Research Article

Treatment efficacy and pregnancy outcomes among pregnant women with syphilis in a low-prevalence setting

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Abstract

Introduction: Vertical transmission of syphilis is a global health concern, and understanding pregnancy outcomes following treatment is essential for addressing this issue on a global or local scale.

Objective: To determine the incidence of early syphilis in pregnancy and to evaluate the effectiveness of treatment in preventing vertical transmission of syphilis.

Method: The study used secondary data. The database was developed based on the case investigation form completed for each pregnant woman diagnosed with syphilis during the period 2017-2020.

Results: There were 181 pregnant women diagnosed with syphilis. Adverse birth outcomes (ABOs) in previous pregnancies were significantly high (37.82%) in the sample (n=119). Among pregnant women with syphilis, 35.36% had early syphilis (primary, secondary and early latent) with an average incidence rate of early syphilis of 5 per 100,000 pregnant women tested per year. All pregnant women with early syphilis were treated with benzathine penicillin, and almost all partners were traced and managed. There was no significant difference in the ABOs between the early syphilis group (9.37%) and the late syphilis group (11.20%) ($p>0.05$). In the early syphilis group, two babies (3.1%) had confirmed congenital syphilis (CS) with none in the late syphilis group.

Conclusion: Adverse pregnancy outcomes during previous pregnancies were high among women diagnosed with syphilis. The study findings confirm the low incidence of early syphilis among pregnant women in Sri Lanka. It further proves that the provision of quality services minimises ABOs due to vertical transmission of syphilis.

Keywords: *congenital syphilis, pregnancy outcomes, Sri Lanka, early syphilis, partner management*

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Introduction

Syphilis is an important infection in pregnancy as it can affect the outcome of pregnancy. The more common adverse birth outcomes (ABOs) in pregnant women with syphilis include miscarriage, premature birth, stillbirth, low birth weight and congenital syphilis (CS) in newborns.[1]

The prevention of vertical transmission of the syphilis programme in Sri Lanka was started in 1952. The programme was strengthened in 2013 as the Elimination of Mother to Child Transmission (EMTCT) of HIV and syphilis programme of Sri Lanka. Sri Lanka was certified as a country that had eliminated vertical transmission of HIV and syphilis by the Global Validation Committee, World Health Organisation (WHO), Geneva, in 2019, as the country had achieved the impact and process indicator targets by the end of 2018.[2] The services were satisfactorily maintained in the years 2019 and 2020.[3]

Pregnant women with syphilis were managed at the Sexually Transmitted Disease (STD) clinics, according to the guidelines on management of syphilis in pregnancy, which were updated in 2016, including appropriate treatment, regular follow-up, partner management and management of the newborn.[4] Services for pregnant women were offered in coordination with the obstetric services and community maternal and child health (MCH) services.

The goal of treatment is to cure the syphilis infection in the pregnant woman and partner/s and to eliminate the possibility of vertical transmission. Prompt treatment of pregnant women with syphilis, at least four weeks before delivery, with intramuscular penicillin G benzathine, cures syphilis in both mother and foetus and can prevent CS.[1] It is therefore important to identify these women early in pregnancy. A circular issued by the Ministry of Health, Sri Lanka, in 2014 highlighted the importance of testing in early pregnancy.[4] A study conducted in the Suzhou district in China from 2012 to 2018 gives a high rate of vertical transmission of syphilis (17.4%) and identifies late diagnosis linked to late treatment or no treatment as a significant risk factor for CS.[5] In this study, pregnant women who received the diagnosis of syphilis at >36 weeks of gestational age were 25 times more likely to deliver an infected baby.

The risk of vertical transmission is higher in early syphilis within the first two years of infection. Response to treatment can be assessed by the fourfold decline of the Venereal Diseases Research Laboratory (VDRL) titre following treatment. This decline can be observed clearly in early syphilis when the VDRL titre is high at the time of diagnosis,.[6] In late syphilis, the VDRL titre is low and the change in the titre is not apparent even after satisfactory treatment. Partner management is an essential component in the management of pregnant women with early syphilis, as untreated infected partners can infect the treated woman.

