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RESEARCH

Trends in diagnostic techniques and factors associated with tuberculosis treatment outcomes in Lesotho, 2010–2015

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Tuberculosis is a global public health problem. Lesotho, a sub-Saharan country with high HIV and tuberculosis burden, launched the Three I's programme of the World Health Organization in 2013. However, the outcomes of this intervention are scarcely known. This study evaluated the profile of tuberculosis diagnostic techniques used, treatment outcomes and the associated factors across the baseline period (2010–2012) and after the launch of the Three I's programme (2013–2015) based on a retrospective cohort review of patient records at a major clinic in Maseru, Lesotho. In total, 812 cases with complete records from 1 066 randomly selected cases treated (every second case from the sampling frame) were included in the study. Factor analysis was based on logistic regression analysis. The use of the GeneXpert MTB/RIF technique remained below 20% throughout the study period. Overall, 28.9% ($n = 812$) cases had unsuccessful tuberculosis treatment. Male gender ($p = 0.046$), extra-pulmonary tuberculosis ($p = 0.002$) and treatment observation by community health workers ($p = 0.001$) were significantly associated with unsuccessful treatment outcome. Overall, treatment outcomes did not differ significantly ($p = 0.636$) before and after the launch of the intervention. These findings indicate the need to strengthen the implementation of the Three I's programme, taking into account the significant factors in this study.

Keywords: community health workers, extra-pulmonary tuberculosis, GeneXpert MTB/RIF, HIV, Three I's programme

Introduction

Tuberculosis (TB) is a severe global public health problem. The incidence of TB in 2013 was about 126 cases per 100 000 global population and the number of annual deaths associated with TB was about 1.3 million.[1] Patients co-infected with human immunodeficiency virus (HIV) and tuberculosis (HIV/TB) have an increased risk of treatment failure, relapse and death.[2] In addition, HIV complicates the diagnosis of TB.[3]

The global strategy to improve TB detection and treatment outcomes remains focused on rapid diagnosis and drug sensitivity testing (DST) of *Mycobacterium tuberculosis* (MTB) strains.[4] Chest X-ray and smear microscopy, regarded as less effective diagnostic techniques for TB, remain predominant in sub-Saharan Africa. The use of GeneXpert MTB/RIF (Cepheid, Sunnyvale, CA, USA) and routine culture of TB suspect specimens remain low due to high cost and laboratory infrastructure constraints.[5] The GeneXpert MTB/RIF test is recommended by the World Health Organization (WHO), particularly for screening TB in HIV co-infected individuals.[6] However, data on the trends of its use in developing countries remain scarce.

The WHO launched the Three I's programme, comprising intensified case finding (ICF), isoniazid preventive therapy (IPT) and tuberculosis infection control, in 2010 to reduce the incidence of TB, particularly in regions with high TB burden in Africa.[7] Lesotho, a sub-Saharan developing country, launched this programme in 2013.[8] The use of GeneXpert MTB/RIF for TB diagnosis and detection of multi-drug resistant TB (MDR-TB) was central to ICF.[9] The Three I's programme was launched after the Directly Observed Treatment Short-course (DOTS), a WHO programme whose goal was to intensify monitoring of adherence and compliance to TB treatment.[7] However, the DOTS programme has been criticised for failing to eradicate TB in the worst-affected areas.[1]

Lesotho continues to face many challenges in tackling the problem of TB. The estimated prevalence of TB has remained above 400 cases per 100 000 population since 2006.[1] In 2014, Lesotho had the fourth highest prevalence of TB worldwide.[1] Dhemba, Mushonga and Mugomeri[10] note that the millennium development goal (MDG) of scaling up the surveillance and treatment of at least 80% TB/HIV co-infected people by 2015 was off-target. Laboratory diagnosis for TB is one such major challenge in the country. Late diagnosis of TB remains a major cause of TB treatment failure, death and increased transmission of the disease.[11] This study therefore reviewed the trends in the use of TB diagnostic techniques, treatment outcomes and identified covariates associated with unsuccessful treatment outcomes across the baseline period (2010–2012) and after the launch of the Three I's programme (2013–2015) in Lesotho.

