Gender differences in treatment outcomes among 15–49 year olds with smear-positive pulmonary tuberculosis in Kenya


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OBJECTIVE: To determine gender differences in treatment outcomes among 15–49 year olds with smear-positive pulmonary tuberculosis (PTB) and factors associated with poor outcomes in Kenya.

DESIGN: Retrospective descriptive cohort.

RESULTS: Of 16,056 subjects analysed, 38% were female and 62% male. Females had a higher risk of poor treatment outcome than males (12% vs. 10%, P < 0.001; adjusted OR 1.29, 95%CI 1.16–1.44, P < 0.001). In the first multivariate model, restricting the analysis to human immunodeficiency virus (HIV) positive patients and adjusting for risk factors and clustering, females had a non-significantly lower risk of poor outcome (OR 0.99, 95%CI 0.86–1.13, P = 0.844). In the model restricted to HIV-negative patients, a non-significantly lower risk was found (OR 0.89, 95%CI 0.73–1.09, P = 0.267). In the second model, restricting analysis to patients on antiretroviral therapy (ART) and adjusting for risk factors and clustering, females had a non-significantly lower risk of poor PTB treatment outcomes (OR 0.98, 95%CI 0.84–1.14, P = 0.792). In the model restricted to HIV-positive patients not on ART, a non-significantly higher risk was found (OR 1.15, 95%CI 0.79–1.67, P = 0.461).

CONCLUSION: Females of reproductive age are likely to have poorer treatment outcomes than males. Among females, not commencing ART during anti-tuberculosis treatment seemed to be associated with poor outcomes.

KEY WORDS: HIV; women; reproductive age

GLOBALLY, TWICE as many tuberculosis (TB) cases are notified among men than women.¹ Studies on gender differences in incidence have examined socioeconomic status, health care access, stigma, societal norms and biological variability. However, the impact of gender on anti-tuberculosis treatment outcomes remains unclear. While four studies have reported a higher likelihood of poor TB treatment outcome among males than females,¹⁻⁴ at least one study demonstrated higher mortality due to TB among women of reproductive age (15–49 years) than among males matched for age. Human immunodeficiency virus (HIV) infection is another factor affecting TB treatment outcomes, and HIV prevalence among young adults of reproductive age is high.⁵,⁶

Of the 8.6 million TB cases reported to the World Health Organization (WHO), more deaths occur in men, who form the bulk of the cases. An examination of the data from the African region, however, shows a reversal in the global trend, with more TB-HIV coinfected deaths among women than men.⁷ In 2012 and 2013, Kenya notified a total of 98,400 and 89,705 TB cases, respectively, with a male-to-female ratio of 1.4 to 1. Of this cohort, 94% reported having knowledge of their HIV status, 39% were TB-HIV coinfected and 74% of HIV-positives were on antiretroviral therapy (ART).⁷ TB treatment success in Kenya was reported to be on average 90%.⁸

In 2007, Kenya’s Division of Leprosy, Tuberculosis and Lung Diseases (DLTLD) rolled out a country­wide electronic data capture system to support TB surveillance and cohort review. This system, known as the Treatment Information from Basic Unit (TIBU), which means treat in Kiswahili, is based on the WHO standard TB register. Individual patient data are entered at facility level into TIBU by zonal TB control officers and relayed to a national Cloud database in real time. TIBU has security encryptions,
and was rated 90% in aiding monitoring and evaluation, support supervision and data quality in 2012. Using this database, in 2013 we carried out an audit to determine whether there are gender differences in smear-positive pulmonary TB (PTB) treatment outcomes in adults of reproductive age (15–49 years) and associated risk factors in poor PTB treatment outcomes.

**METHODS**

**Study design**

This was a retrospective descriptive cohort analysis based on routinely collected programme data in the TIBU database.

**Setting**

Situated in East Africa with an estimated population of 43 million people, and divided into 47 counties, Kenya is one of the world’s 22 high TB burden countries. In 2012, national HIV prevalence among adults aged 15–64 years was 5.6%, with higher prevalence among women (6.9%) than men (4.4%). Adult HIV prevalence varies according to county, with counties in the Nyanza Province reporting the highest prevalence, of up to 15.1%.