Investigating pregnancy outcomes following treatment can help to assess the effectiveness of interventions in preventing ABOs. A longitudinal study was conducted in Brazil by Da Silva et al to evaluate the association between syphilis in pregnancy and low birth weight, small for gestational age, and preterm birth from 2011 to 2017. Among 155,214 babies exposed to syphilis during pregnancy, maternal syphilis increased the odds of low birth weight (aOR 1.88, 95% CI: 1.85–1.91), small for gestational age (aOR 1.53, 95% CI: 1.51–1.56), and preterm birth (aOR 1.35, 95% CI: 1.33–1.37).[7] A study conducted in Tanzania in 2000 shows a high stillbirth rate, low birth weight and preterm livebirths among women with high titre active syphilis with risk ratios of 18.1, 3.0 and 6.1, respectively.[8]

According to the statistics published by the Family Health Bureau for the year 2023, the stillbirth rate among the general population was 6.5 per 1000 pregnancies.[9] A national survey conducted in Sri Lanka in 1999 reported an abortion rate of 45 per 1000 women in the 15-49 age group.[10]

This study is the first in Sri Lanka to evaluate the effectiveness of treatment on syphilis associated pregnancy outcomes. The objective of the study was to determine the incidence of early syphilis among pregnant women and to evaluate the effectiveness of treating early syphilis in pregnant women on pregnancy outcomes. In addition, the study also evaluated the current practices of managing partners of pregnant women with early syphilis.

Methods

The study was conducted among all pregnant women newly diagnosed with syphilis during the period from January 2017 to December 2020. All pregnant women were offered the VDRL test at the antenatal clinic. VDRL reactive samples were further tested using Treponema Pallidum Particle agglutination Assay (TPPA) () for confirmation. Pregnant women who were diagnosed previously (before the current pregnancy) were excluded from the sample. One hundred and eighty one (181) pregnant women were newly diagnosed with syphilis at government STD clinics during this period.

When a pregnant woman is diagnosed with syphilis, a case investigation form is completed by the consultant or medical officer in charge of the STD clinic and sent to the EMTCT unit of the National STD AIDS Control Programme (NSACP). This format includes basic socio-demographic characteristics, details about the current pregnancy, staging of syphilis, treatment, VDRL results at diagnosis and at delivery, partner management and details regarding management of the newborn. Staging of pregnant women with syphilis was done based on the history, medical examination findings, VDRL titre and partners' details.[11]

Details on the diagnosis, staging, treatment regimen and response to treatment were further verified through the case records maintained at the STD clinics. Baby's details were collected, including the VDRL test results at the time of delivery and at 6 months, diagnosis, treatment and follow-up assessment. CS diagnosis was made according to the WHO Global case definition.[1]

Data were analysed using the SPSS package.

Results

During the period, 1,345,692 pregnant women were tested for syphilis, and 181 were diagnosed as having syphilis. In the sample, none were HIV positive, and one woman was previously diagnosed as having Hepatitis B infection.

As shown in Table 1, more than half of the diagnosed were in the 20–29-year age group (54.7%), followed by the 30-39-year age group (34.25%) with 7.73% in the <19-year age group. Three-fourths of the sample were Sinhalese (73.48%), followed by Tamils (21.55%) and Muslims (4.97%). One third of pregnant women were primigravidae (34.25%), and those who had 4 or more

children were 13.26%. More than half of the samples (51.93%) were tested in the first trimester of pregnancy. However, 4.42% were tested only in the third trimester. All diagnosed pregnant women received treatment either with penicillin (n=170; 93.92%) or erythromycin (n=11; 6.07%).

Table 1: Pregnant women with syphilis by sociodemographic, clinical, laboratory and pregnancy-related factors (n=181)

Variable	Number	Percentage
Age group (years)		
15-19	14	7.73
20-29	99	54.70
30-39	62	34.25
>=40	6	3.31
Ethnicity		
Muslim	9	4.97
Tamil	39	21.55
Sinhala	133	73.48
Parity		
P1	62	34.25
P2	49	27.07
P3	46	25.41
P4+	24	13.26
Trimester at 1st VDRL		
1st Trimester	94	51.93
2nd Trimester	74	40.88
3rd Trimester	8	4.42
unknown	5	2.76
Stage of syphilis		
early syphilis	64	35.36
late latent syphilis	117	64.64
VDRL titre at diagnosis		
NR	14	7.73
Weakly reactive	14	7.73
R1:1	6	3.31
R1:2	45	24.86
R1:4	27	14.92
R1:8	20	11.05
R1:16	27	14.92
R1:32	18	9.94
R1:64	4	2.21
R1:128	4	2.21
Not available*	2	1.1
*Tested after delivery.		

