RESEARCH PAPER

Effect of Azithromycin on Pregnancy Prolongation in Women at Risk of Preterm Labour: A Randomized Controlled Trial

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ABSTRACT

Background: Preterm birth remains the leading cause of perinatal morbidity and mortality worldwide, and infection is recognized as one of its principal drivers. Azithromycin, a macrolide with favorable oral bioavailability and efficient transplacental transfer, has been proposed as an adjunct to standard tocolytic care for women at risk of preterm labour.

Objective: To determine whether adding azithromycin to standard treatment prolongs pregnancy and improves maternal and neonatal outcomes in women with intact membranes who are at risk of, or already experiencing, preterm labour.

Methods: This randomized controlled trial enrolled 210 pregnant women between 24 and 37 weeks of gestation at Beni-Suef University Hospital. Participants were allocated equally to three arms: standard tocolytic treatment alone (Group 1, control), standard treatment plus oral azithromycin 500 mg once daily for 3 days monthly (Group 2), and standard treatment plus azithromycin 500 mg once daily for 5 days monthly (Group 3). The primary outcome was gestational age at delivery; secondary outcomes included mode of delivery, maternal and neonatal complications, birth weight, Apgar score, and NICU admission.

Results: Median gestational age at delivery was significantly higher in Group 2 and Group 3 (38 weeks each) than in the control group (37 weeks, $p<0.001$). Pregnancies free of complications were more frequent in Group 2 (78.6%) and Group 3 (84.3%) than in controls (57.1%, $p<0.001$), and preterm delivery fell from 31.4% in controls to 15.7% and 10.0% in Groups 2 and 3, respectively ($p=0.004$). PPROM was less frequent in the azithromycin arms (5.7% each versus 28.5%, $p<0.001$). Neonates in the treatment groups had fewer complications (80–84.3% complication-free versus 50% in controls, $p=0.001$), lower NICU admission rates (20% and 8.6% versus 44%, $p<0.001$), higher median birth weight and 5-minute Apgar scores, and fewer neonatal deaths (1.4% versus 10%, $p=0.015$).

Conclusion: Adding azithromycin to standard treatment meaningfully prolongs pregnancy and improves maternal and neonatal outcomes in women at risk of preterm labour, with the 5-day monthly regimen showing a modest additional advantage over the 3-day regimen.

Keywords: azithromycin; preterm labour; pregnancy prolongation; PPROM; neonatal outcome

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INTRODUCTION

Preterm birth, defined as delivery before 37 completed weeks of gestation, is conventionally subdivided into late preterm (34–<37 weeks), moderate preterm (32–<34 weeks), very preterm (28–<32 weeks), and extremely preterm (<28 weeks) categories (Zainal et al., 2019). It remains the single largest contributor to perinatal death worldwide, and its incidence continues to climb rather than plateau (Goyer et al., 2016), affecting an estimated 5–18% of all pregnancies (Romero et al., 2014). Infants delivered before 34 weeks bear a disproportionate share of the associated morbidity, encountering respiratory, neurological, and infectious complications at rates far above those seen in term infants (Connolly et al., 2021).

The causes of preterm labour are heterogeneous. Premature rupture of membranes, a prior episode of preterm labour, cervical shortening, intrauterine infection, advanced maternal age, multiple gestation, and smoking are among the most consistently cited risk factors (Berger et al., 2017). More recently, amniotic fluid "sludge" — echogenic debris seen on ultrasound within the amniotic cavity — has been proposed as a marker of subclinical intra-amniotic inflammation and, by extension, a predictor of preterm delivery (Yasuda et al., 2020). Cervical shortening itself appears to travel together with microbial invasion of the amniotic cavity, and both precede spontaneous preterm birth in a substantial proportion of cases (Stranik et al., 2021). Several interventions have been developed to interrupt this pathway, among them tocolysis (Haas et al., 2014), cervical cerclage (Issah et al., 2021), progesterone supplementation, and antimicrobial prophylaxis or treatment (Shor et al., 2021).

