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RESEARCH ARTICLE

A randomised comparative study to determine the effects of screening for lower genital tract infections on fetomaternal outcomes

Dimple Makhijani, HP Anand

Corresponding author: Dr Dimple Makhijani, Senior resident, Department of Obstetrics and Gynecology, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India; Email: dimple.dm26@gmail.com

ABSTRACT

Objectives: The study aimed to determine the prevalence of lower genital tract infections (LGTI) in asymptomatic pregnant women and then compare the maternal and neonatal outcomes in screened and unscreened group. **Methods**: A randomized comparative study was conducted in the Department of Obstetrics and Gynaecology of Safdarjung hospital over a period of 18 months. It included 300 singleton low risk asymptomatic pregnant women with period of gestation <20 weeks. All the recruited participants were randomly divided into two groups: Group A: screened group, and Group B: unscreened group. The screened participants (if found positive for infections) were managed as per the hospital protocol. Feto-maternal outcomes were assessed and compared. **Results:** LGTI was present in 30.67% patients which included B. Vaginosis (65.22%), Candida (21.74%), T. Vaginalis (6.52%), N. Gonorrhoea (4.35%) and Chlamydia (2.17%). Compared to the unscreened group, in terms of maternal outcomes, women in the screened group had significantly more vaginal deliveries (84% vs 74.67%, p=0.046), significantly more spontaneous labour (80.67% vs 62.67%, p=0.0005); significantly less preterm labour (2.67% vs 13.33%, p=0.001); significantly less PPROM (3.33% vs 10%, p= 0.021); significantly less chorioamnionitis (0% vs 5.33%, p=0.007); significantly less wound gaping (0% vs 5.33%, p=0.007) and significantly less preterm births (2.67% vs 20%, p<.0001); and in terms of neonatal outcomes, neonates born to screened group women had significantly more birth weight (2.71 ± 0.26 vs 2.59 ± 0.31, p=0.0005), significantly more APGAR at 5 minutes (96% vs 90%, p=0.042); and significantly less NICU admission (6% vs 13.33%, p=0.032). **Conclusion**: There is a high prevalence of LGTI in asymptomatic pregnant women. Screening of infections and the simultaneous management results in significant improvement in the maternal and neonatal outcomes.

Keywords: Fetomaternal, genital tract infections, outcomes, prevalence.

Genital tract infections in women are common in clinical medicine and are one of the significant causes of morbidity. These infections may occur due to various causes like sexual transmission, overgrowing of normal vaginal flora or iatrogenically induced during medical procedures like abortions or instrumental deliveries (performed in an improper way).[1]

Female genital tract infections are divided into two categories - (1) the upper genital tract infections (UGTI) where uterus, fallopian tube and ovaries may be involved and (2) lower genital tract infections (LGTI) where the primary organs involved are cervix, vagina or vulva, vagina, cervix and vulva.[2, 3]

The importance of LGTI is much acknowledged since UGTI are also primarily the result of LGTI ascending upwards.[2] The most common LGTI in pregnancy are Candidiasis, Bacterial Vaginosis (BV) and Trichomoniasis. Other infections include Chlamydiasis and Gonorrhoea.[3]

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Pregnancy provides a conducive environment for the occurrence of such infections in the form of hormonal milieu (progesterone and estrogen levels), congestion and hypertrophy of the mucosa of the vagina and cervix, lowering of local immunity (number of B cells) and local pH alterations. These changes overall favour bacterial growth and increased opportunistic infections.[4] Moreover, these infections may be transmitted to the fetus, with some cases being unaffected due to fetal immunity but others showing symptomatic infections. Factors such as immunity of the mother and the fetus, and gestational age can affect the incidence of LGTI.[4-6]

Such infections have shown adverse influence on the fetomaternal outcomes in the form of premature births, neurological disturbances in the fetus, increased neonatal deaths and neonatal ICU admissions.[5] Recent WHO fact sheet (Feb 2018) states that world-wide, 15 million neonates are born preterm every year and 1 million neonates die annually from the complications of LGTI. Recently due to COVID-19 pandemic, the figures remain lower in the recent two years. India remains one of the countries in the list of top ten, contributing to 60% premature deliveries of the world's data. It is widely supposed that genitourinary infections in pregnant females play an important role in pathogenesis of preterm labor and delivery and are responsible for 25 - 40% of preterm births. Other complications include fetal blindness, low weight and neonatal pneumonia.[6]

Despite a high prevalence and strong adverse influence on the fetomaternal outcomes, genitourinary tract infections are poorly diagnosed and managed in developing countries.[7] This may be because the detection of LGTI is difficult since the women are mainly asymptomatic in nature. Owing to this, screening becomes important during pregnancy to rule out or diagnose LGTI and manage them appropriately.[5]

Thus, the present study was undertaken in the department of obstetrics and gynecology where all asymptomatic pregnant women were screened for LGTI and if found positive, were effectively treated for the infections. We evaluated and compared the effects of screening on the maternal and the neonatal outcome.

