
Inpatient Versus Outpatient Management of Preterm Prelabour Rupture of Membrane. A Prospective Cohort Study

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Short title:

Outpatient management of preterm prelabour rupture of membrane

Abstract

Objective: To assess the effectiveness and safety of the outpatient management approach for patients with preterm prelabour rupture of membrane regarding the latency period, incidence of chorioamnionitis, and neonatal outcomes.

Patients and Methods: This prospective cohort study included 63 Patients with confirmed diagnosis of PPRM. All included patients were admitted to the inpatient ward for 48 hours where they received IV antibiotics and corticosteroids for fetal lung maturation then, 31 patients were managed as outpatient and 32 patients were managed as inpatient. The primary outcome was the latency period and gestational age at birth while the incidence of chorioamnionitis, and neonatal outcomes in terms of neonatal weight, neonatal intensive care (NICU) admission, and neonatal sepsis were secondary measures of outcome.

Results: The latency period (days) was significantly longer (29.4 ± 15.8 vs 17.7 ± 11.9 , $p 0.002$) and the gestational age (weeks) at birth was significantly higher (35.0 ± 1.8 vs 33.6 ± 1.9 , $p 0.004$) among the outpatient arm. There was no significant difference between the two arms regarding the incidence of chorioamnionitis, neonatal weight, NICU admission and neonatal sepsis.

Conclusion: Outpatient management of patients with PPRM is safe approach which can be adopted particularly in low risk patients.

Key words: Preterm prelabor rupture of membrane, outpatient management, latency period, chorioamnionitis, neonatal outcomes.

Introduction

Preterm prelabour rupture of membranes (PPROM) complicates 2-3% of pregnancies and it's responsible for approximately one-third of preterm births. Half of

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the women with PPRM deliver within one week of the membrane rupture. The greatest consequence of PPRM is preterm birth which contributes to neonatal morbidity and mortality (1). Other complications that can be a consequence of PPRM include cord prolapse, cord compression, intra-amniotic infection, and placental abruption (2).

Gestational age at the time of PPRM is a key factor in deciding the management with the continuation of pregnancy seems reasonable if membrane rupture occurs between 24 and 34 weeks. Antibiotics and antenatal corticosteroids improve short term neonatal outcomes in case of expectant management (3).

According to the available guidelines, hospital based care of patients with PPRM until delivery is the standard practice (4). However, outpatient management can be implemented after 48 hours of hospital admission provided that the patient is vitally stable with no clinical or biological features suggesting chorioamnionitis. This policy of home-based care has been addressed by several retrospective studies (5)

Our study aimed to compare inpatient and outpatient care of patients with PPRM in terms of latency, gestational age at delivery, intraamniotic infection, and neonatal outcomes.

Patients & Methods

This prospective observational study was conducted at Ain Shams University Maternity Hospital during the period from March 2022 to March 2023. Before the initiation of the study, approval of the Ethical Committee of the Faculty of Medicine, Ain Shams University was obtained (MS 614/2021, FWA 000017585). Using PASS 11 for sample size calculation, setting power at 99%, alpha error at 5%, and after reviewing previous results obtained by Beckman & Gardener (6), that showed that the number of days from ruptured membranes to birth among patients with PPRM who had inpatient

care versus those who had outpatient care was (12 {4.2 – 14.6} versus 32.6 {14.3-43.2} respectively); based on that, a sample size of at least 60 patients with PPRM divided into 2 groups (30 patients in each group) will be sufficient to achieve study objective. The study was registered at ClinicalTrials.gov (ID: NCT05755841)

Age of the included participants ranged from 18 to 40 years. Gestational age at recruitment ranged from 28wks+0 days to 34wks+0 days based on late first or early second trimesteric ultrasound, and date of last menstrual period. Diagnosis of membrane rupture was based on 3 features; history of gush of watery vaginal discharge, pooling of fluid at the posterior fornix or leakage of fluid through the cervix by speculum examination, and ultrasound evidence of oligohydramnios ie deep vertical pocket < 2cm. Patients who had PPRM associated with medical disorders such as diabetes mellitus, preeclampsia, systemic lupus erythematosus, and renal or hepatic impairment were excluded from the study. Moreover, patients with associated symptomatic or asymptomatic placenta previa, fetal malformations, and history of classic cesarean section were excluded as well.

