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Cervicovaginal microbial colonization in preterm labour and preterm premature rupture of membranes and its association with maternal and neonatal outcomes: a prospective observational study from a tertiary care centre in South India

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Abstract

Background. Preterm labour (PTL) and preterm premature rupture of membranes (PPROM) are leading contributors to perinatal morbidity and mortality and are frequently associated with lower genital tract infection. The role of cervicovaginal microbial colonization in adverse maternal and neonatal outcomes remains incompletely defined in South Asian settings. We aimed to determine the prevalence of abnormal vaginal flora among women presenting with PTL or PPROM and to evaluate its association with maternal and neonatal outcomes.

Methods. We conducted a prospective observational study at a tertiary care teaching hospital in Karnataka, India, from May 2023 to December 2024. High vaginal swabs were collected from consecutive antenatal women presenting with PTL or PPROM and processed by standard microbiological culture and antibiotic susceptibility testing. Women were classified as having normal or abnormal vaginal flora. Maternal outcomes (mode of delivery, postpartum complications) and neonatal outcomes (birth weight, APGAR scores, neonatal intensive care unit [NICU] admission, neonatal sepsis) were compared. Associations were assessed using the chi-square or Fisher exact test and the Mann–Whitney U test; multivariable logistic regression was used to estimate the independent association of abnormal flora with NICU admission.

Results. Of 81 women recruited, 79 with an evaluable culture were analysed. Abnormal vaginal flora was identified in 30 women (38.0%). The commonest isolates were Klebsiella pneumoniae (33.3%), Candida non-albicans (23.3%) and Candida albicans (13.3%). Abnormal flora was significantly associated with NICU admission (53.3% vs 14.3%; odds ratio [OR] 6.86, 95% confidence interval [CI] 2.34–20.08; $p < 0.001$), neonatal sepsis among NICU-admitted neonates ($p = 0.019$), lower median birth weight (2.49 vs 2.68 kg; $p = 0.019$) and lower APGAR scores at 1 and 5 minutes ($p = 0.001$ and $p = 0.013$). After adjustment for birth weight, abnormal flora remained independently associated with NICU admission (adjusted OR 6.06, 95% CI 1.62–22.69; $p = 0.007$). Women with abnormal flora were younger and had a higher total leucocyte count. Caesarean delivery (70.0% vs 49.0%; $p = 0.110$) and postpartum complications (20.0% vs 12.2%; $p = 0.542$) were more frequent with abnormal flora but did not differ significantly, nor did presenting diagnosis, gravidity or residence.

Conclusions. Abnormal cervicovaginal flora was present in more than one-third of women with PTL or PPROM and was independently associated with adverse neonatal outcomes, particularly NICU admission and neonatal sepsis. Routine high vaginal swab screening with early, culture-directed treatment may help mitigate neonatal risk in this population.

Background

Preterm birth, defined by the World Health Organization as birth before 37 completed weeks of gestation, remains a leading cause of neonatal mortality and long-term morbidity worldwide. An estimated 13.4 million preterm births occur annually, more than a third of them in South Asia, and India carries one of the largest absolute burdens of any country. Preterm labour (PTL) and preterm premature rupture of

membranes (PPROM) together account for the majority of spontaneous preterm deliveries and are the clinical presentations through which most preventable preterm birth is encountered.

A substantial body of evidence implicates ascending lower genital tract infection in the pathophysiology of both PTL and PPROM. Micro-organisms colonizing the cervicovaginal compartment can trigger a local inflammatory cascade, up-regulate contraction-associated proteins and prostaglandin synthesis, and weaken the fetal membranes, culminating in preterm uterine activity or membrane rupture. Organisms recovered from the amniotic cavity in women delivering preterm are frequently also present in the lower genital tract, and colonization with virulent organisms such as group B streptococcus and Gram-negative bacilli is associated with an increased risk of early-onset neonatal infection.