Study population and methods

Study setting

The study was conducted at Senkatana HIV and TB clinic in Maseru District, Lesotho. Senkatana is the largest government-owned antiretroviral therapy (ART) centre in Maseru. Lesotho is an enclave in South Africa with about two million people.[12] The country is divided into 10 administrative districts with the capital city, Maseru, in Maseru District. With 40% of its population living below the official poverty line of US$1.25 per day, the United Nations[13] classifies the country as a low-income country. Approximately 23% of the population is infected with HIV and about 75% of patients with TB are co-infected with HIV.[11]

Study design, population and sample size

A retrospective cohort review of the tuberculosis (TB) patients' registers at Senkatana HIV and TB clinic in Maseru District, Lesotho was conducted between March and April 2016.

According to the records, 2 132 patients were treated for TB at Senkatana from 2010 to 2015. Data were extracted from the TB patients' registers using a systematic random sampling technique based on a sampling frame. A list of all records available at the data collection site represented the sampling frame. Every second record, in consecutive order, was selected from the sampling frame and was included in the study. Only patients with TB treatment outcomes reported in their records were included in the study. Patients enrolled before January 1, 2010 and after December 31, 2015 and records with missing data on the variables studied were excluded from the study.

Data collection and analysis

Data comprising demographic, clinical variables, TB treatment regimens and outcomes were extracted using a Microsoft Access® (Microsoft Corp, Redmond, WA, USA) database tool designed by the researchers. Data were collected between March and April 2016. Statistical significance ($p < 0.05$) of the associations between demographic and clinical variables, including HIV status, and treatment outcomes were tested using univariate and multivariate logistic regression in Stata® version 13 software (StataCorp, College Station, TX, USA).

Treatment failure, default, cure and treatment completion were defined according to the DOTS treatment protocol of the WHO.[7] Overall, unsuccessful treatment referred to treatment failure, default, death or transfer out, while treatment success referred to a positive cure outcome or treatment completion.

Ethical considerations

The research proposal was approved by the Institutional Ethical Review Board of the Faculty of Health Sciences at the National University of Lesotho and the Ethics Committee of the Ministry of Health of Lesotho. Permission to conduct the study was also granted by the hospital authority. Patient names were not collected and all data were treated with confidentiality.

Results

Of 1 066 reviewed, only 812 (76.2%) records had data on TB treatment outcomes and were included in the final analysis. The ages of the patients ranged from 1 to 90 years and the median age was 35 (interquartile range 29–44). Table 1 presents patient characteristics categorised by TB treatment outcomes. Males constituted 55.2% and about 84.7% were new TB cases, while 83.0% were HIV-positive. In total, 60.3% patients had pulmonary

Table 1: Tuberculosis treatment outcomes stratified by demographic characteristics

	Treatment outcome			
Characteristics	Successful	Unsuccessful	Total (%)	*p*-value
Gender				
Male	298 (51.6)	150 (64.2)	448 (55.2)	< 0.001
Female	279 (48.4)	85 (35.8)	364 (44.8)	
Total	577 (100)	235 (100)	812 (100)	
Age (years)				
1–5	3 (0.6)	4 (1.8)	7 (0.9)	0.055
6–12	11 (2.0)	5 (1.8)	16 (2.0)	
13–18	152 (25.6)	52 (23.4)	204 (25.1)	
19–30	211 (35.4)	70 (31.5)	281 (34.6)	
31–60	169 (29.4)	78 (34.5)	247 (30.4)	
61–90	31 (7.0)	26 (9.4)	57 (7.0)	
Total	577 (100)	235 (100)	812 (100)	
Employment status				
Employed	142 (24.6)	162 (69.0)	304 (37.4)	< 0.001
Self-employed	232 (40.2)	27 (11.5)	259 (31.9)	
Unemployed	203 (35.2)	46 (19.5)	249 (30.7)	
Total	577 (100)	235 (100)	812 (100)	
Treatment type				
New case	484 (83.9)	204 (86.8)	688 (84.7)	0.168
Transfer-in	12 (2.1)	0 (0.0)	12 (1.5)	
Relapse	30 (5.2)	21 (8.9)	51 (6.3)	
Treatment failure	26 (4.5)	6 (2.6)	32 (4.0)	
Other	25 (4.3)	4 (1.7)	29 (3.5)	
Total	577 (100)	235 (100)	812 (100)	
TB infection site				
Extra-pulmonary	149 (25.8)	173 (73.6)	322 (39.7)	< 0.001
Pulmonary	428 (74.2)	62 (26.4)	490 (60.3)	
Total	577 (100)	235 (100)	812 (100)	

Table 1: (*Continued*)