Informed consent was taken from study participants before enrollment and after a thorough explanation of the purpose of the study. Patients who were diagnosed with PPRM were admitted to the hospital for 48 hours where monitoring of the patient for manifestations of intra-amniotic infection and preterm labor was ensured. All included patients received antibiotics according to the ACOG guidelines (7), and corticosteroids for fetal lung maturity. After the first 48 hours, patients who were discharged and managed as an outpatients or stayed in the hospital to be managed as an inpatients during the study period were documented and evaluated

Regarding the outpatient arm, the following criteria were ensured before managing patients as an outpatient; available transportation to the hospital throughout the day, checking

and recording temperature regularly every 4 hours, and awareness of fetal kicks so that she can feel any decrease in fetal kick count. Each patient from the outpatient arm was instructed to attend follow-up visit at the outpatient clinic during which non-stress test and complete blood count were carried out twice weekly with weekly clinical examination and ultrasound assessment. All patients were instructed about the warning features which necessitate urgent assessment at the hospital, these features included fever, constant lower abdominal pain, labor pains, vaginal bleeding, and decrease the perception of fetal kicks. As for the inpatient's arm, the same protocol was applied. In the absence of any of the warning features that necessitated delivery, delivery was planned between 36 and 37 weeks.

The primary outcome of the study was the latency period from the time of membrane rupture till delivery. Incidence of chorioamnionitis, NICU admission, neonatal sepsis, and oxygen requirements were secondary measures of outcome.

Statistical analysis

Regarding the statistical analysis, quantitative variables were presented using mean and standard deviation, qualitative variables were presented using count and percentage. Student t-test was used to compare quantitative variables between two independent groups, Chi-square test was used for qualitative variables. Fisher's Exact or Monte Carlo correction was used for correction for chi-square when more than 20% of the cells have an expected count of less than 5. P value less than or equal to 0.05 was considered statistically significant.

Results

This prospective study aimed to evaluate the safety and effectiveness of outpatient management of patients with PPRM with inpatient management. **Figure 1** represents a

flow chart of the study participants. **Table 1** assessed the demographic data of both arms; there was no significant difference between both approaches regarding age, BMI, parity, and hemoglobin (at PPRM and delivery). **Table 2** showed that there was no difference between the two arms regarding the mode of delivery. Gestational age when PPRM occurred, latency period, and gestational age at delivery were shown in **table 3**; the latency period was significantly longer and the gestational age at delivery was more advanced among the outpatient arm while there was no significant difference between the two arms of the study regarding the gestational age at the time of PPRM. **Figure 2** represented the rate of delivery among the study arms. **Tables 4 and 5** showed that there was no significant difference between both arms regarding hemoglobin and total leucocytic count respectively. **Table 6** showed similar rates of chorioamnionitis among the two arms of the study. **Tables 7-9** addressed the neonatal outcomes of the study participants; **table 7** showed that there was no significant difference between the two arms of the study regarding neonatal weight while **table 8** was concerned with NICU admission, oxygen requirements, and neonatal sepsis with no significant difference observed between the two arms of the study regarding these variables. **Table 9** showed no significant difference between the two arms regarding perinatal and neonatal mortality.

Discussion

This prospective cohort study was conducted at Ain Shams University Maternity Hospital during the period from March 2022 to March 2023. The study aimed to compare inpatient management of patients with PPRM with outpatient management regarding the latency period, the incidence of intra-amniotic infection, neonatal weight, and neonatal complications.

Seventy-one patients with preterm prelabour

rupture of the membranes were enrolled in the study after obtaining informed consent. Out of these 71 patients, 6 patients from the outpatient cohort were lost at follow up and 2 patients from the inpatient cohort were discharged against medical advice. Out of the remaining 63 patients, 31 were managed as inpatients while 32 were managed as outpatients. There was no significant difference between the two arms of the study regarding the demographic data (Age, BMI, parity, previous cesarean section, and blood group).

The mode of delivery was assessed in our study and there was no significant difference between the two arms of the study regarding the mode of delivery. The incidence of cesarean section was 71.9 % in the inpatient arm and 77.4% in the outpatient arm. Such a high incidence of a cesarean section can be attributed to the high number of previous cesarean sections among study participants which was approximately 50% in either arm and the high number of preterm birth among study participants. Results by Guckert et al., showed similar results with no significant difference between the two arms of the study regarding the mode of delivery but the incidence of cesarean section was much lower than in our study which can be due to the high number of nulliparous women in both outpatient and inpatient groups (44.2% and 40.7% respectively), high number of cephalic presentation among both groups (66% and 68.8 %), and low number of growth restricted fetuses among both arms (8).