Despite this biological plausibility, the clinical value of cervicovaginal screening in women who already present with PTL or PPROM is not firmly established, and data from Indian tertiary care settings quantifying the association between abnormal vaginal flora and downstream maternal and neonatal outcomes remain limited. The high vaginal swab (HVS) is an inexpensive, widely available tool that can identify colonizing pathogens and guide directed antimicrobial therapy. We therefore undertook a prospective observational study to (i) determine the prevalence and microbial profile of abnormal vaginal flora among women presenting with PTL or PPROM at a tertiary care teaching hospital in South India, and (ii) evaluate the association of abnormal flora with maternal and neonatal outcomes, including the independent contribution of colonization to neonatal intensive care unit (NICU) admission.

Methods

Study design and setting

This was a prospective observational study conducted in the Department of Obstetrics and Gynaecology, in collaboration with the Departments of Microbiology and Neonatology, at BGS Global Institute of Medical Sciences, a tertiary care teaching hospital in Bengaluru, Karnataka, India, over a 20-month period from May 2023 to December 2024. The study is reported in accordance with the STROBE statement for observational studies.

Participants

Consecutive antenatal women admitted with a diagnosis of PTL or PPROM between 28 and 36 weeks and 6 days of gestation were eligible. PTL was defined as regular uterine contractions with cervical change, and PPROM as spontaneous rupture of the membranes before the onset of labour prior to 37 weeks. Women with a clinically evident cause of preterm birth unrelated to infection (for example, multiple pregnancy managed by planned delivery, major fetal anomaly, or antepartum haemorrhage from placenta praevia), those who had received antibiotics within the preceding 7 days, and those who declined consent were excluded. Written informed consent was obtained from all participants.

Specimen collection and microbiological processing

Specimen collection and microbiological processing
A high vaginal swab was collected under aseptic speculum examination at admission, before administration of antibiotics. Specimens were transported immediately to the microbiology laboratory and processed by standard techniques, including Gram staining, aerobic culture on blood and MacConkey agar, and fungal culture where indicated. Isolates were identified by colony morphology, Gram reaction and standard biochemical tests, and antibiotic susceptibility was determined by the Kirby–Bauer disc diffusion method according to prevailing Clinical and Laboratory Standards Institute (CLSI) breakpoints. Growth of a recognized uropathogen or genital pathogen, or of Candida species, was classified as abnormal vaginal flora; growth of normal commensal flora only was classified as normal.

Outcomes and variables

The primary exposure was vaginal flora status (abnormal vs normal). Maternal outcomes were mode of delivery (vaginal vs lower-segment caesarean section [LSCS]) and postpartum complications (puerperal sepsis, fever or wound gaping). Neonatal outcomes were birth weight, APGAR score at 1 and 5 minutes, NICU admission, and neonatal sepsis (clinical sepsis with supportive investigations among NICU-admitted neonates), assessed jointly with the Department of Neonatology. Baseline variables recorded included maternal age, residence, gravidity, gestational age, total leucocyte count and, for PPROM, the interval between membrane rupture and admission.

Statistical analysis

Categorical variables are summarized as frequencies and percentages and continuous variables as mean (standard deviation, SD) or median (interquartile range, IQR) according to distribution. Associations between flora status and categorical outcomes were tested using the Pearson chi-square test, or the Fisher exact test where expected cell counts were small; odds ratios (OR) with 95% confidence intervals (CI) were computed. Continuous outcomes were compared using the Mann–Whitney U test. To assess whether abnormal flora was independently associated with the principal neonatal outcome, a multivariable logistic regression model was fitted for NICU admission with adjustment for birth weight; a sensitivity model adjusting for maternal age was also fitted. Given 23 NICU events, the number of covariates was deliberately constrained to avoid over-fitting. A two-sided p-value < 0.05 was considered statistically significant. Analyses were performed using Python (SciPy and statsmodels).

Ethics

The study was approved by the Institutional Ethics Committee of BGS Global Institute of Medical Sciences, Bengaluru (Ref. No. BGSGIMS/IEC/App/Apr/2023/031, dated 24 April 2023; approved at the Ethics Committee meeting held on 13 April 2023; IEC Registration No. ECR/1307/Inst/KA/2019). Written

informed consent was obtained from all participants prior to enrolment, and the study was conducted in accordance with the Declaration of Helsinki.