**Management of TB patients**

The DLTLD’s anti-tuberculosis drug regimen for adult new and retreatment TB patients is the same for females and males and is based on WHO recommendations. The DLTLD promotes a patient-centred approach to facilitate adherence to treatment, including directly observed treatment (DOT). DLTLD policy recommends that the prescribing provider identify an appropriate treatment supporter—health care worker, family member or community volunteer—acceptable to the patient. Documentation of DOT is provided on the patient’s treatment card, which allows daily capture of DOT visits during the intensive phase and dates of drug delivery during the continuation phase. TIBU captures DOT status in a yes/no format (‘yes’, assigned to DOT or ‘no’, not assigned to DOT), but does not capture further individual adherence data. Community health care workers linked to the health facility through the community health strategy follow up patients who default from treatment.

TB treatment outcomes are classified by the DLTLD according to WHO-recommended categories as cured (smear-negative at end of 6 months), treatment completed (no smear performed), failure (smear- or culture-positive at month 5 or later during treatment), dead, lost to follow-up and not evaluated. Treatment success as defined by the WHO is cured and treatment completed.

**HIV diagnosis and management**

HIV testing uptake among adults in the general population in Kenya is approximately 70%. HIV testing is offered for all TB patients as an entry point to comprehensive HIV care in the context of counselling, consent and confidentiality. At the time of this cohort, Kenya’s national policy recommended ART treatment for all TB-HIV co-infected patients, regardless of CD4 cell count. Cotrimoxazole prophylaxis is provided universally for all HIV-positive TB patients.

**Integration of TB and HIV services**

All TB services in Kenya are decentralised to the lowest level of the health system, the community. Comprehensive HIV services are decentralised to hospital level and to a limited extent to the health centre level, mainly for HIV testing. This poses a challenge for TB-HIV co-infected patients to start on ART in health centres that do not offer comprehensive HIV services.

**Study population**

The study population comprised female and male smear-positive patients of reproductive age (15–49 years) in the DLTLD TIBU database who had completed PTB treatment in 2013. All patients with a definitive treatment outcome, i.e., cured, failure or dead, i.e., confirmed by smear microscopy or death, were included in the study. Patients who had completed treatment, were lost to follow-up or were not evaluated were excluded, as the outcomes were not confirmed by a smear result. Culture-proven multidrug-resistant TB (MDR-TB) was also excluded, as MDR-TB has a different treatment protocol and database. Extra-pulmonary TB, relapsed extra-pulmonary TB and relapsed smear-negative cases were also excluded.

**Variables**

The outcome variable was PTB treatment outcome. Two outcome variables for PTB treatment were created: cured—considered a favourable PTB outcome, and failure or dead—considered a poor TB treatment outcome.

Exposure variables were sex, age, body mass index (BMI), DOT (stratified by type of supporter), type of patient (new, smear-positive relapse, return after default, failure and transfer in from other facilities), county of residence, HIV status and ART.

**Data management and analysis**

Data were extracted from the TIBU database, cleaned and exported to Stata v11 (StataCorp, College Station, TX, USA) for analysis. We present proportions stratified by PTB treatment outcome for categorical exposures and mean (stan-
standard deviation (SD)) for continuous variables. The \( \chi^2 \) test for association was used for categorical data, and Student’s \( t \)-test was used for comparison of means. Univariate logistic regression was performed to determine the association between PTB treatment outcomes and the various exposure variables. A multivariate analysis to identify significant predictors of poor PTB treatment outcome in females compared to males was developed. A step-wise forward selection method was used. Hosmer-Lemeshow criteria were used with exposure factors, with a \( P \) value of 0.2 being taken forward into the multivariate analysis, stratified by HIV status and ART treatment. A likelihood ratio test was used to determine a model that best fit the data, and a cut-off of \( P < 0.05 \) was used to define significance.

While our aim was to provide results indicative of overall PTB treatment outcomes, we noted variations across counties. To demonstrate this, we used funnel plots to indicate the variability of poor PTB treatment outcome across the 47 counties and the corresponding 95% and 99% ranges. Similar multivariate models for HIV status (positive and negative) and ART (with and without) were thus developed with and without clustering using mixed-effects modelling approaches, and the intra-class correlation values reported. For logistic regression, the odds ratios (ORs) and corresponding \( P \) values and 95% confidence intervals (CIs) are reported.