The gestational age when preterm prelabour rupture of membranes occurred was evaluated and there was no significant difference between the inpatient and the outpatient arm. However, the latency period was significantly longer in the outpatient arm which led to a more advanced gestational age at delivery. Our results were consistent with Mirteimouri et al., who conducted a non-randomized controlled trial to evaluate both outpatient and inpatient management of cases with

preterm prelabour rupture of membranes; the latency period was significantly longer compared with the inpatient group (18.7 ± 12.9 vs. 7.1 ± 5.8 days, $p < 0.001$) (9). Our results were consistent with Dussaux et al., who showed a longer latency period among patients with PPRM who received home care compared with those who received hospital care in their retrospective study which included 414 patients (29.9 ± 17.6 days vs 11.5 ± 10.5 days, $p < 0.01$); the outpatient arm had significantly higher gestational age at delivery ($33.6 \{31.1-34.4\}$ vs $32 \{29.4-33.8\}$, $p < 0.01$), however, the home care patients had a lower gestational age at the time of membrane rupture which could be a reason for the longer latency period among them ($28.8 \{26.6-30.5\}$ vs $30.3 \{27.6-32.1\}$, $p < 0.01$). Moreover, cervical length at admission was significantly shorter among the inpatient arm (3); this was not in agreement with our study which showed no significant difference between both arms of the study regarding the gestational age when rupture of the membranes occurred; this can be attributed to the nature of the included participants as our study included patients with gestational age from 28+0 weeks to 34+0 weeks which was a narrower range compared to Dussaux et al., (24 to 34 weeks). Results obtained by Guckert et al., were similar to our results as well with longer latency period and gestational age at delivery being observed in the outpatient arm (8). Catt et al., showed similar results as well with the latency period being significantly longer in the outpatient group (18 {IQR 24} vs 11 {IQR 12}, $p = < 0.001$) and consequently the gestational age at delivery ($32.3 \{2.7\}$ vs $30.6 \{3.1\}$, $p = < 0.001$), an interesting finding in that study could be the explanation of the lower gestational age at delivery among the inpatient group that is the significantly higher incidence of chorioamnionitis on placental pathology with funisitis among the inpatient cohort (10). Rouzaire et al., had similar results as well with the latency period being significantly longer (38.6 ± 23.1 vs $11.2 \pm$

10.2, $p = 0.01$) and gestational age at delivery is significantly higher (36.2 ± 2.5 vs 31.8 ± 3.9 , $p = < 0.001$) among the outpatient group (5). There are several hypotheses to explain this difference in latency periods. First, inpatient care may increase the likelihood of earlier delivery by increasing the risk of hospital-acquired infections. Second, the high stress condition associated with prolonged antenatal hospitalization may have a negative psychological impact which might indirectly decrease the latency period. Third, hospitalization may play an important role in the occurrence of more interventions (i.e., vaginal examination) (9). Our results were in disagreement with Bouchghoul et al., who showed in their multicenter retrospective study that the latency period ($30.6\{19.0\}$ vs $25.4\{23.2\}$, $p = 0.16$) and the gestational age at delivery ($32+4\{3\}$ vs $31+5\{4\}$, $p = 0.13$) didn't differ significantly between those who were managed as inpatient and those with effective outpatient care policy after propensity score matching; this can be attributed to the fact that tocolytic administration was significantly higher in the inpatient group (11).

Both hemoglobin and total leucocytic count were assessed in our study at the time of PPRM and at the time of delivery; there was no significant difference between the two arms of the study regarding both parameters neither at membrane rupture nor at the time of delivery. Our results were similar to Dussaux et al., who showed that the inpatient's arm had non significantly higher total leucocytic count (14.4% vs 13.4%, $p = 0.82$) (3). Our results were not consistent with Guckert et al., who showed higher leucocytic count among the inpatient's arm; this could be explained by the higher incidence of infection among the inpatient arm which was obvious by the higher CRP (44.6% vs 29%, $p = 0.002$) and clinical chorioamnionitis among the inpatient's arm (24% vs 15.7%, $p = 0.039$) (8).