Results

Participant characteristics

Of 81 women recruited during the study period, two were excluded because no evaluable high vaginal swab culture result was recorded, leaving 79 women for analysis. Abnormal vaginal flora was identified in 30 women (38.0%) and normal flora in 49 (62.0%). The mean maternal age was 25.7 (SD 5.2) years (range 18–42); 55 women (69.6%) were from urban areas and 49 (62.0%) were multigravida. The presenting diagnosis was PPROM in 44 women (56.4%) and PTL in 34 (43.6%), and the great majority were late preterm (34–36 weeks). Baseline characteristics by flora status are shown in Table 1. Women with abnormal flora were younger (mean 24.1 vs 26.7 years; p = 0.024) and had a higher total leucocyte count (median 14,400 vs 11,300 cells/mm³; p = 0.029); residence, gravidity and presenting diagnosis did not differ significantly.

Table 1
Baseline maternal characteristics by vaginal flora status (N = 79).

Characteristic	Abnormal flora (n = 30)	Normal flora (n = 49)	p-value
Age, years — mean (SD)	24.1 (4.3)	26.7 (5.5)	0.024
Age, years — median (IQR)	23 (21–26)	26 (23–29)	0.024
Urban residence — n (%)	21 (70.0)	34 (69.4)	1.000
Multigravida — n (%)	16 (53.3)	33 (67.3)	0.314
Presenting as PPROM — n (%)	18 (60.0)	26 (54.2)	0.787
TLC, cells/mm³ — median (IQR)	14,400 (11,050–18,625)	11,300 (9,500–14,500)	0.029

IQR interquartile range; SD standard deviation; PPROM preterm premature rupture of membranes; TLC total leucocyte count. p-values from chi-square/Fisher exact (categorical) or Mann–Whitney U (continuous) tests. One woman had an unclassifiable diagnosis (denominator 78 for PPROM proportion).

Microbial profile

Among the 30 women with abnormal flora, the commonest isolate was Klebsiella pneumoniae (33.3%), followed by Candida non-albicans (23.3%), Candida albicans (13.3%) and Escherichia coli (10.0%). Gram-negative bacilli together accounted for half of all isolates and Candida species for more than a third. The distribution of isolates is shown in Table 2.

Table 2
Distribution of micro-organisms isolated from women with abnormal vaginal flora (n = 30).

Organism	n	%
Klebsiella pneumoniae	10	33.3
Candida non-albicans	7	23.3
Candida albicans	4	13.3
Escherichia coli	3	10.0
MRSA	2	6.7
Enterobacter spp.	2	6.7
Streptococcus spp.	1	3.3
Pseudomonas aeruginosa	1	3.3
Total	**30**	**100.0**

MRSA methicillin-resistant Staphylococcus aureus. Detailed antibiotic susceptibility patterns are reported separately.

Maternal outcomes

Lower-segment caesarean section was more frequent among women with abnormal flora (70.0% vs 49.0%), but the association did not reach statistical significance (OR 2.43, 95% CI 0.93–6.35; p = 0.110). Postpartum complications — puerperal pyrexia, puerperal fever or wound gaping — were likewise somewhat more common in the abnormal-flora group (20.0% vs 12.2%) without reaching significance (OR 1.79, 95% CI 0.52–6.17; p = 0.542) (Table 3). Fetal distress was the leading indication for emergency caesarean section.

Neonatal outcomes

Neonatal outcomes were consistently worse in the abnormal-flora group. NICU admission occurred in 16 of 30 neonates (53.3%) born to mothers with abnormal flora compared with 7 of 49 (14.3%) in the normal-flora group (OR 6.86, 95% CI 2.34–20.08; p < 0.001). Among NICU-admitted neonates in whom a sepsis evaluation was performed, clinical/culture-supported sepsis was substantially more frequent in the abnormal-flora group (13/14 vs 1/4; p = 0.019). Median birth weight was lower (2.49 vs 2.68 kg; p = 0.019) and APGAR scores at both 1 and 5 minutes were lower among neonates of mothers with abnormal flora (p = 0.001 and p = 0.013, respectively). The median duration of NICU stay did not differ significantly between groups. Associations of flora status with maternal and neonatal outcomes are summarized in Table 3.