**Ethical considerations**

As this was an audit of routinely collected programme data, ethics approval for the study was not required by the Kenya Ministry of Health. Counties and patients were de-identified before analysis. Counties were assigned random numbers (1–47) before analysis. No additional data other than routinely collected data were collected or analysed.

**RESULTS**

Of 16 056 patients who met the eligibility criteria and were included in the analysis, 6109 (38%) were female and 9947 (62%) male. Female cohort participants were younger than males, with a mean age of 29.1 (SD 8.2) vs. 31.3 (SD 8.4) years (\( P < 0.001 \)). A higher mean BMI was recorded in females than in males (18.1, SD 5 vs. 17.6, SD 4; \( P < 0.001 \)). More females were HIV-positive (2478/6109, 41% vs. 2520/9947, 25%; \( P < 0.001 \)) and on ART (2214/6109, 36% vs. 2237/9947, 23%; \( P < 0.001 \)). For both females and males, household members were more likely to offer DOT. Overall, more females than males had poor PTB treatment outcomes (725/6109, 12% vs. 1013/9947, 10%; \( P < 0.001 \); Table 1).

<table>
<thead>
<tr>
<th></th>
<th>Female (n = 6109)</th>
<th>Male (n = 9947)</th>
<th>( P ) value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean ± SD*</td>
<td>29.1 ± 8.2</td>
<td>31.3 ± 8.4</td>
<td>&lt;0.001†</td>
</tr>
<tr>
<td>Body mass index, kg/m², mean ± SD</td>
<td>18.1 ± 5</td>
<td>17.6 ± 4</td>
<td>&lt;0.001†</td>
</tr>
<tr>
<td>Directly observed treatment by:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Household member</td>
<td>5384 (88)</td>
<td>8397 (84)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Health care worker</td>
<td>621 (10)</td>
<td>1350 (14)</td>
<td></td>
</tr>
<tr>
<td>Community volunteer</td>
<td>101 (2)</td>
<td>193 (2)</td>
<td></td>
</tr>
<tr>
<td>Not recorded</td>
<td>3 (0)</td>
<td>7 (0)</td>
<td></td>
</tr>
<tr>
<td>Type of patient</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New</td>
<td>5613 (92)</td>
<td>8853 (89)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Smear-positive relapse</td>
<td>344 (6)</td>
<td>769 (8)</td>
<td></td>
</tr>
<tr>
<td>Resumed after default</td>
<td>44 (1)</td>
<td>163 (2)</td>
<td></td>
</tr>
<tr>
<td>Failure</td>
<td>31 (1)</td>
<td>57 (1)</td>
<td></td>
</tr>
<tr>
<td>Transferred in from other facilities</td>
<td>77 (1)</td>
<td>105 (1)</td>
<td></td>
</tr>
<tr>
<td>HIV-positive</td>
<td>2478 (41)</td>
<td>2520 (25)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>On ART</td>
<td>2214 (36)</td>
<td>2237 (23)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Poor PTB treatment outcome</td>
<td>725 (12)</td>
<td>1013 (10)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* \( \chi^2 \) test.  
† \( t \)-test.  
PTB = pulmonary tuberculosis; SD = standard deviation; HIV = human immunodeficiency virus; ART = antiretroviral therapy.
and adjusting for risk factors but not clustering (Table 2), females had a non-significant low risk of poor PTB treatment outcomes (OR 1.00, 95% CI 0.86–1.14, \( P = 0.944 \)); when clustering was adjusted for, females had a non-significant lower risk of poor PTB treatment outcomes (intraclass correlation [ICC] 0.043, OR 0.99, 95% CI 0.86–1.13, \( P = 0.844 \)). In the same model, restricting the analysis to HIV-negative patients, including those not tested for HIV and adjusting for risk factors but not clustering, females also had a non-significant lower risk of poor PTB treatment outcomes (OR 0.91, 95% CI 0.75–1.10, \( P = 0.329 \)); similar findings were found when clustering was adjusted for (ICC 0.020, OR 0.89, 95% CI 0.73–1.08, \( P = 0.246 \)). When the analysis was restricted to only HIV-negative patients, the non-significant risk of poor PTB treatment outcomes was even lower (ICC 0.022, OR 0.89, 95% CI 0.73–1.09, \( P = 0.267 \)).