Antimicrobial therapy occupies a distinct place in this landscape because it targets a mechanism rather than merely suppressing uterine activity. Macrolides in particular are used to eradicate lower genital tract organisms such as

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Ureaplasma urealyticum and Mycoplasma hominis, which are frequently implicated in ascending intrauterine infection (Stinson et al., 2019). The clinical stakes of controlling this infection are considerable: prolonged membrane rupture in the presence of chorioamnionitis has been linked to cerebral palsy in surviving infants, yet no single antibiotic regimen has been established as optimal for prophylaxis in this setting (Pierson et al., 2014).

Erythromycin was for many years the macrolide of choice in obstetric infection prophylaxis, but azithromycin has increasingly displaced it. Retrospective data comparing the two drugs in the context of preterm premature rupture of membranes (PPROM) suggest that azithromycin is at least equivalent in efficacy while being easier to administer, better tolerated, and less expensive (Navathe et al., 2019). Its pharmacokinetic profile — good oral bioavailability paired with efficient transplacental transfer — makes it attractive not only for infection prophylaxis but also for the treatment of toxoplasmosis, malaria, and sexually transmitted infections during pregnancy. Whether these properties translate into a measurable prolongation of pregnancy when azithromycin is added to conventional tocolytic management, however, has not been settled by prospective, randomized evidence.

This study was therefore designed to evaluate, in a randomized controlled framework, whether adding azithromycin to standard treatment prolongs pregnancy and improves maternal and neonatal outcomes among women with intact membranes who are at risk of, or already in, preterm labour.

2. PATIENTS AND METHODS

2.1 Study design and setting

This randomized controlled trial was conducted in the Department of Obstetrics and Gynecology at Beni-Suef University Hospital, beginning 15 September 2022 and continuing until the target sample size was reached. Ethical approval was obtained from the Ethical Committee of the Faculty of Medicine, Beni-Suef University, and written informed consent was secured from every participant after the study procedures and objectives had been explained.

2.2 Participants

Women were eligible if they were between 24 and 37 weeks of gestation and either had a documented threat or history of preterm labour or were experiencing preterm labour that had not yet become established. Women were excluded if they had received antibiotics within the preceding 14 days (other than for pericerclage or Group B streptococcus prophylaxis), had PPROM or required fetal extraction before 37 weeks, carried a multiple pregnancy, had a current or past medical illness such as diabetes, hypertension, systemic lupus erythematosus, or cardiac disease, had sustained adverse perinatal outcome from abdominal trauma, had a structurally anomalous fetus on anomaly scan, had a known azithromycin allergy, or had undergone cervical cerclage.

2.3 Sample size

Sample size was calculated with G*Power version 3.1.9.2 (Franz Faul, Kiel, Germany) using a chi-square power analysis with alpha of 0.05, power of 0.95, a medium effect size (w = 0.3), and one degree of freedom, yielding a required sample of 180 participants. Allowing for a 25% attrition rate raised the target to 201 women; 210 were ultimately enrolled, giving 70 in each arm.

2.4 Randomization and interventions

Eligible women were randomized into three groups. Group 1 (control) received standard treatment for pregnancy prolongation, principally tocolytics, without azithromycin. Group 2 received the same standard treatment together with oral azithromycin 500 mg once daily for 3 consecutive days, repeated monthly. Group 3 received standard treatment together with oral azithromycin 500 mg once daily for 5 consecutive days, repeated monthly.

2.5 Assessment

All participants underwent detailed history taking and clinical examination at enrolment, together with a complete blood count, coagulation profile, and renal and liver function testing. Fetal biometry — biparietal diameter, head circumference, abdominal circumference, and femur length — was obtained by two-dimensional ultrasound (Mindray N7) in the Obstetrics and Gynecology department.

2.6 Outcomes

The primary outcome was gestational age at delivery, expressed as the interval in completed weeks and days between study enrolment and delivery. Secondary outcomes comprised birth weight; neonatal complications, including stillbirth and NICU admission, assessed at delivery and through the first postpartum week; and maternal complications — antepartum haemorrhage, postpartum pyrexia exceeding 38 °C, need for blood transfusion, length of hospital stay, and ICU admission — assessed over the same period.