	Treatment outcome			
Characteristics	**Successful**	**Unsuccessful**	**Total (%)**	***p*-value**
Treatment observer				
Health worker	252 (43.7)	61 (26.0)	313 (38.6)	< 0.001
Community health worker	65 (11.3)	79 (33.6)	144 (17.7)	
Family member/friend	260 (45.0)	95 (40.4)	355 (43.7)	
Total	577 (100)	235 (100)	812 (100)	
HIV status				
HIV positive	476 (82.5)	198 (84.2)	674 (83.0)	1.00
HIV negative	87 (15.1)	35 (14.9)	122 (15.0)	
Declined to be tested	14 (2.4)	2 (0.9)	16 (2.0)	
Total	577 (100)	235 (100)	812 (100)	
Year of diagnosis				
2010	49 (8.5)	19 (8.1)	68 (8.4)	0.031
2011	84 (14.6)	28 (11.9)	112 (13.8)	
2012	29 (5.0)	25 (10.6)	54 (6.7)	
2013	166 (28.7)	87 (37.0)	253 (31.1)	
2014	123 (21.3)	38 (16.2)	161 (19.8)	
2015	126 (21.9)	38 (16.2)	164 (20.2)	
Total	577 (100)	235 (100)	812 (100)	
Period of diagnosis				
2010–2012 (baseline period)	162 (28.1)	72 (30.6)	234 (28.8)	0.636
2013–2015 (Three I's period)	415 (71.9)	163 (69.4)	578 (71.2)	
Total	577 (100)	235 (100)	812 (100)	

Note: Unsuccessful treatment = treatment failure, default, death or transfer out; treatment success = a cure outcome or treatment completion.

TB, while 39.7% had extra-pulmonary TB (Table 1). Only 37.4% were employed while an additional 31.9% were self-employed.

Only 197 patients had data on occupations (see Figure 1). Notably, factory workers (28.4%, *n* = 197), miners/ex-miners (23.4%), taxi drivers (14.7%), security services personnel (8.1%) and health workers (4.6%) were the most predominantly known occupations.

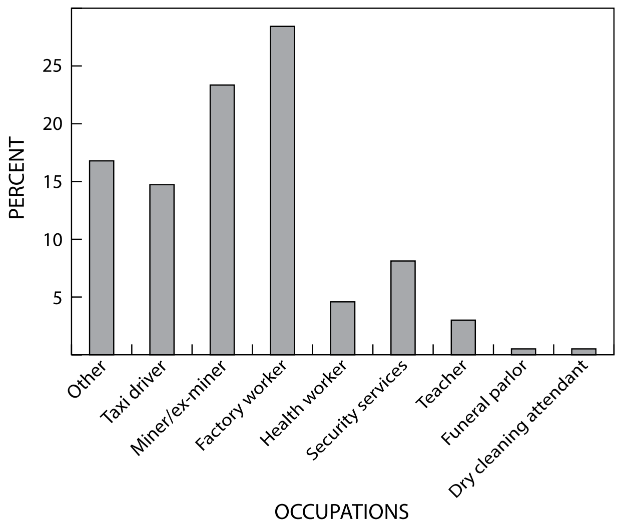

Figure 1: Percentage (%) distribution of tuberculosis cases by occupation (*n* = 197).

Figure 2 presents the TB diagnostic techniques utilised at Senkatana HIV and TB clinic between 2010 and 2015 (*n* = 12). Chest X-ray was the most common diagnostic technique used from 2010 to 2015, followed by smear microscopy. The use of GeneXpert MTB/RIF increased by 17.0% between 2010 and 2012. However, the trend in GeneXpert MTB/RIF usage dropped to 4.6% in 2013 but then rose by 10.3% between 2013 and 2015.

Figure 3 presents the TB treatment outcomes. Overall, 28.9% (*n* = 812) of patients had unsuccessful treatment outcomes. This category with unsuccessful treatment outcomes comprised 89 (11.0%, *n* = 235) treatment defaults, 83 (10.2%) treatment failures, 49 (6.0%) deaths and 13 (1.6%) transfer-out cases. Only one (0.1%) patient had stopped treatment due to side effects.

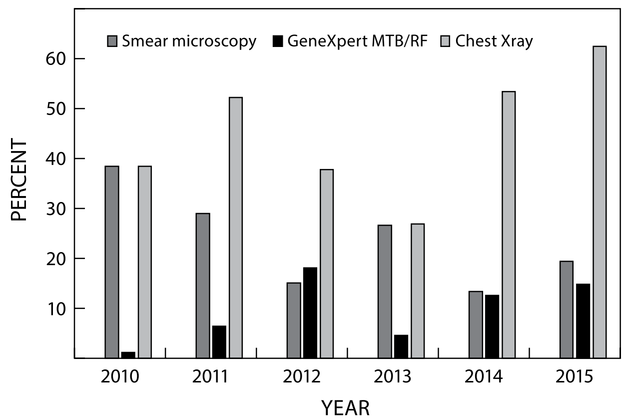

Figure 2: Diagnostic techniques used for tuberculosis at Senkatana Clinic in different years (*n* = 812).