Despite the gestational age at delivery was significantly earlier among the inpatient's

arm, the incidence of clinical chorioamnionitis among the study participants was almost the same. The reason for this finding is not clear; histologic chorioamnionitis was not evaluated in our study which could be higher in the inpatient's arm. Intra-uterine infection and associated inflammation are believed to be an important cause of PTB, and histologic chorioamnionitis is associated with PTB and lower gestational age at delivery among PTBs (12). Subclinical chorioamnionitis was observed in the study conducted by Catt et al., who showed a significantly higher incidence of histologic chorioamnionitis (64% vs 47%, $p = 0.008$) despite similar rates of clinical chorioamnionitis (10). Our results were consistent with Garabedian et al., who showed no difference in the incidence of chorioamnionitis between homecare and hospital-based care among patients with PPRM (13). The same finding was observed in the study conducted by Palmer et al., who showed no significant difference between both management policies regarding neither clinical nor histologic chorioamnionitis (2). Beckmann & Gardener, obtained similar results in their retrospective study that compared home-based management of patients with PPRM with hospital-based care. (6). However, the study conducted by Guckert et al., showed a significantly higher incidence of clinical chorioamnionitis in the inpatient's arm; this can be attributed to the fact that invasive procedures such as amniocentesis and chorionic villus sampling (CVS) were higher in the inpatient's arm ($21\{3,10\}$ vs $10\{2,5\}$, $p = 0.062$) (8).

The neonatal weight was lower in the inpatient's arm but with no statistical significance; this finding could be attributed to the lower gestational age at delivery which was encountered in the inpatient's arm. Our results were similar to those obtained by Bouchghoul et al., who showed lower birth weight in the inpatient's arm; however, the birth weight in both arms was lower compared to our study due to lower gestational age at

delivery (11). In the previously mentioned research, patients with different risk factors for preterm delivery such as history of spontaneous preterm delivery, smoking, low-lying placenta, or placenta previa; this can explain the earlier gestational age at delivery compared to our study that excluded patients with these risk factors. Guckert et al., obtained similar results as well with a significant difference regarding neonatal birth weight in favor of the outpatient arm which was explained by earlier gestational age at delivery among the inpatient's arm taking into consideration that there was no significant difference between the two arms regarding the incidence of growth restricted babies (8).

Rates of NICU admission were similar between the two arms of the study. Among the inpatient's arm, 8 neonates were admitted to the NICU; 6 out of these 8 neonates required oxygen therapy in the form of oxygen mask (3 patients), CPAP (2 patients), and mechanical ventilator (1 patient), the remaining 2 neonates were admitted due to neonatal jaundice. As for the outpatient arm, 8 neonates were admitted to the NICU; 7 out of them were admitted for oxygen therapy which was in the form of oxygen mask (1 patient), CPAP (5 patients), and mechanical ventilator (1 patient). These findings could be explained by the fact that despite the significant difference between the two arms regarding gestational age at delivery, the mean gestational age in both arms lay in the late preterm category (34+0 - 36+6 weeks). Moreover, similar rates of chorioamnionitis were observed among the study participants. Our results were similar to those obtained by Bouchghoul et al., who showed no difference between the two management policies regarding the neonatal composite outcome (11). Our results were in disagreement with Dussaux et al., who showed higher NICU admission among the inpatient arm (209/312 {67%} vs 47/86 {54.7%}, $p=0.03$); these observations could be explained by several findings that were reported in the

study as lower birth weight, shorter course of antibiotic therapy, and lower gestational age at delivery (3). Guckert et al., showed a significantly higher rate of NICU admission in the inpatient's arm (49.2% versus 77.2%, $p < 0.001$); a higher rate of chorioamnionitis and neonatal complications, and significantly lower birth weight among the inpatient's arm could be the explanation (8).

Neonatal sepsis was reported with no significant difference between the two arms. Beckman & Gardener, had similar results with no significant difference between the two groups regarding the incidence of neonatal infection (6). The same finding was observed in the study conducted by Palmer et al., who showed no difference regarding neonatal sepsis between home-based care and hospital care for patients with PPRM (11.5% vs 6.9%, $p = 0.43$) (2). Guckert et al., showed a slightly higher incidence of neonatal infection among the inpatient's arm (22.1 % vs 13.9 %, $p = 0.037$); the highly significant difference between the two arms regarding the gestational age at delivery and the birth weight put the neonates of the inpatient's arm at greater risk of infection along with the higher incidence of clinical chorioamnionitis and the longer length of stay in the NICU which was reported (8).