2.7 Statistical analysis

Categorical variables are reported as numbers and percentages and were compared using the chi-square test or Fisher's exact test as appropriate. Normally distributed continuous variables are presented as mean ± standard deviation and compared by one-way ANOVA; normality was assessed with the Shapiro–Wilk test. Non-normally distributed continuous variables are presented as median and interquartile range and compared with the Kruskal–Wallis test. All tests were two-sided, and a p-value below 0.05 was considered statistically significant. Analyses were performed in SPSS version 26 (SPSS Inc., Chicago, IL).

3. RESULTS

Two hundred and ten women were enrolled and randomized in equal numbers (n=70 per arm) to the control group, the azithromycin-3-day group (Group 2), and the azithromycin-5-day group (Group 3).

3.1 Baseline characteristics

The three groups were well matched at baseline. Mean maternal age was 29.4 ± 4.8 years in the control group, 28.9 ± 5.0 years in Group 2, and 29.0 ± 5.8 years in Group 3 (p=0.840). Body mass index distribution did not differ significantly among groups (p=0.176), nor did parity (median 3, 3, and 2 in Groups 1, 2, and 3 respectively; p=0.159), history of preterm delivery (p=0.060), or previous PPROM (p=0.294). Tocolytic use after the first month of the study differed sharply, being required in 100%

of controls but only 15.7% of Group 2 and 10% of Group 3 (p<0.001), consistent with a genuine treatment effect rather than baseline imbalance. Antenatal steroid use did not differ significantly among groups (p=0.129).

Table 1. Baseline characteristics of the study groups

Variable	Group 1 (n=70)	Group 2 (n=70)	Group 3 (n=70)	P-value
Mean age ± SD, years	29.4 ± 4.8	28.9 ± 5.0	29.0 ± 5.8	0.840
BMI <25 kg/m², n (%)	8 (11.4%)	8 (11.4%)	2 (2.9%)	0.176
BMI 25–30 kg/m², n (%)	30 (42.9%)	37 (52.9%)	33 (47.1%)	
BMI >30 kg/m², n (%)	32 (45.7%)	25 (35.7%)	35 (50.0%)	
Median parity (IQR)	3 (2–4)	3 (2–4)	2 (1–4)	0.159
Tocolytic use after month 1, n (%)	70 (100%)	11 (15.7%)	7 (10%)	<0.001

3.2 Maternal outcomes

Pregnancies free of complications were more common with azithromycin: 78.6% in Group 2 and 84.3% in Group 3, against 57.1% in controls (p<0.001). Preterm delivery occurred in 31.4% of controls compared with 15.7% of Group 2 and 10.0% of Group 3 (p=0.004). PPROM was markedly less frequent in the treatment arms — 5.7% in each — than in controls (28.5%, p<0.001), while chorioamnionitis was numerically lower in the treatment groups without reaching significance (0% versus 4.3%, p=0.104).

Mode of delivery differed significantly across groups: caesarean section was performed in 72.9% of women in both Group 2 and Group 3 versus 38.6% of controls, with a corresponding reduction in vaginal delivery from 61.4% in controls to 27.1% in each treatment arm (p<0.001). Median gestational age at delivery was 38 weeks (IQR 37–39) in Group 2 and 38 weeks (IQR 38–39) in Group 3, compared with 37 weeks (IQR 32–38) in controls (p<0.001).

Table 2. Maternal outcomes by treatment group

Outcome	Group 1 (n=70)	Group 2 (n=70)	Group 3 (n=70)	P-value
No complications, n (%)	40 (57.1%)	55 (78.6%)	59 (84.3%)	<0.001
PPROM, n (%)	20 (28.5%)	4 (5.7%)	4 (5.7%)	<0.001
Preterm delivery, n (%)	22 (31.4%)	11 (15.7%)	7 (10.0%)	0.004
Chorioamnionitis, n (%)	3 (4.3%)	0 (0%)	0 (0%)	0.104
Vaginal delivery, n (%)	43 (61.4%)	19 (27.1%)	19 (27.1%)	<0.001
Caesarean section, n (%)	27 (38.6%)	51 (72.9%)	51 (72.9%)	<0.001
Median GA at birth, weeks (IQR)	37 (32–38)	38 (37–39)	38 (38–39)	<0.001