Table 2: ABOs among women who experienced previous pregnancies

Adverse Pregnancy Outcomes	Number of Pregnant women	Percentage of pregnant women%
One Abortion T1*	18	40.00
Two abortions T1	7	15.56
One abortion T1+ perinatal death	1	2.22
One abortion T1+ stillbirth	3	6.67
Four abortions T1+ stillbirth	1	2.22
One abortion T2**	4	8.89
One still birth/stillbirth	3	6.67
One perinatal death	2	4.44
Two stillbirths	1	2.22
Three abortionsT1+ perinatal death	1	2.22
One abortion T2+one Abortion T1	1	2.22
Infant death at 6/12	1	2.22
Ectopic	1	2.22
Death at 3 years+ one abortion T2	1	2.22
Total	**45**	**100**

*T1 - pregnancy trimester, first
**T2 - pregnancy trimester, second

Among women newly diagnosed with syphilis, 119 had previous pregnancies. Of them, 45 (37.82%) experienced one or more ABOs. Among multigravidas with a past history of ABOs, two-thirds (66.66%) were in the late syphilis stage. None of these women were previously diagnosed as having syphilis. As shown in Table 2, ABOs included abortions, stillbirths and perinatal deaths. Eight pregnant women had stillbirths in a previous pregnancy (17.8%), and three women experienced perinatal deaths (6.66%).

Among pregnant women with syphilis, 64 (35.36%) were diagnosed as having early syphilis. (Table 1) This included two pregnant women with primary syphilis and secondary syphilis each, and 62 pregnant women with early latent syphilis. As shown in Table 3, early syphilis incidence per 100,000 pregnant women tested ranged from 3.18 in 2018 to 5.91 in 2017. The mean incidence rate for early syphilis was 5 per 100,000.

Table 3: Early syphilis incidence rate (2017-2020)				
Year	**Total no tested**	**No of pregnant women with early syphilis**	**Rate per 100,000**	**95% confidence intervals**
2017	338,662	20	**5.91**	3.54 – 8.56
2018	345,657	11	**3.18**	1.45 – 5.21
2019	334,475	16	**4.78**	2.69 – 7.18
2020	323,521	17	**5.25**	2.78 – 8.04

Table 4. Early syphilis cases by sociodemographic, clinical, laboratory and pregnancy-related factors (n=64)		
Variable	**Number**	**Percentage**
Age group		
15-19	5	7.81
20-29	40	62.50
30-39	18	28.13
>=40	1	1.56
Ethnicity		
Sinhalese	47	73.44
Tamil	14	21.88
Muslim	3	4.69
Parity		
P1	24	37.50
P2	18	28.13
P3	16	25.00
p4+	6	9.38
Trimester at 1st VDRL		
1st Trimester	33	51.56
2nd Trimester	24	37.50
3rd Trimester	7	10.94
Unknown	0	0.00
VDRL titre at diagnosis		
NR	1	1.56
Weakly reactive	1	1.56
R1:1	0	0.00
R1:2	1	1.56
R1:4	3	4.69
R1:8	8	12.50
R1:16	25	39.06
R1:32	18	28.13
R1:64	3	4.69
R1:128	4	6.25
VDRL titre at delivery		
NR	13	20.31
Weakly reactive	3	4.69
R1:1	4	6.25
R1:2	12	18.75
R1:4	15	23.44
R1:8	7	10.94
R1:16	3	4.69
R1:32	0	0.00
R1:64	1	1.56
R1:128	0	0.00

Table 4 presents the socio-demographic, clinical and laboratory parameters of pregnant women diagnosed as having early syphilis. Among pregnant women with early syphilis, more than 90% were in the 20-39 age group, and one third were primigravidae. Three-fourths were Sinhala, followed by Tamil (21.88%). Close to 50% were diagnosed in the pregnancy trimester, first. However, 11% of pregnant women with early syphilis were diagnosed in the third trimester.

All pregnant women with early syphilis received one or more weekly Penicillin G benzathine 2.4 mu IM. Seven pregnant women (10.94%) received treatment during the third trimester of pregnancy. All responded with a decline in VDRL titer, except two. One who was diagnosed at POA 27 weeks with VDRL 1:128 and had a premature birth two weeks later at 29 weeks POA. One pregnant woman had VDRL R1:16 throughout the pregnancy.

All partners of pregnant women with early syphilis were offered screening for syphilis. All 64 partners except one had case records maintained at the respective clinics. Three-fourths of the partners were diagnosed as having syphilis based on the VDRL and TPPA results. All partners who were diagnosed with syphilis received treatment. One partner came for screening after delivery. According to the guidelines, all partners of pregnant women with early syphilis should to be treated appropriately irrespective of the serology results (epidemiological treatment).[4] However, among 15 with negative results, only three received treatment (20.00%).