Perinatal mortality was evaluated in our study with no significant difference between the two arms regarding neither perinatal nor neonatal mortality. Our results were consistent with those obtained by Catt et al., who showed no difference between the two approaches regarding stillbirth or neonatal mortality (3% vs 4%, $p > 0.999$) (10). Bouchghoul et al., had similar results as well with no difference between the two groups regarding either composite perinatal outcome measure or neonatal mortality (11).

Discussion

Study limitations: Our study was not without limitations; the major limitation was

the inability to determine whether outpatient management of PPRM is associated with adverse neonatal outcome compared with inpatient management. Prospective studies with larger sample size are needed for a better assessment of the difference in neonatal outcome between home-based care and hospital care in cases of PPRM.

Conclusion

The study concluded that outpatient management of patients with preterm prelabour rupture of the membranes is safe and cost-effective approach. Compared with inpatient management, it's associated with a longer latency period, higher gestational age at delivery, and higher birthweight along with similar rates of chorioamnionitis. Home-based care is suitable for patients with PPRM who are considered low-risk patients from maternal and fetal perspectives.

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Declarations of interest

a) Ethical approval and informed consent:

Informed consent was obtained from study participants. The study was registered in Clinicaltrials.gov, ID: NCT05755841 , and was approved by the Research Ethics Committee, Faculty of Medicine, Ain Shams University (MS 614/2021, FWA 000017585). All methods were carried according to the relevant guidelines and regulations in the Declaration of Helsinki

b) Consent for publication:

Not applicable

c) Availability of data and materials:

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

d) Conflicts of interest:

The authors declare that there are neither financial nor non-financial conflicts of interest concerned with the manuscript of the study

e) Funding:

The study was based on investigators' self-funding

f) Authors' contribution:

Author Ahmed Mohammed Elmaraghy & Author Nermeen Rabea Kamal designed the study, and collected and analyzed the data. Author Bassem Aly Islam ensured that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Author Adel Shafik Salah El-din revised the study for intellectual content and approved the final version of the manuscript to be published

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Figure legends

Figure 1: Flow chart of study participants

Figure 2: Kaplan-Meier curve from rate of delivery among study participants

Tables**Table 1:**

Variables		Inpatient care (Total=32)	Outpatient care (Total=31)	p-value
Age (years)	Mean \pm SD	28.6 \pm 7.2	26.8 \pm 4.5	\wedge 0.235
	Range	18.0–45.0	18.0–35.0	
BMI (kg/m ²)	Mean \pm SD	27.1 \pm 3.7	26.6 \pm 3.3	\wedge 0.600
	Range	19.2–34.2	19.7–32.1	
Parity	Nulli	11 (34.4%)	8 (25.8%)	#0.459
	Parous	21 (65.6%)	23 (74.2%)	
Previous cesarean section		16 (50.0%)	16 (51.6%)	#0.898
ABO	A	15 (46.9%)	18 (58.1%)	§0.348
	B	10 (31.3%)	6 (19.4%)	
	O	7 (21.9%)	5 (16.1%)	
	AB	0 (0.0%)	2 (6.5%)	
RH	Positive	30 (93.8%)	30 (96.8%)	§0.999
	Negative	2 (6.3%)	1 (3.2%)	

Baseline characteristics among the study participants

BMI: Body Mass Index. \wedge : Independent t-test. #: Chi square test. §: Fisher's Exact test.

Table 2:

Mode of delivery	Inpatient care (Total=32)	Outpatient care (Total=31)	p-value
Cesarean	23 (71.9%)	24 (77.4%)	#0.613
Vaginal	9 (28.1%)	7 (22.6%)	

Mode of delivery among the study participants. #: Chi square test

Table 3:

Variables		Inpatient care (Total=32)	Outpatient care (Total=31)	p-value
PPROM	Mean \pm SD	31.1 \pm 1.6	30.8 \pm 2.2	\wedge 0.558
	Range	28.1–32.9	28.0–33.9	
Delivery	Mean \pm SD	33.6 \pm 1.9	35.0 \pm 1.8	\wedge 0.004*
	Range	29.5–36.2	29.8–36.9	
Latency	Mean \pm SD	17.7 \pm 11.9	29.4 \pm 15.8	\wedge 0.002*
	Range	1.0–57.0	5.0–60.0	