Table 3
Association of abnormal vaginal flora with maternal and neonatal outcomes.

Outcome	Abnormal flora	Normal flora	OR (95% CI)	p-value
Maternal				
LSCS — n (%)	21/30 (70.0)	24/49 (49.0)	2.43 (0.93–6.35)	0.110
Postpartum complication — n (%)	6/30 (20.0)	6/49 (12.2)	1.79 (0.52–6.17)	0.542
Neonatal				
NICU admission — n (%)	16/30 (53.3)	7/49 (14.3)	6.86 (2.34–20.08)	< 0.001
Neonatal sepsis — n (%) †	13/14 (92.9)	1/4 (25.0)	39.0 (1.9–817.7)	0.019
Birth weight, kg — median (IQR)	2.49 (2.10–2.75)	2.68 (2.32–3.02)	—	0.019
APGAR at 1 min — median (IQR)	8 (7–8)	8 (8–8)	—	0.001
APGAR at 5 min — median (IQR)	9 (8–9)	9 (9–9)	—	0.013

CI confidence interval; IQR interquartile range; LSCS lower-segment caesarean section; NICU neonatal intensive care unit; OR odds ratio. Categorical outcomes tested by chi-square/Fisher exact test; continuous outcomes by Mann–Whitney U test. † Restricted to NICU-admitted neonates in whom a sepsis evaluation was completed and recorded (n = 18 of 23 admitted). APGAR scores were available for 78 of 79 neonates.

Neonatal mortality was not analysed as a study endpoint because discharge outcome was recorded for only a minority of the cohort. One fully documented neonatal death (at 32 weeks, following PPROM, attributed to patent ductus arteriosus with aspiration pneumonia) occurred in a participant excluded from analysis for want of a culture result; no deaths with complete supporting documentation occurred among the 79 analysed women.

Independent association of abnormal flora with NICU admission

In a multivariable logistic regression model, abnormal vaginal flora remained independently associated with NICU admission after adjustment for birth weight (adjusted OR 6.06, 95% CI 1.62–22.69; p = 0.007), with lower birth weight also predicting admission (adjusted OR 0.01 per kg, 95% CI 0.001–0.15; p < 0.001; model McFadden pseudo-R^2 0.38). The association was robust in a sensitivity model adjusting for maternal age (adjusted OR 5.75, 95% CI 1.91–17.28; p = 0.002). Model estimates are presented in Table 4.

Table 4
Multivariable logistic regression for NICU admission (n = 79; 23 events).

Predictor	Adjusted OR (95% CI)	p-value
Abnormal vaginal flora	6.06 (1.62–22.69)	0.007
Birth weight (per kg)	0.01 (0.001–0.15)	< 0.001
Sensitivity model (adjusting for age)		
Abnormal vaginal flora	5.75 (1.91–17.28)	0.002
Maternal age (per year)	0.90 (0.79–1.02)	0.096

CI confidence interval; NICU neonatal intensive care unit; OR odds ratio.

Discussion

In this prospective study of women presenting with PTL or PPROM at a South Indian tertiary care centre, abnormal cervicovaginal flora was present in 38% of women and was strongly and independently associated with adverse neonatal outcomes. The most striking finding was a nearly seven-fold higher odds of NICU admission among neonates of colonized mothers, an association that persisted after adjustment for birth weight and was reproduced when adjusting for maternal age. Colonized mothers also had neonates with significantly lower birth weight and APGAR scores, and a markedly higher frequency of neonatal sepsis among those requiring intensive care.

The predominance of Gram-negative bacilli — particularly Klebsiella pneumoniae and Escherichia coli — together with a substantial burden of Candida species is consistent with reports from other Indian and South Asian centres and contrasts with the group B streptococcus-dominant profiles more commonly described in high-income settings. This microbial pattern has direct implications for empirical therapy, since it favours agents with reliable Gram-negative cover while highlighting the non-trivial contribution of fungal colonization, which is not addressed by standard antibacterial prophylaxis.