As shown in Table 5, 90.63% in the early syphilis group and 88.79% in the late syphilis group had live births. There were 6 (9.37%) ABOs in the early syphilis group including one perinatal death and one premature birth. In the late syphilis group 13 experienced (11.21%) ABOs including 11 abortions. There was no significant difference in pregnancy outcomes between pregnant women with early syphilis and late syphilis. Among babies born to women with early syphilis, 20.31% had a birth weight <2500g, while among the late syphilis group, it was 12.82%. However, this difference was not statistically significant (p>0.05).

Table 5. Pregnancy outcome by stage of syphilis

Pregnancy outcome	**Early syphilis**	**Percentage**	**Late syphilis***	**Percentage**	**X^{2} value**
Live birth	58	90.63	103	88.79	
ABOs	6	9.37	13	11.21	
Total	**64**	**100**	**116**	**100**	0.146 P=0.95
Birth weight	**Early syphilis**	**%**	**late syphilis**	**%**	**X^{2} value**
<2500g	13	20.31%	15	12.82%	
2500g+	41	64.06%	76	64.96%	
NA	10	15.63%	26	22.22%	
Grand Total	**64**	**100.00%**	**117**	**100.00%**	2.411 P=0.10

*Pregnancy outcome was not available for one pregnant woman.

CS was diagnosed in two babies (3.45%) born to pregnant women with early syphilis and none in the late syphilis group. All babies of mothers with syphilis received a single dose of Penicillin G benzathine as prophylaxis and babies suspected of having CS were treated with crystalline penicillin for 10 days. Six months after delivery, the babies were screened with VDRL tests, and all tested had nonreactive results, excluding syphilis in the infants.

All pregnant women with syphilis (early and late) were treated with benzathine penicillin or erythromycin.

Discussion

Sri Lanka was certified as a country that had eliminated vertical transmission of syphilis in 2019 by the WHO Global Validation Committee. Elimination of vertical transmission of syphilis services was established countrywide by the end of 2016.[2] This study was the first in Sri Lanka to evaluate the effectiveness of syphilis treatment on pregnancy outcomes. In this study, secondary data were used, which were reported from district STD clinics countrywide. Pregnant women newly diagnosed with syphilis during 2017-2020 were included in the sample.

Among 1,345,692 pregnant women tested during the period, 181 pregnant women were newly diagnosed as having syphilis. This included primary, secondary, early latent and late latent syphilis. The risk of vertical transmission of syphilis is highest in the early syphilis stage, which includes primary, secondary and early latent syphilis. Incidence of early syphilis in pregnancy in the country remains low, with an average of 5 per 100,000 pregnant women tested. Among the newly diagnosed 181, close to one-third (35.36%) were diagnosed as having early syphilis. Response to treatment can be assessed by a four-fold decline in the VDRL titre, which is typically observed when the VDRL titre at the time of diagnosis is high. Sixty-four pregnant women with

early syphilis were further analysed to assess their response to treatment. All 64 received a single dose of penicillin G benzathine injection. Except for one woman, all had treatment 30 days prior to delivery. As shown in Table 4, the decline in VDRL titre is evident from the diagnosis to a level close to delivery.

Early diagnosis, appropriate treatment, partner management and follow-up of the pregnant woman and the newborn are essential components of the EMTCT of syphilis programme. According to WHO guidelines, if the woman can be treated within 28 days before delivery, MTCT of syphilis can be eliminated.[1] Close to 11% of pregnant women with early syphilis were diagnosed in the third trimester. This affects timely treatment. In this sample, the latest treatment was given at 32 weeks of POA. Delayed diagnosis led to one CS case, as the pregnant woman was screened at 27 weeks. She had a premature birth at 29 weeks, only two weeks after completing treatment. Baby had high VDRL titre (R 1:256) at the time of delivery and was treated for CS with crystalline penicillin for 10 days. Similar findings are presented in a study conducted in the Suzhou district in China from 2012 to 2018, with pregnant women who received the diagnosis of syphilis at >36 weeks of gestational age being 25 times more likely to deliver an infected baby.[5]

Partner management is another important pillar in the comprehensive case management of early syphilis. If the partner is having untreated infectious syphilis, it is possible to reinfect the pregnant woman. Partner screening was satisfactory, with all except one undergoing screening. The pregnant woman of the unscreened partner had VDRL titre R1:16 throughout the pregnancy, and the baby also had a high VDRL titre at the time of delivery. The baby was diagnosed with CS and treated. Among partners of pregnant women with early syphilis, 75% were diagnosed as syphilis and received appropriate treatment. Of the partners in whom syphilis was excluded, only 20% received epidemiological treatment. This is a concern as they may have been in the very early stage of infection at the time of screening, with negative treponemal and non-treponemal test results. According to the recommendations of the country guidelines, partners of pregnant women with early syphilis need treatment irrespective of the diagnosis.[4]

Except for the two babies diagnosed with CS, all babies had VDRL non-reactive or lower titers than the mother at birth, showing the response to treatment.