Methods

A randomized comparative study conducted in the department of obstetrics and gynaecology, Safdarjung hospital over a period of 18 months (January 2019 till June 2020). It included singleton low risk asymptomatic pregnant women with gestational age <20 weeks. Any patient with congenital abnormalities of the uterus, ante partum hemorrhage, severe anemia (haemoglobin <5 g/dL), history of pregnancy induced hypertension in previous pregnancy, known medical disease like hypertension, diabetes mellitus, kidney disease, liver disease or heart disease, chronic documented urinary tract infection and multiple pregnancies were excluded.

The sample size was calculated based on the study of Lata I et al,[8] (2010) who observed that preterm labour occurred in 22.6% of patients in non-treated group. Considering these for reference and assuming a 12% difference in preterm labour between the screened and unscreened group, 80% study power and 5% alpha error, the sample required was 147 patients per group. Considering the fallouts, we undertook this study on 300 pregnant women (150 patients per group).

The study was begun after institutional ethical clearance (IEC/ VMMC/ SJH/ Thesis/ October/ 2018 - 183, dated 31.10.2018, New Delhi). A duly informed written consent obtained from them. The data of the study patients were collected using a standard study proforma. Group A and B participants were subjected to questions regarding menstrual cycle, parity, past medical and surgical intervention and previous/present medication. A detailed clinical examination was also conducted.

The study patients were block randomised into two groups of 150 each. Figure 1 shows the patient flow diagram.

Group A: Interventional group - The group underwent screening for the lower genital tract infections at 28 weeks of pregnancy.

Group B: Observational group - The patients were routine investigated and managed during the antenatal period. No screening or testing for any genital infections was done in this set of patients.

Screening in group A

• 6 vaginal and 4 endocervical specimens were collected aseptically, using sterile swabs. These specimens were subjected to following investigations:

The endocervical swabs were used for-

1. Swab-1 was used for preparing a smear and staining with Gram's stain, to look for Gram negative Cocci (GNC) in pairs.
2. Swab - 2 was used for inoculation on culture media for N. Gonorrhoeae (Ng).
3. Swab - 3 was used for Chlamydia Trachomatis (Ct) antigen detection by ELISA/DFA.
4. Swab - 4 was processed for detection of Ng and Ct by Realtime PCR, subject to availability of PCR kits.