Restricting the analysis to patients on ART and adjusting for risk factors but not clustering (Table 3), females had a non-significant lower risk of poor PTB treatment outcomes (OR 0.99, 95% CI 0.85–1.14, \( P = 0.853 \)); similar findings were obtained when clustering was adjusted for (ICC 0.041, OR 0.98, 95% CI 0.84–1.14, \( P = 0.792 \)). In the same model, when the analysis was restricted to patients not on ART including those who were HIV-negative, and adjusted for risk factors but not clustering, females had a non-significantly higher risk of poor PTB treatment outcomes (OR 1.16, 95% CI 0.99–1.36, \( P = 0.070 \)); similar findings were found when clustering was adjusted for (ICC 0.048, OR 1.10, 95% CI 0.94–1.30, \( P = 0.222 \)). When the analysis was restricted to only HIV-positive patients not on ART, although non-significant, the risk increased (ICC 0.178, OR 1.15, 95% CI 0.79–1.67, \( P = 0.461 \)). When the analysis was restricted to only HIV-negative patients, females had a non-significantly lower risk of a poor PTB treatment outcome (ICC 0.021, OR 0.89, 95% CI 0.73–1.09, \( P = 0.021 \)).

**DISCUSSION**

Based on our findings, women of reproductive age (15–49 years) in Kenya have a greater risk of having a poor PTB treatment outcome than their male counterparts. This appears to be driven by HIV-positive patients who were not started on ART while on anti-tuberculosis treatment. These findings are supported by our analysis, which showed that HIV-positive female patients on ART and those who were HIV-negative had a low risk of poor PTB treatment outcomes, as did HIV-negative female patients and those who had not been tested for HIV. County clustering variability contributed to these findings to a lesser extent (2–5%). Although these results are statistically non-significant, they have important clinical and policy implications.

That women in our setting have a higher likelihood of poor PTB treatment outcomes than men can be explained to some extent by socio-economic differences and cultural inequalities, which are observed

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**Table 2** Multivariate analysis for the odds of poor PTB treatment outcomes in females when stratified by HIV status and adjusted for clustering among smear-positive patients aged 15–49 years who had completed PTB treatment, Kenya, 2013*

<table>
<thead>
<tr>
<th></th>
<th>OR (95%CI)</th>
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<tbody>
<tr>
<td>Crude OR</td>
<td>1.19 (1.07–1.31)</td>
<td>0.001</td>
</tr>
<tr>
<td>Adjusted for risk factors and clustering</td>
<td>1.29 (1.16–1.44)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Adjusted for risk factors but NOT clustering and restricted to HIV-positive patients</td>
<td>1.00 (0.86–1.14)</td>
<td>0.944</td>
</tr>
<tr>
<td>Adjusted for risk factors and clustering and restricted to HIV-positive patients†</td>
<td>0.99 (0.86–1.13)</td>
<td>0.844</td>
</tr>
<tr>
<td>Adjusted for risk factors but NOT clustering and restricted to HIV-negative patients and those not tested for HIV</td>
<td>0.91 (0.75–1.10)</td>
<td>0.329</td>
</tr>
<tr>
<td>Adjusted for risk factors and clustering and restricted to HIV-negative patients and those not tested for HIV²</td>
<td>0.89 (0.73–1.08)</td>
<td>0.246</td>
</tr>
<tr>
<td>Adjusted for risk factors and clustering and restricted to HIV-negative patients²</td>
<td>0.89 (0.73–1.09)</td>
<td>0.267</td>
</tr>
</tbody>
</table>

* Multivariate model adjusted for age, body mass index, directly observed therapy and type of patient.

† ICC = 0.043.

‡ ICC = 0.020.

§ ICC = 0.022.