According to the available literature, over half of the pregnancies among women with untreated early syphilis result in stillbirth, perinatal death, a premature birth, low birth weight, or serious neonatal infection.[1] The ideal methodology to assess the response to treatment is by comparing the pregnancy outcome between treated and untreated pregnant women with syphilis. As this is not ethically feasible, as a proxy, we assessed the ABOs of previous pregnancies in the sample.

Among 181 pregnant women newly diagnosed with syphilis, 119 (65.74%) experienced previous pregnancies. In this group, close to 40% experienced ABOs during their previous pregnancies. This is much higher than the estimated foetal wastage among pregnant women in the country.[9] Among multigravida with a history of ABOs, 60% experienced more than one event, indicating the possible relationship of foetal wastage to syphilis diagnosis. None of these women were previously diagnosed as having syphilis, and two thirds had late syphilis at the time of diagnosis. As this may have been the first opportunity for them to be diagnosed, the influence of untreated syphilis on pregnancy outcomes in previous pregnancies resulting in ABOs cannot be ignored.

However, we cannot link all these ABOs solely to syphilis, as we could not gather data related to other medical problems during previous pregnancies.

Similar results are reported in a study conducted in Suzhou, China. Among pregnant women, high rates of abortions and stillbirths were noted in the untreated group.[5] A study conducted in Brazil by Da Silva et al in 2017 shows a strong association between gestational syphilis and adverse birth outcomes, with increased odds observed among women with higher VDRL titers, lack of treatment, and fewer prenatal appointments. These results highlight the need for adequate screening and treatment for gestational syphilis during pregnancy to mitigate the risk of adverse birth outcomes.[7]

According to the literature, the risk of vertical transmission in early syphilis is close to 50% and a much lower risk in late syphilis.[1] We therefore compared the outcomes of the current pregnancy between appropriately managed pregnant women with early syphilis and late syphilis. During the current pregnancy, 9.37% in the early syphilis group, and 11.21% in the late syphilis group experienced ABOs. ,. There was one perinatal death in the early syphilis group due to pregnancy-induced hypertension. This pregnant woman was adequately treated and had a clear decline of the VDRL titre close to delivery, excluding the possibility of CS. Among babies exposed to early syphilis, 20.31% had a birth weight <2500 g, while this percentage was much lower (12.82%) among the babies born to women with late syphilis. However, records of the birth weight data were not available in 19.89%, which may have affected the results. There was no significant difference in pregnancy outcomes or birth weight between the early syphilis and late syphilis groups following appropriate treatment ($p>0.05$). This demonstrates the effect of early diagnosis and treatment of early syphilis in improving pregnancy outcomes.

There were some limitations. We could not assess the relationship with some sociodemographic factors such as education, occupation, income level and health issues in previous pregnancies as we used secondary data. We also could not compare pregnancy outcomes between healthy women and women with syphilis.

Conclusion

The findings in this study confirms the low prevalence of syphilis among pregnant women in Sri Lanka. High foetal wastage during previous pregnancies observed among pregnant women with syphilis emphasises the possible effects of syphilis infection on pregnancy outcome even in low-prevalence settings. It further demonstrates the effectiveness of providing high-quality services for the elimination of MTCT of syphilis and for improvement in pregnancy outcomes.

Declarations

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Conflicts of interest: The authors of this manuscript declare that they have no conflicts of interest that could influence the objectivity or integrity of the research presented in this paper.

Ethics statement: Ethical clearance was obtained from the Ethical Review Committee of the National Hospital of Sri Lanka, Colombo, Sri Lanka (Ref AAJ/ETH/COM/2024/FEB). Permission to conduct the study was obtained from the Director, National STD/ AIDS Control Programme, Sri Lanka. The Case Investigation form did not include personal identification details to maintain anonymity and confidentiality. The master number was used for verification purposes.

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Author contributions:

LR: Conceptualisation and development of the manuscript.; NDVJ : Maintained the quality of data and improvements.
AKAM: Assisted in statistics, data gathering and analysis. JPE: Contributed to laboratory work.
DRP: Gathered data and maintained a line listing.

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