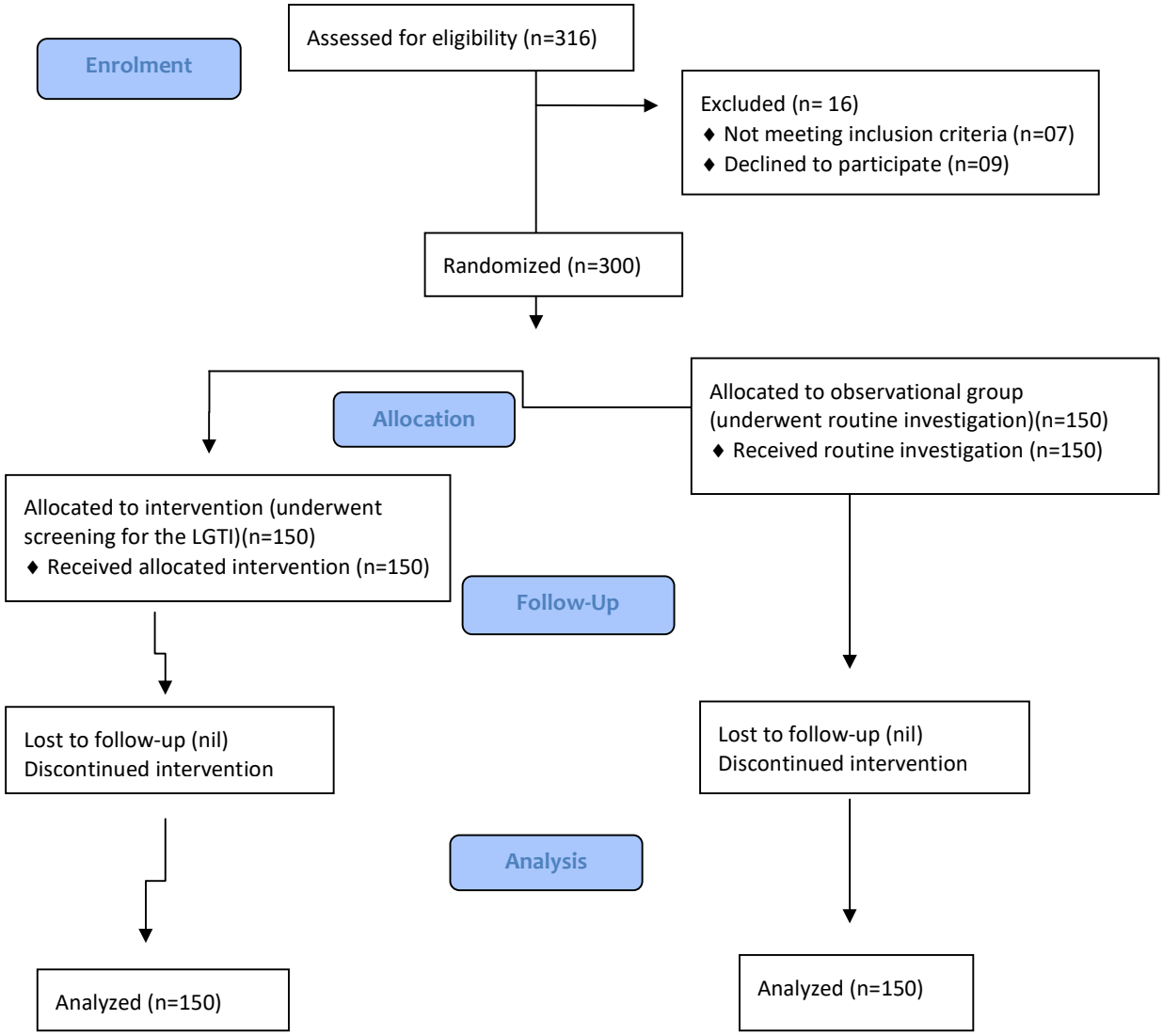

Figure 1: Participant flow algorithm

The vaginal swabs were used for -

1. Swab - 1 was used for preparing a smear and staining with Gram's stain, to look for Candida, Bacterial Vaginosis (Nugent's criteria).
2. Swab - 2 was used for KOH preparation to look for fungal elements.
3. Swab - 3 was used for inoculation on Sabouraud's dextrose agar (SDA) for Candida.
4. Swab - 4 was used for "wet mount preparation" to diagnose T. Vaginalis.
5. Swab - 5 was used for inoculation on Kupferberg media for T. Vaginalis.
6. Swab - 6 was processed for detection of T. Vaginalis by Realtime PCR, subject to availability of PCR kits.

These investigations were done to look for vulvo-vaginal candidiasis, bacterial vaginosis (BV), trichomoniasis, chlamydiasis and gonorrhoea. After investigations, all the participants in group A who tested positive for any of the above infections were treated as per the hospital protocol. All the participants in both the groups were followed up to assess and quantify the maternal and neonatal outcome at the time of delivery and after 6 weeks. The outcomes measures included the prevalence of lower genital tract infections in

asymptomatic pregnancy and comparison of fetomaternal outcomes in the screened and non-screened group.

Statistical analysis - The data presentation is done in the tables and graphs after entering into "Microsoft EXCEL spreadsheet". Qualitative variables were analysed using "Unpaired t-test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups". Qualitative variables were compared using "Chi-Square test /Fisher's exact test". The final analysis was done by "Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 21.0". For statistical significance, "p value of less than 0.05" was considered statistically significant.

Results

The mean age of group A patients were 23.92 ± 3.08 years and group B patients were 24.29 ± 2.75 years. Majority of them were primigravida (83.33% in group A and 80% in group B) with a mean body mass index (BMI, kg/m^2) of 23.45 ± 3.08 in group A and 24.05 ± 2.1in group B respectively. The baseline demographic characteristics of the two groups were comparable (p>0.05) and are shown in table 1.

Table 1: Baseline demographic characteristics

Parameters	Group A	Group B
Age (Mean ± SD) years	23.92 ± 3.08	24.29 ± 2.75
Gravida – Primi	125 (83.33%)	120 (80%)
BMI (Mean ± SD) kg/m^2	23.45 ± 3.08	24.05 ± 2.1
P > 0.05		

In our study, a lower genital tract infection was present in 30.67% patients among the screened group (figure 2). Among them, the most common type of lower genital tract infections were B. Vaginosis (65.22%) followed by Candida (21.74%), T. Vaginalis (6.52%), N. Gonorrhoea (4.35%) and Chlamydia (2.17%) (table 2).

Table 2: Distribution of type of lower genital tract infections of screened study subjects.

