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EVALUATION OF TREATMENT OUTCOMES AND ASSOCIATED FACTORS AMONG PATIENTS MANAGED FOR TUBERCULOSIS IN VIHIGA COUNTY, 2012- 2015

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ABSTRACT

Background: **Tuberculosis (TB) treatment outcomes are used to evaluate program and patient success. Despite this, factors driving and sustaining high rates of poor TB treatment outcomes in Vihiga County are not well understood.**
Objective: **To evaluate treatment outcomes and associated factors among patients managed for TB in Vihiga County between 2012 and 2015.**
Design: **Descriptive cohort study.**
Setting: **Vihiga County.**
Subjects: **Notified TB patients >15years who were on drug susceptible TB treatment.**
Results: **Of the 3288 eligible patients more than half were male 1961 (60%), 85% were from the public sector while 23% were over 45years. Among the TB patients, 2865 (87%) were successfully treated, 299 (9%) died and 124 (4%) had other poor treatment outcomes. On multivariate analysis, advancing age (Adjusted Odds Ratio (AOR) 3.3, 95% CI2.03-5.38, P<0.001), HIV positive (AOR1.78, 95% CI1.27-2.49, P0.001), previously treated (AOR1.78, 95% CI1.2-2.49, P<0.001) and unknown HIV status (AOR 2.11, 95% CI 1.21-3.68, P 0.008) increased the risk of death. TB patients with positive sputum results during initiation of treatment (AOR=0.68, CI=0.50-0.94, P-value 0.018) and those with normal body mass index (BMI) (AOR 0.37, 95% CI 0.24-0.58, P<0.001), were less likely to die.**
Conclusion: **While higher BMI and bacteriological confirmation reduced the risk of death, advancing age, unknown HIV status, HIV positive, being a previously treated TB case increased the risk of death. We recommend early and accurate diagnosis of TB cases, TB/HIV integration and active involvement of community health volunteers in TB management.**

INTRODUCTION

Globally, an estimated 9.6 million people suffer from TB and 1.5 million of them die. Of these deaths, 480,000 are women and 140, 000 are children(1). TB is fuelled by HIV infection, population increase and poverty(2).The African Region contributes to more than a quarter of world's TB cases and deaths relative to population (3). Kenya, is listed among the 22 high burden TB countries, that together account for more than 80% of the world's TB cases(4).

In Kenya, the burden of TB is higher in males, the HIV un-infected and those living in urban settings(5).

TB Treatment outcomes are used to evaluate program and patient success(3). Unfavourable TB treatment outcome has a devastating effect on individual patients, families and the health system (6). Previous studies have demonstrated that higher mortality is observed in, TB/HIV co-infection and low BMI (2,4,7–10). Additionally, a study to establish cause of death in notified TB patients in a rural South African hospital indicated that only 56% of patients who die had TB, 12% had no TB while 36% died of other illnesses(10)

Vihiga County has not achieved the national TB treatment success rate target of 90%, due to deaths and to lost to follow ups(11,12). In 2014, the death rate among notified TB cases in Vihiga County was 10%, making it one of the counties with highest death rates in Kenya (11). Despite this, factors driving and sustaining high rates of poor TB treatment outcomes in Vihiga County are not well understood. As such, we conducted this study to determine the characteristics, treatment outcomes and factors associated with all-cause mortality among notified TB patients, 2012-2016 in Vihiga County.

METHODS AND MATERIALS

Study design: This was a descriptive cohort study using routine National Tuberculosis and Leprosy program data.

Setting: Vihiga County is located in Western region of Kenya with a population of 614,000. The HIV prevalence rate is 5% and TB notification rate <175/100,000 population (13). Across the five sub-counties in within the County, TB services are offered by one county referral hospital, five sub-county A clinically confirmed TB case is diagnosed by a clinician or other medical practitioner based on a clinical algorithm(14). TB cases are further classified by the site of TB disease; pulmonary tuberculosis (PTB) involves the lung parenchyma or the trachea-bronchial tree while extra-pulmonary tuberculosis (EPTB) involves hospitals and 47 level II and III health care facilities.