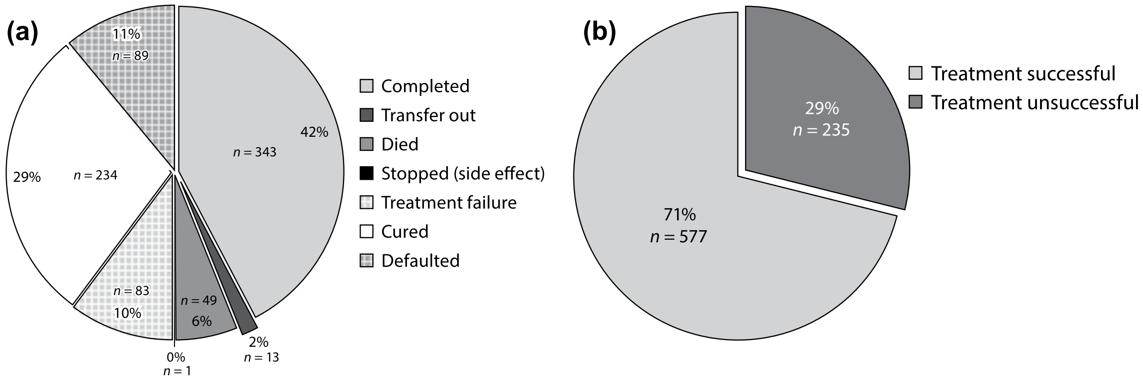

Figure 3: Tuberculosis treatment outcomes by category (A) and overall treatment outcomes (B) (*n* = 812).

Among the group with unsuccessful treatment outcomes, males had significantly ($p < 0.001$) higher (64.2%, $n = 235$) unsuccessful treatment outcomes compared with females (35.8%). The 31–60 age group, with 34.5% ($n = 235$) unsuccessful treatment outcomes, had the highest proportion of unsuccessful treatment outcomes, followed by the 19–30 age group (31.5%). The 1–5 and 6–12 age groups, with 0.9% and 2.0%, respectively, had the lowest proportions of unsuccessful treatment outcomes. However, age group was not significantly ($p = 0.055$) associated with the treatment outcomes.

Employment status was significantly ($p < 0.001$) associated with unsuccessful treatment outcome. In total, 69.0% ($n = 235$) of employed patients had unsuccessful treatment outcomes. About 86.8% ($n = 235$) of new TB cases had unsuccessful TB treatment outcomes. However, treatment type was not significantly ($p = 0.168$) associated with treatment outcome (Table 1).

About 84.2% ($n = 235$) HIV-positive patients had unsuccessful TB treatment outcomes. However, HIV status was not significantly ($p = 1.000$) associated with treatment outcome. Extra-pulmonary TB cases had a significantly ($p < 0.001$) higher proportion (73.6%, $n = 235$) of unsuccessful treatment outcomes compared with pulmonary TB (26.4%).

Only 1.2% ($n = 812$) patients had records for TB microbial culture tests. Of these, 70% ($n = 10$) had positive TB culture results. In addition, only 6.8% ($n = 812$) had records for drug sensitivity tests (DST), inclusive of GeneXpert MTB/RIF tests (data not shown). Of these, 90.9% ($n = 55$) and 9.1% of patients had rifampicin and isoniazid (INH) mono resistance, respectively. Further, 81.2% ($n = 812$) patients had records indicating initiation of cotrimoxazole/dapsone for opportunistic fungal infections.