Gestational age at PPRM and delivery, and latency period among the study participant

\wedge : Independent t-test. *: Significant

Table 4:

Variables		Inpatient care (Total=32)	Outpatient care (Total=31)	p-value
PPROM	Mean ± SD	10.5±1.1	10.2±1.0	^0.263
	Range	8.1–12.0	7.8–11.8	
Delivery	Mean ± SD	10.0±1.1	9.6±0.9	^0.110
	Range	7.8–12.6	7.5–11.0	
#Change	Mean ± SD	-0.6±0.8	-0.6±0.8	^0.988
	Range	-3.1–0.9	-2.5–1.7	

Hemoglobin levels (gm/dl) at admission and delivery among the study participants:

Change = Delivery – Admission, negative values indicate reduction. ^: Independent t-test.

Table 5:

Variables		Inpatient care (Total=32)	Outpatient care (Total=31)	p-value
PPROM	Mean ± SD	10.0±3.6	10.1±3.6	^0.846
	Range	5.1–21.9	4.6–17.4	
Delivery	Mean ± SD	10.9±3.4	10.6±3.1	^0.772
	Range	5.5–23.0	6.0–18.9	
#Change	Mean ± SD	0.9±1.5	0.5±2.3	^0.402
	Range	-2.3–5.8	-3.8–5.3	

Total leucocytic count (x103/mL) at PPRM and delivery among the study groups

Change = Delivery – Admission, negative values indicate reduction. ^: Independent t-test.

Table 6:

	Inpatient care (Total=32)	Outpatient care (Total=31)	p-value
Chorioamnionitis	3 (9.4%)	3 (9.7%)	§0.999

Chorioamnionitis among the study participants. §: Fisher’s Exact test

Table 7:

Measures	Inpatient care (Total=32)	Outpatient care (Total=31)	p-value
Mean±SD	2.2±0.5	2.4±0.6	^0.095
Range	0.8–3.3	0.9–3.6	

Neonatal weight (Kg) among the study participants. ^: Independent t-test

Table 8:

Condition	Inpatient care (Total=32)	Outpatient care (Total=31)	p-value
NICU admission	8 (28.1%)	8 (25.8%)	#0.836
Oxygen requirements			
Total	6 (18.8%)	7 (22.6%)	#0.707
CPAP	2 (6.3%)	5 (16.1%)	§0.257
Mechanical ventilator	1 (3.1%)	1 (3.2%)	§0.999
Oxygen mask	3 (9.4%)	1 (3.2%)	§0.613
Neonatal sepsis			
Number & %	5 (15.6%)	3 (9.7%)	§0.708

NICU admission, oxygen requirements and neonatal sepsis among the study participants

#: Chi square test. §: Fisher’s Exact test

Table 9:

Vatiables	Inpatient care (Total=32)	Outpatient care (Total=31)	p-value
Perinatal mortality	5 (15.6%)	2 (6.5%)	§0.426
Still birth	1 (3.1%)	0 (0.0%)	§0.999
Neonatal mortality	4 (12.5%)	2 (6.5%)	§0.672

Perinatal mortality, stillbirth, and neonatal mortality among study participants.