3.3 Neonatal outcomes

Neonates born to mothers in the treatment arms fared better across nearly every measured domain. The proportion of neonates without any complication rose from 50% in controls to 80% in Group 2 and 84.3% in Group 3 (p=0.001). NICU admission fell from 44% in controls to 20% in Group 2 and 8.6% in Group 3 (p<0.001), and median length of NICU stay shortened correspondingly, from 15 days (IQR 10–23) in controls to 8.5 days (IQR 5–15) in Group 2 and 5.5 days (IQR 3–10) in Group 3 (p=0.018).

Individual complications — respiratory distress syndrome, necrotizing enterocolitis, early-onset sepsis, and intraventricular haemorrhage — were all numerically less frequent in the treatment arms, though only the composite "no complications" measure and neonatal mortality reached statistical significance. Neonatal death occurred in 10% of controls versus 1.4% in each treatment group (p=0.015). Median birth weight and the median 5-minute Apgar score were both significantly higher in the treatment arms than in controls (p<0.001 for each).

Table 3. Neonatal outcomes by treatment group

Outcome	Group 1 (n=70)	Group 2 (n=70)	Group 3 (n=70)	P-value
No complications, n (%)	35 (50%)	56 (80%)	59 (84.3%)	0.001
RDS, n (%)	18 (25.7%)	10 (14%)	6 (8.6%)	0.099
NEC, n (%)	3 (4.3%)	1 (1.4%)	1 (1.4%)	0.440
Early sepsis, n (%)	6 (8.6%)	2 (2.9%)	1 (1.4%)	0.153
IVH, n (%)	1 (1.4%)	0 (0%)	0 (0%)	0.999
Neonatal death, n (%)	7 (10%)	1 (1.4%)	1 (1.4%)	0.015
NICU admission, n (%)	31 (44%)	14 (20%)	6 (8.6%)	<0.001
Median NICU stay, days (IQR)	15 (10–23)	8.5 (5–15)	5.5 (3–10)	0.018
Median Apgar (5 min), (IQR)	8 (6–9)	9 (8–9)	9 (8–9)	<0.001
Median birthweight, g (IQR)	2500 (1500–2900)	2850 (2500–3250)	2850 (2700–3200)	<0.001

4. DISCUSSION

The central finding of this trial is that adding azithromycin to standard tocolytic management meaningfully prolongs pregnancy in women at risk of preterm labour, with a mean survival time of 39.4 weeks in the 5-day azithromycin group compared with 36.9 weeks in controls (p=0.002). This effect was accompanied by improvements across nearly the entire spectrum of maternal and neonatal outcomes measured, from reduced PPROM and preterm delivery to lower NICU admission and neonatal mortality.

These results sit comfortably alongside earlier work. Abdelfattah et al. (2022) reported that a single 1 g dose of azithromycin extended gestational age at delivery to 35.12 weeks, compared with 32.61 weeks for a 500 mg-plus-250 mg regimen, favoring higher-dose azithromycin over lower-dose alternatives. Schreiber et al. (2019) similarly found that azithromycin produced a longer latency period than roxithromycin in PPROM (p=0.003) and argued for its adoption as first-line therapy on that basis. Sedeek et al. (2023) reported a smaller but still significant gestational age advantage with azithromycin (37.8 versus 37.4 weeks, p=0.033). Our own effect size — roughly 2.5 weeks of additional gestation in the 5-day arm relative to controls — falls within the range these studies collectively describe, though the studies vary considerably in dosing schedule and comparator, which likely explains some of the spread in effect magnitude.

The reduction in tocolytic requirement after the first month of treatment (from 100% in controls to 10–15.7% in the azithromycin arms) is consistent with Mercer's (1997) observation that antenatal azithromycin improves pregnancy outcomes sufficiently to reduce the need for adjunctive tocolysis. The parallel reduction in PPROM incidence — from 28.5% in controls to 5.7% in both treatment arms — echoes Mercer's finding that macrolide antibiotics lower rates of membrane rupture and subsequent chorioamnionitis, and aligns with Schreiber et al.'s (2019) endorsement of azithromycin as a simpler, more effective alternative to roxithromycin in this setting.