Patients supported by family members (40.4%, $n = 235$) had the highest proportion of unsuccessful treatment outcomes, followed by community health workers (33.6%) and health workers (26.0%). However, 43.7% ($n = 812$) of the patients were observed by family members or their friends, while 38.6% ($n = 812$) were observed by health workers. Only 17.7% ($n = 812$) of

Table 2: Logistic regression analysis of variables associated with unsuccessful TB treatment outcomes

	Treatment outcome					
Characteristics	**Successful, *n* (%)**	**Unsuccessful, *n* (%)**	**Unadjusted OR (95% CI)**	***p*-value**	**Adjusted OR (95% CI)**	***p*-value**
Gender						
Female	298 (51.6)	150 (64.2)	1	0.001	1	
Male	279 (48.4)	85 (35.8)	1.7 (1.2–2.3)		1.4 (1.0–1.8)	0.046
Total	577 (100)	235 (100)				
Employment status						
Unemployed	142 (24.6)	162 (69.0)	1		1	
Self-employed	232 (40.2)	27 (11.5)	0.5 (0.3–0.9)	0.011	1.0 (0.7–1.5)	0.960
Employed	203 (35.2)	46 (19.5)	5.0 (3.4–7.4)	0.001	1.0 (0.7–1.5)	0.936
Total	577 (100)	235 (100)				
TB infection site						
Pulmonary	428 (74.2)	62 (26.4)	1	1		
Extra-pulmonary	149 (25.8)	173 (73.6)	8.0 (5.6–11.3)	0.001	3.5 (2.7–4.6)	0.002
Total	577 (100)	235 (100)				
Treatment observer						
Health worker	252 (43.7)	61 (26.0)	1		1	
Community health worker	65 (11.3)	79 (33.6)	5.1 (2.7–9.3)	0.001	6.2 (4.0–10.0)	0.001
Family member/friend	260 (45.0)	95 (40.4)	1.5 (0.9–2.6)	0.138	1.3 (0.9–1.9)	0.130
Total	577 (100)	235 (100)				

the patients were observed by community health workers. The type of treatment observer, specifically community health worker, was significantly ($p < 0.001$) associated with unsuccessful treatment outcome (see Table 1). Overall, there were no significant ($p = 0.636$) differences in TB treatment outcomes between the baseline period (2010–2012) and the period after the launch of Three I's programme (2013–2015).

Table 2 presents logistic regression analysis results of variables associated with unsuccessful TB treatment outcomes. In univariate logistic regression analysis, gender, employment status, TB infection site and treatment observer were significantly ($p < 0.05$) associated with unsuccessful treatment outcome. However, in multivariate analysis, male gender ($p = 0.046$), extra-pulmonary TB ($p = 0.002$) and community health worker ($p = 0.001$) remained significant in the final model.

Discussion

Overall, 28.9% ($n = 812$) of tuberculosis (TB) patients—consisting of treatment defaults (11.0%, $n = 235$) cases, treatment failures (10.2%) and deaths (6.0%)—had unsuccessful treatment outcomes. Treatment defaults and failure of TB treatment are therefore a major concern. The fact that there was no notably significant ($p = 0.636$) improvement in TB treatment outcomes between the baseline period (2010–2012) and the period after the launch of Three I's programme (2013–2015) highlights the need to improve or appropriately modify the implementation of the Three I's programme.[8] In particular, there is a need to improve the tracking of treatment defaulters. Harries *et al.*[14] emphasise early tracking of initial defaulters, stating that failure to keep track of, register and report on initial defaulters is, in effect, 'sloppy' DOTS. Furthermore, the predominance of new TB cases (84.7%, $n = 812$) in this study population highlights the need to increase infection-control efforts. The high proportion (83.0%, 648) of HIV/TB co-infection in this population is well described by GoL.[11] This highlights the need to further integrate HIV/TB intervention programmes.

Smear microscopy tests and chest X-ray were the most used diagnostic techniques in this study. The use of GeneXpert MTB/RIF remained below 20% ($n = 812$) between 2010 and 2015. In addition, only 1.2% ($n = 812$) patients had records for TB microbial culture tests, while only 6.8% ($n = 812$) of patients' files had records for drug sensitivity tests (DST). This highlights the need to scale up the use of GeneXpert MTB/RIF and DST. Ahmad and Mokaddas[4] and the WHO[6] stress the need to scale up the use of the GeneXpert MTB/RIF test and drug sensitivity testing of *M. tuberculosis* strains. The fact that 90.9% ($n = 55$) and 9.1% patients had rifampicin and isoniazid mono-resistance highlights the need to scale up drug sensitivity testing.

The proportion (23.8%, $n = 1\ 066$) of patients' files without records on treatment outcomes highlights the need to improve record management. Maama-Maim, *et al.*[15] corroborate the problem of poor data management in TB programmes. Tweya *et al.*[16] note that electronic data management may lead to improved adherence to clinical guidelines and improved quality of patient care.