PTB = pulmonary tuberculosis; HIV = human immunodeficiency virus; OR = odds ratio; CI = confidence interval; ICC = intraclass correlation.
Table 3  Multivariate analysis for the odds of poor PTB treatment outcomes in females when stratified by ART and adjusted for clustering among smear-positive patients aged 15–49 years who had completed PTB treatment, Kenya, 2013*

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<td>1.29 (1.16–1.44)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Adjusted for risk factors but NOT clustering and restricted to patients on ART</td>
<td>0.99 (0.85–1.14)</td>
<td>0.853</td>
</tr>
<tr>
<td>Adjusted for risk factors and clustering and restricted to patients on ART†</td>
<td>0.98 (0.84–1.14)</td>
<td>0.792</td>
</tr>
<tr>
<td>Adjusted for risk factors but NOT clustering and restricted to patients not on ART, including HIV-negative patients</td>
<td>1.16 (0.99–1.36)</td>
<td>0.070</td>
</tr>
<tr>
<td>Adjusted for risk factors and clustering and restricted to patients not on ART, including HIV-negative patients†</td>
<td>1.10 (0.94–1.30)</td>
<td>0.222</td>
</tr>
<tr>
<td>Adjusted for risk factors and clustering and restricted to HIV-positive patients not on ART§</td>
<td>1.15 (0.79–1.67)</td>
<td>0.461</td>
</tr>
<tr>
<td>Adjusted for risk factors and clustering and restricted to HIV-negative patients¶</td>
<td>0.89 (0.73–1.09)</td>
<td>0.267</td>
</tr>
</tbody>
</table>

* Multivariate model adjusted for age, body mass index, directly observed therapy and type of patient.
† ICC = 0.048.
‡ ICC = 0.178.
§ ICC = 0.21.
¶ PTB = pulmonary tuberculosis; ART = antiretroviral therapy; OR = odds ratio; CI = confidence interval; HIV = human immunodeficiency virus; ICC = intraclass correlation.

more among women in resource-constrained settings, as reported in previous studies.1,3 Our finding that Kenyan women have a higher risk of poor PTB treatment outcomes than men differs from studies in other regions of the world, such as Taiwan, Mexico, India and Bangladesh, however. We postulate that this difference may have been due to the younger age and higher female HIV prevalence in the cohort.1,3,13 The Bangladesh study also acknowledged male-female disparities, leading to excessively lower numbers of case finding in females and low numbers of women seeking out-patient care for respiratory complaints. In the same study, women had higher cure rates than men.14 In all of these studies, women had lower case notification rates than men, and unlike our study, women had better TB treatment outcomes.

Early ART initiation within 2–4 weeks of anti-tuberculosis treatment in TB-HIV co-infected patients with PTB has been associated with reduced mortality.15,16 The WHO recommends ART initiation within 2–8 weeks of anti-tuberculosis treatment, regardless of CD4 count.17 ART reduces mortality by 64–95%.18 This benefit is greater among patients with advanced immunosuppression, i.e., those with CD4 cell counts ≤50 cells/mm3.15 Recent evidence indicates that TB occurs at a much lower CD4 cell count (<200 cells/mm3) than earlier supposed.6 We speculate that the HIV-positive patients not on ART in our cohort possibly had low CD4 cell counts, hence the poor PTB treatment outcomes. Another possible factor that could contribute to delay in early ART initiation after anti-tuberculosis treatment is the trade-off with the risk of immune reconstitution inflammatory syndrome (IRIS), although overall risk has been found to be low.15 Other plausible causes of delay are the degree of integration of HIV and TB services18 and unknown HIV status.16 All of these factors need to be evaluated in future studies in the Kenyan context.

There are several limitations to this study. The results point to a gender difference but do not indicate whether this difference is biological or socio-economic. This is largely because of the limitations of the TB register, which has only a limited number of variables, and the retrospective nature of the study design. County-specific factors to explain the variability observed were not available in the database. Despite these limitations, the study is important because of its programmatic, clinical and policy implications. The Kenyan TB programme needs to explore ways to reduce gender differences and ensure ART initiation during anti-tuberculosis treatment.

In conclusion, females of reproductive age are more likely to have poor PTB treatment outcomes than males. HIV-positive females who are not started on ART during anti-tuberculosis treatment seem to be greater risk of poor outcomes.