The independent association between abnormal flora and NICU admission is biologically coherent: ascending colonization can provoke a fetal inflammatory response and predispose to early-onset neonatal infection, which in turn drives intensive care requirements independent of prematurity itself. That the association held after adjustment for birth weight suggests that colonization contributes to neonatal risk beyond its effect on gestational maturity, and supports a role for active screening and directed treatment rather than reliance on gestational age alone for risk stratification.

Notably, in the present analysis flora status was not significantly associated with the presenting diagnosis (PTL vs PPROM), gravidity, residence, mode of delivery or postpartum maternal complications. The absence of a statistically significant association with caesarean delivery and maternal morbidity — despite rates that were numerically higher in the colonized group (70.0% vs 49.0% and 20.0% vs 12.2%

respectively) — most likely reflects limited statistical power for these endpoints in a single-centre sample, and should be interpreted as an inconclusive result rather than as evidence of no effect.

The clinical implication is that a simple, low-cost high vaginal swab at presentation can identify a subgroup at substantially elevated neonatal risk. Where local microbiology mirrors the Gram-negative and Candida predominance observed here, culture-directed therapy has the potential to reduce early-onset neonatal sepsis and associated intensive care needs. These findings strengthen the rationale for embedding routine cervicovaginal screening into the management pathway for PTL and PPROM in comparable settings.

Strengths and limitations

Strengths include the prospective design, the collection of swabs before antibiotic exposure, paired microbiological and clinical follow-up with joint neonatology input, and a multivariable analysis that isolates the contribution of colonization to the principal neonatal outcome. Several limitations should be acknowledged. First, this was a single-centre study with a modest sample size; the number of events for some outcomes was small, yielding wide confidence intervals — most conspicuously for neonatal sepsis, where the interval spans two orders of magnitude and the point estimate should not be read as a precise measure of effect — and limiting power to detect associations with maternal endpoints. Second, culture-based classification may under-detect fastidious and anaerobic organisms and does not capture the full vaginal microbiome. Third, some secondary fields were incompletely recorded: a sepsis evaluation was documented for 18 of 23 NICU-admitted neonates, and discharge outcome was recorded for a minority of the cohort, so neonatal mortality could not be analysed. Fourth, two of 81 recruited women had no evaluable culture and were excluded, which could introduce selection bias, although this represents only 2.5% of the cohort. Fifth, as an observational study, residual confounding cannot be excluded and causality cannot be established. Finally, outcomes were assessed during the birth admission only, without longer-term neonatal follow-up. Multicentre studies with larger samples and molecular characterization of the vaginal microbiome are warranted to confirm these associations and to test whether screening-directed treatment improves neonatal outcomes.

Conclusions

Abnormal cervicovaginal flora was identified in more than one-third of women presenting with PTL or PPROM and was independently associated with adverse neonatal outcomes, particularly NICU admission and neonatal sepsis, as well as lower birth weight and APGAR scores. Gram-negative bacilli and Candida species predominated. Routine high vaginal swab screening at presentation, coupled with early culture-directed treatment, may help identify and mitigate neonatal risk in this population and merits evaluation in larger, multicentre studies.

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Ethics Committee of BGS Global Institute of Medical Sciences, Bengaluru (Ref. No. BGSGIMS/IEC/App/Apr/2023/031, dated 24 April 2023; IEC Registration No. ECR/1307/Inst/KA/2019). Written informed consent to participate was obtained from all participants prior to enrolment. Participants were informed about the purpose, procedures, potential risks and benefits of the study, and their right to withdraw at any time without affecting their clinical care, before providing written consent. All methods were carried out in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

AVK conceived the study, collected the data and drafted the manuscript. RN supervised the clinical obstetric component and revised the manuscript. BC, SDC and RAK supervised the microbiological component, performed and interpreted culture and antibiotic susceptibility testing, and revised the manuscript. SCN supervised neonatal outcome assessment and revised the manuscript. DSK contributed to the study design, performed the statistical analysis and critically revised the manuscript. All authors read and approved the final manuscript.

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