Type of lower genital tract infections	Frequency	Percentage
Bacterial vaginosis	30	65.22%
Vulvo vaginal candidiasis	10	21.74%
Chlamydiasis	1	2.17%
Gonorrhoea	2	4.35%
Trichomoniasis	3	6.52%
Total	46	100.00%

Compared to the unscreened group, women in the screened group had significantly more vaginal deliveries (84% vs 74.67%, p=0.046), significantly more spontaneous labour (80.67% vs 62.67%, p=0.0005); significantly less preterm labour (2.67 % vs 13.33 %, p = 0.001); significantly wound gape (0% vs 5.33%, p=0.007) and significantly less preterm births (2.67% vs 20%, p<.0001). There was no significant difference between the occurrence of PPH and puerperal sepsis between the two groups (table 3).

Table 3: Comparison of maternal outcome between screened and unscreened group

Maternal outcomes	Screened (n=150)	Unscreened (n=150)	Total	P value	Test performed
Mode of delivery					
LSCS	24 (16%)	38 (25.33%)	62 (20.67%)	0.046	Chi square test,3.985
Vaginal delivery	126 (84%)	112 (74.67%)	238 (79.33%)		
Spontaneous/Induced					
Induced	29 (19.33%)	56 (37.33%)	85 (28.33%)	0.0005	Chi square test,11.967
Spontaneous	121 (80.67%)	94 (62.67%)	215 (71.67%)		
Preterm Labour					
No	146 (97.33%)	130 (86.67%)	276 (92%)	0.001	Fisher Exact test
Yes	4 (2.67%)	20 (13.33%)	24 (8%)		
PPROM					
No	145 (96.67%)	135 (90%)	280 (93.33%)	0.021	Chi square test,5.357
Yes	5 (3.33%)	15 (10%)	20 (6.67%)		
PPH					
No	149 (99.33%)	150 (100%)	299 (99.67%)	1	Fisher Exact test
Yes	1 (0.67%)	0 (0%)	1 (0.33%)		
Chorioamnionitis					
No	150 (100%)	142 (94.67%)	292 (97.33%)	0.007	Fisher Exact test
Yes	0 (0%)	8 (5.33%)	8 (2.67%)		
Puerperal sepsis					
No	150 (100%)	149 (99.33%)	299 (99.67%)	1	Fisher Exact test
Yes	0 (0%)	1 (0.67%)	1 (0.33%)		
Wound infection/Gape					
No	150 (100%)	142 (94.67%)	292 (97.33%)	0.007	Fisher Exact test
Yes	0 (0%)	8 (5.33%)	8 (2.67%)		

Compared to the unscreened group, neonates born to screened group women had significantly more birth weight (2.71 ± 0.26 vs 2.59 ± 0.31, p=0.0005), significantly more APGAR at 5 minutes (96% vs 90%, p=0.042); and significantly less NICU admission (6% vs 13.33%, p=0.032). There was no significant difference between the APGAR 1' and occurrence of neonatal sepsis between the two groups (p>0.05) (table 4).

Discussion

We found that LGTI were present in 30.67% patients who were screened for the infections. Among other previous studies, Diadhiou et al,[9] Mayaud et al,[10] and Prabha MLS et al,[11] reported a higher prevalence of 69.6%, 68%, and 33.1%, respectively and Bánhidy F et al,[12] and Caiyan et al,[13] reported a lower prevalence of 7.1%, and 11.4–21%, respectively.

In present study, most common type of LGTI were B. Vaginosis (65.22%) followed by Candida (21.74%), T. Vaginalis (6.52%), N. Gonorrhoea (4.35%) and Chlamydia (2.17%). Among other previous studies, type of LGTI has been reported to be partial bacterial vaginosis in 19.7% patients by Poojari et al,[14] candidiasis in 13% patients by Tellapragada et al [15] and candidiasis in 11.1% by Anh PK et

al.[16] In a study by Tellapragada C et al,[15] candidiasis (13%), anaerobic vaginitis (9%), trichomoniasis (8%) and BV (2%) were the most common lower genital tract infections.