Male gender, employment status, extra-pulmonary site of TB infection and the use of community health workers as treatment observers proved to be important variables associated with unsuccessful treatment outcomes in univariate analysis. However, male gender (adjusted odds ratio (OR) = 1.4; 95% confidence interval (CI) 1.0–1.8; $p = 0.046$), extra-pulmonary TB (OR = 3.5; 95% CI 2.7–4.6; $p = 0.002$) and community health workers as treatment observers (OR = 6.2; 95% CI 4.0–10.0; $p = 0.001$) emerged as significant factors in multivariate analysis.

Males constituted a higher proportion (55.2%, $n = 812$) of the study population compared with females in this study. Floyd *et al.*[17] corroborate this finding in Russia, where males constituted 70% ($n = 3\ 352$) of TB patients. Riskier occupations such as working in the mines, alcohol abuse and smoking may explain higher TB rates among men, including poor treatment outcomes.[18–20] This highlights the need to scale up interventions aimed at improving diagnosis and treatment of TB in men complemented by behaviour and lifestyle change programmes.

The fact that extra-pulmonary TB emerged as a significant factor (p = 0.002) associated with unsuccessful treatment outcome highlights that extra-pulmonary TB is more difficult to treat in this population. Sama *et al.*[21] highlight that there is a need for new drugs and/or dosage forms to treat extra-pulmonary TB.

TB treatment observation by community health workers is particularly less effective in this population compared with observation by other groups of observers. This may be due to inadequate staffing levels of community health workers. Interruption of treatment services during weekends and holidays may also be affecting treatment observation by health workers. This highlights the need to increase the number of community health workers and strengthen their role in monitoring TB treatment. Community health workers are an important component of the DOTS and the Three I's programmes.[7] Therefore, their role is critical to the success of these programmes.

Although statistically insignificant in multivariate analysis, employment status was significantly ($p < 0.001$) associated with treatment outcomes in univariate analysis. Notably, factory workers (28.4%, $n = 197$), miners/ ex-miners (23.4%), taxi drivers (14.7%), security services personnel (8.1%) and health workers (4.6%) were the most predominant occupations in this study. However, the least common occupations included teachers (3.0%, $n = 197$), funeral parlour attendants (0.51%) and dry-cleaning attendants (0.51%). There is a need to increase infection control and prevention efforts and scale up TB screening in these occupations. Stuckler *et al.*[22] attribute higher transmission rates of TB among miners to incomplete treatment due to high rates of treatment defaults associated with migration. Further, there is a need to strengthen adherence to infection control guidelines by healthcare workers. Bhebhe, Van Rooyen and Steinberg[23] note that only 22.0% ($n = 129$) of nurses in Lesotho follow appropriate methods of sputum collection, while Mugomeri *et al.*[24] note that 43.6% ($n = 55$) of the nurses have poor adherence to TB infection control guidelines.

High rates of TB infection among taxi drivers highlight the need to scale up infection control efforts in the public transport system in Maseru, Lesotho. The occurrence of tuberculosis among funeral parlour and dry-cleaning attendants is an important public health issue. Lauzardo *et al.*[25] note that the transmission of *Mycobacterium tuberculosis* is highly possible during routine practice in funeral parlours.

One major limitation of this study was that data for CD4 counts, which indicate the immune status of patients,[26] was not available. The immune status of the patients was therefore a potential confounding variable for some factors investigated in this study, particularly with regard to the effect of pulmonary and extra-pulmonary TB on treatment outcomes of TB, as noted by Musa *et al.*[27] Another limitation is that the study was conducted in only one district of Lesotho. Although Senkatana HIV and TB Clinic is the largest ART centre in Maseru District, further studies in other districts of the country are required. However, this study contributes towards the improvement of TB treatment outcomes in the country and regions worst affected by TB, particularly in countries implementing the Three I's programme of the WHO.

Conclusion

Overall, a considerable proportion of TB patients had unsuccessful treatment outcomes. The lack of significant improvement in TB treatment outcomes after the launch of the Three I's programme (2013–2015) highlights the need to improve the implementation of this programme. There is a need to scale up TB screening in high-risk groups. Male gender, extra-pulmonary TB and the use of community health workers as treatment observers are important prohibitive factors to consider in TB intervention programmes in this population. Effective drugs and/or dosage forms for improved therapeutic outcomes in extra-pulmonary TB should be considered. Furthermore, there is a need to scale up the use of rapid diagnostic techniques, particularly GeneXpert MTB/RIF.

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Authors' contributions – EM conceptualised the study, supervised data collection, analysed the data and drafted the manuscript with editorial inputs from BSB, CM and Prof. CT.

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