§: Fisher’s Exact test

Figures

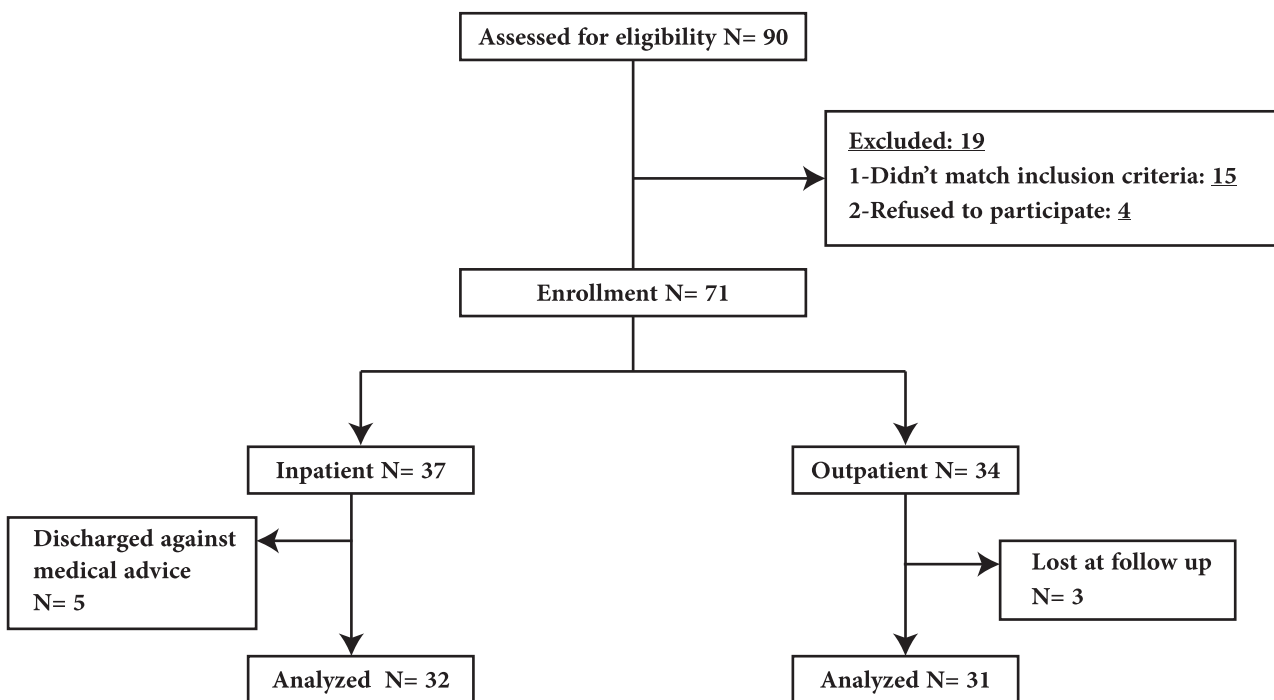


Figure 1: Flow chart of study participants

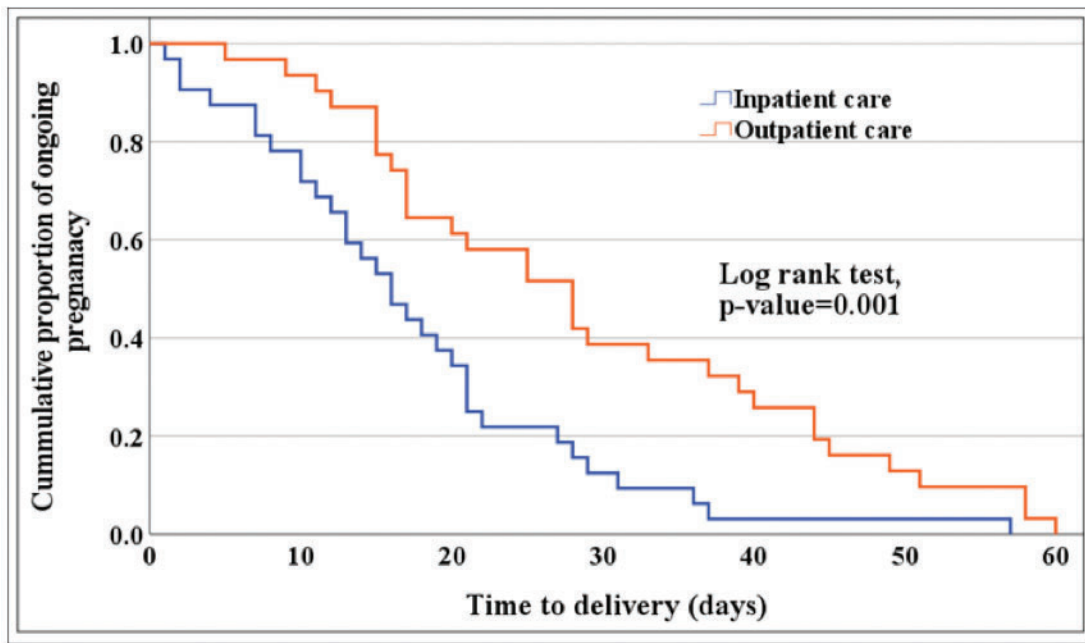


Figure 2: Kaplan-Meier curve from rate of delivery among study participants