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The authors are grateful to the Division of Leprosy, Tuberculosis and Lung Diseases Programme, Nairobi, Kenya, and to the patients whose records we reviewed.

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Conflicts of interest: none declared.

References


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OBJECTIF : Déterminer les différences en fonction du genre des résultats du traitement de la tuberculose pulmonaire à frottis positif chez les patients âgés de 15–49 ans et les facteurs associés à des résultats médiocres au Kenya.

SCHEMA : Etude de cohorte rétrospective.

RÉSULTATS : Des 16 056 cas analysés, 38% étaient des femmes et 62% d’hommes. Les femmes ont eu un risque plus élevé de mauvais résultats du traitement que les hommes (12% vs. 10% ; P < 0,001 ; OR ajusté 1,29 ; IC95% 1,16–1,44 ; P < 0,001). Dans le premier modèle multivarié, restreignant l’analyse aux patients positifs au virus de l’immunodéficience humaine (VIH) et ajusté sur les facteurs de risque et les regroupements, les femmes avaient un risque significativement plus faible de mauvais résultats du traitement (OR 0,99 ; IC95% 0,86–1,13 ; P = 0,844). Dans le modèle restreint aux patients VIH négatifs, un risque plus faible a été trouvé (OR 0,89 ; IC95% 0,73–1,09 ; P = 0,267). Dans le second modèle, restreignant l’analyse aux patients sous traitement antirétroviral (ART) et ajusté sur les facteurs de risque et le regroupement, les femmes ont eu un risque plus faible mais non significatif de mauvais résultats du traitement (OR 0,98 ; IC95% 0,84–1,14 ; P = 0,792). Dans le modèle restreint aux patients VIH positifs sans l’ART, on a trouvé un risque plus élevé mais non significatif (OR 1,15 ; IC95% 0,79–1,67 ; P = 0,461). CONCLUSION : Les femmes en âge de procréer ont plus souvent un mauvais résultat du traitement que les hommes. Le fait de ne pas débuter l’ART pendant le traitement antituberculeux semble associé à un mauvais résultat chez les femmes.

OBJETIVO: Determinar las diferencias del desenlace de la tuberculosis pulmonar en función del género, en personas de edad de 15–49 años y definir los factores que se asocian con los desenlaces desfavorables en Kenia.

MÉTODO: Fue este un estudio de cohortes descriptivo retrospectivo.

RESULTADOS: Se analizaron 16 056 casos, de los cuales el 38% era de sexo femenino y el 62% masculino. Las mujeres exhibieron un mayor riesgo de presentar un desenlace desfavorable del tratamiento que los hombres (12% y 10% respectivamente; P < 0,001; OR ajustado [ORa] 1,29; IC95% 1,16–1,44; P < 0,001). En el primer modelo multifactorial, al restringir el análisis a los pacientes positivos frente al virus de la inmunodeficiencia humana (VIH) y corregir en función de los factores de riesgo y los conglomerados, las mujeres exhibieron un riesgo menor, no significativo, de presentar desenlaces terapéuticos desfavorables (ORa 0,99; IC95% 0,86–1,13; P = 0,844). En este modelo, al limitarse a los pacientes seronegativos frente al VIH, se observó un riesgo menor, no significativo (ORa 0,89; IC95% 0,73–1,09; P = 0,267). En el segundo modelo, al restringir el análisis a los pacientes que recibían tratamiento antirretrovírico (ART) y corregir en función de los factores de riesgo y los conglomerados, las mujeres presentaron un riesgo menor, no significativo, de alcanzar desenlaces terapéuticos desfavorables (ORa 0,98; IC95% 0,84–1,14; P = 0,792). En este modelo, al limitarse a los pacientes seropositivos frente al VIH que no recibían ART, se observó un aumento no significativo del riesgo (OR 1,15; IC95% 0,79–1,67; P = 0,461). CONCLUSIÓN: Es más probable que las mujeres en edad reproductiva presenten desenlaces desfavorables del tratamiento que los hombres. El hecho de no comenzar el ART durante el tratamiento de la tuberculosis en las mujeres, parece asociarse con un desenlace desfavorable.