Table 4: Comparison of fetal outcome between screened and unscreened group

Fetal outcomes	Screened (n=150)	Unscreened (n=150)	Total	P value
Term/Pre-term				
Pre -Term	4 (2.67%)	30 (20%)	34 (11.33%)	<.0001
Term	146(97.33%)	120 (80%)	266(88.67%)	
Low birth Weight				
No	142 (94.67%)	108 (72%)	250 (83.33%)	<.0001
Yes	8 (5.33%)	42 (28%)	50 (16.67%)	
Birth weight (kg)				
Mean ± Stdev	2.71 ± 0.26	2.59 ± 0.31	2.65 ± 0.29	
Median (IQR)	2.7(2.6-2.9)	2.6(2.4-2.8)	2.7(2.5-2.9)	0.0005
Range	1.5-3.5	1.8-3.4	1.5-3.5	
APGAR score at 1 minute				
<7	7 (4.67%)	15 (10%)	22 (7.33%)	0.076
≥7	143 (95.33%)	135 (90%)	278 (92.67%)	
APGAR score at 5 minutes				
<7	6 (4%)	15 (10%)	21 (7%)	0.042
≥7	144 (96%)	135 (90%)	279 (93%)	
Nursery/NICU admission				
No	141 (94%)	130(86.67%)	271 (90.33%)	0.032
Yes	9 (6%)	20 (13.33%)	29 (9.67%)	
Neonatal sepsis				
No	149 (99.33%)	144 (96%)	293 (97.67%)	0.121
Yes	1 (0.67%)	6 (4%)	7 (2.33%)	

It is known that maternal genital infections are associated with adverse reproductive outcomes such as premature rupture of membranes, preterm delivery, intrauterine growth restriction, miscarriage, stillbirth, ectopic pregnancy, tubal infertility, and neonatal morbidity (lesions on the skin, conjunctivitis, pneumonia, sepsis, meningitis, encephalitis, and multi-organ dysfunction), and mortality.[17,18]

The present study agrees with the adverse feto-maternal outcomes in association with the occurrence of LGTI. Moreover, our study showed that there was a significant improvement in the maternal outcomes of the screened group as compared to the unscreened group owing to the treatment for LGTI.

Overall, compared to the unscreened group, neonates born to screened group women had significantly more birth weight (2.71 ± 0.26 vs 2.59 ± 0.31, p=0.0005), significantly more APGAR at 5 minutes (96% vs 90%, p=0.042); and significantly less NICU admission (6% vs 13.33%, p=0.032). Among other previous studies, Gupta et al,[19] witnessed higher rates of miscarriage and preterm births in relation to the abnormal vaginal flora presence. Similarly, Sangkomkamhang US et al,[20] in a case control study showed that screening significantly reduced the odds of preterm births (3% in screening group vs 5% in control group) with a reduced risk of 0.55. Another study by Swadpanich et al[3] backed these findings which showed reduced risk (relative risk 0.48) of low-birth-weight babies through screening and treatment of LGTI. Svare et al [21] found that vaginosis increased the odds of chorioamnionitis and premature births. Mijović G et al [22] further supported our findings and stated that diagnosis and management of LGTI improves the feto-maternal outcomes.

Considering the current study and various other studies, a definite link between the LGTI and adverse outcomes cannot be ignored. It may therefore be possible to say that screening pregnant women for abnormal vaginal flora and LGTI with subsequent treatment may help improve the feto-maternal outcomes.

Moreover, it needs to be said here that early screening and treatment of LGTI is potentially feasible in under-resourced settings. Although the resources and expertise needed to screen all pregnant women for asymptomatic LGTI with Gram-stained vaginal smears may not be available in all under-resourced settings, but the widely available antibiotics in developing countries may make it feasible to treat pregnant women with clinical symptoms of the lower genital tract infection.

Limitations of the study - Our study suffers from the limitation that it was conducted in a setting which caters to patients belonging primarily to the lower or middle socio-economic strata and the data thus primarily reflects the situation in this cohort. Thus, in the future, the prevalence of LGTI must be assessed in various settings to arrive at a regional prevalence rate. As present study is a single-centre hospital-based study, its results cannot be extrapolated to study the prevalence of LGTI among asymptomatic pregnant women in the general population. Lastly, the treatment protocol of the patients was not studied.

Conclusion

We report an LGTI prevalence of 30.67%. Bacterial vaginosis was the most common type of LGTI (65.22%) followed by Candida (21.74%), T. Vaginalis (6.52%), N. Gonorrhoea (4.35%) and Chlamydia (2.17%). Women after screening and treatment had significantly less preterm labor, PPROM, chorioamnionitis, wound gape, and preterm births. Neonates born to screened group women had significantly more birth weight and APGAR at 5 minutes, and significantly less NICU admission. Thus, it can be concluded that infection screening for asymptomatic pregnant women alongwith treatment programs may help better the outcomes of the mother and the baby.

Conflict of interest: None. **Disclaimer:** Nil.

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Dimple Makhijani [1], HP Anand [2]

[1] Senior resident, Department of Obstetrics and Gynecology, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India; [2] Consultant, Department of Obstetrics and Gynecology , Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India.