Incidence of failed induction active in group was 11.6% and in conservative group 44.2% (p=0.001). About 5% of patients in active group developed uterine hyperstimulation, 2.3% uterine tachysystole and another 2.3% nausea/ vomiting while none of the patients in conservative group developed the same complications. A significant proportion of women in the conservative group (18.6%) developed chorioamnionitis and 14% showed the presence of group-E Streptococci in high vaginal swab. In contrast, only 1(2.3%) patient in active group

experienced chorioamnionitis and 9.3% exhibited group-E Streptococci in high vaginal swab culture. In terms of mode of delivery, the active group had a significantly higher rate of normal vaginal delivery (88.5%) with fewer caesarean section compared to the conservative group (53.5%) ($p<0.001$). Chorioamnionitis is a potentially serious complication resulting from conservative treatment because of the increased interval between PROM and delivery. Five (11.6%) of the active group had foetal distress compared to 6(14%) of conservative group ($p = 0.747$). About 5% of patients in conservative group had neonatal sepsis while none of patients in active group had the same complication ($p = 0.121$). There was no significant differences between the groups with respect to Apgar score at 1 minute of birth and number of vaginal digital examinations ($p = 0.063$ and 0.569 respectively). Almost similar findings were reported by Ayaz et al.[17] They reported that only three (7%) women in study group developed complications (two cases of uterine hyperstimulation and one of uterine tachysystole), while six (14%) patients in conservative group experienced complications (five cases of chorioamnionitis and one nausea and vomiting). Overall, the foetal/neonatal complication rate in the two groups was equal (5%). Seven percent of patients had Apgar score <7 at 1 minute of birth in the active group compared to 10% in the conservative group. Gibbs et al[18] however, found a high rate of chorioamnionitis.

CONCLUSION

From the findings of study, it can be concluded that management of premature rupture of membrane with unfavourable cervix using vaginal misoprostol increases the rate of vaginal delivery thereby reducing the risk of caesarean section, while conservative management usually fails to induce spontaneous onset of labour and thus vaginal delivery.

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