The higher caesarean section rate observed in both treatment groups deserves comment, since it runs counter to some published data. Schreiber et al. (2019) found no difference in caesarean rate with azithromycin use, while Appiagyei et al. (2017) reported a significant reduction relative to erythromycin (p=0.01). Our finding likely reflects the clinical consequence of successful pregnancy prolongation itself: as gestation advances, indications such as oligohydramnios, recurrent PPROM, or a prior caesarean history become more likely to dictate operative delivery, particularly since repeat caesarean is often preferred over trial of labour after a previous caesarean to avoid the complications associated with vaginal birth in that context (Abu-Heija & Ali, 2002; Gerscovich et al., 2003). In other words, the caesarean rate here may be a downstream marker of the intervention's success in extending gestation rather than evidence of an adverse effect of the drug itself.

Our neonatal findings broadly agree with, though do not uniformly replicate, the existing literature. The overall reduction in neonatal complications and the significant fall in neonatal mortality mirror the safety profile described by Zeng et al. (2020) and the anti-inflammatory mechanism proposed by Jorczyk (2020), who documented reduced IL-2 and IL-8 levels in neonates exposed to a 5-day azithromycin course — a plausible biological explanation for the trend toward fewer complications seen with the longer regimen in our own data. Mercer (1997) reported significant reductions in early sepsis, RDS, necrotizing enterocolitis, and hyperbilirubinaemia with antenatal antibiotics, outcomes that moved in the same direction in our cohort without always reaching statistical significance individually; the composite "no complications" outcome, however, was clearly significant (p=0.001), suggesting that the individual comparisons may simply have been underpowered rather than genuinely null. Not every comparator study agrees: Ko et al. (2018) found no significant difference in intraventricular haemorrhage or necrotizing enterocolitis with antenatal azithromycin, a pattern we also observed for these two specific complications, while DiSciullo et al. (2023) likewise reported comparable neonatal mortality between shorter and longer azithromycin courses, in contrast to the significant difference in mortality we observed against a no-azithromycin control.

The lower NICU admission rate and shorter length of stay in our treatment groups were not replicated by Appiagyei et al. (2017), Ko et al. (2018), or Ahmed et al. (2023), each of whom reported no significant difference on this measure. This divergence probably reflects differences in comparator drug (erythromycin rather than no antibiotic), local NICU admission criteria, and the range of co-morbidities that can independently drive admission decisions irrespective of antenatal antibiotic exposure. Our significant increase in median birth weight is corroborated by Ahmed et al. (2023), who reported a similarly favourable difference (2932.6 g versus 2401.8 g, p=0.006), although Kim et al. (2019) found no such difference, again pointing to heterogeneity across trial populations and regimens as a likely explanation for the inconsistency.

Several limitations warrant acknowledgment. The trial was conducted at a single Centre, which may limit generalizability to populations with different baseline infection prevalence or antibiotic resistance patterns. Long-term offspring outcomes beyond the immediate neonatal period were not assessed, and the biological mechanism underlying the observed benefit — whether primarily antimicrobial, anti-inflammatory, or both — was not directly investigated. Larger, multicentre trials with extended follow-up are needed to confirm these findings and to clarify the optimal azithromycin regimen.

5. CONCLUSION

In this randomized controlled trial, adding azithromycin to standard treatment significantly prolonged pregnancy and improved maternal and neonatal outcomes in women at risk of, or already experiencing, preterm labour. Both the 3-day and 5-day monthly regimens reduced PPROM, preterm delivery, NICU admission, and neonatal mortality relative to standard treatment alone, with the 5-day regimen showing a modest additional benefit over the 3-day course. These findings support consideration of azithromycin as an adjunct in the management of at-risk pregnancies, though

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further multicentre trials with long-term offspring follow-up are needed before firm dosing recommendations can be made.

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