Context: The Kenya and international TB guidelines are adhered to in management of TB. A case of TB disease is defined as bacteriologically or clinically confirmed TB (14,15). A bacteriologically confirmed TB case, is one in which biological specimen is positive by phenotypic (smear microscopy and or culture) or molecular methods such as gene-xpert or line probe assay (LPA). organs other than the lung. Additionally, TB patients are classified by previous TB treatment history and this include new, relapses, treatment after failure, treatment after loss to follow up and other previously treated TB cases (14).

A composite outcome of treatment success comprises of cured and treatment completed and is often used to evaluate TB program (14). Adverse TB treatment outcomes result from treatment failure, lost to follow up and death. Previously, patients who went out of control were prosecuted and compelled to take medication. However, in March 2016, the high court declared that the practice of incarnating TB patients is illegal and unconstitutional, and directed the government to develop a policy that incorporates international principles on handling the disease(16). To implement this, the NTLD-P directed County governments to construct inpatient facilities for this purpose. However, most Counties including Vihiga have not implemented the directive, making it difficult to handle patients who refuse TB treatment. Also, to account for patients being transferred out of health facilities initiating their treatment, in 2014, SCTLs were authorized to follow up patients and declare their outcomes.

Data collection: The primary data for this study was abstracted from the TIBU database. TB Program utilizes TIBU data management as central database of the NTLD-P which is a web based solution integrated with mobile/tablet technology developed and introduced in Kenya in the year 2012 with inter-sector support. Patients with TB upon diagnosis, are notified, treated and followed up with primary record capture obtained from patient records and TB log book entered into registers as a summary of the data entered in the registers. This data is subsequently uploaded at Sub-County level into TIBU by sub-county TB coordinators electronically via mobile computer tablets. TIBU has internal consistency checks to ensure that data entry errors are minimized. The TB program has quarterly data quality audits at the county level and biannually at the national level.

Analysis and statistics: Data was extracted from the TIBU database and exported to *Stata* version 14 for cleaning and analysis. Categorical data were summarized as proportions while continuous data were reported as means (SD) and median (IQR) for normally and non-normally distributed data respectively. Chi square test and logistic regression were conducted to examine the association between treatment outcomes and the various demographic and clinical characteristics. To determine significant predictors of treatment success a multivariable model was fitted to the data. Crude and adjusted odds ratios are presented with accompanying 95% confidence interval while the P-value was reported at the 5% significance level.

Study participants: Study participants were notified TB patients >15years old on drug susceptible TB treatment, 2012-2015.

Ethical approval: This research proposal was approved by the Moi University College of Health Sciences (MU/CHS) and Moi Teaching & Referral Hospital (MT&RH) Institutional Review Board (IREC).

RESULTS

We abstracted data from records of 3288 patients aged more than 15 years. Table1 shows demographic and clinical characteristics for notified TB patients. Most of patients were men (60%), new cases (86%) and had pulmonary TB (82%). Of the total, 39% of were TB/HIV co-infected. Vihiga and Hamisi treatment zones contributed 31% and 32% of all patients respectively while the public sector contributed 85%of cases.

Table 1

Demographic and clinical characteristics of patients managed for tuberculosis, 2012-2015

Characteristic	Frequency	Percentage
Gender		
Female	1327	40
Male	1961	60
Age category		
15-24	509	15
25-29	371	11
30-34	446	14
35-39	484	15
40-44	716	22
>45	759	23
Sector		
Private	478	15
Public	2810	85
Treatment Zone		
Emuhaya	721	22
Hamisi	1032	32
Sabatia	507	15
Vihiga	1028	31
Sputum Examination at 0th month		
Not done	687	21
Negative	1058	32
Positive	1543	47
Type of TB P/EP		
EPTB	607	18
PTB	2681	82
Type of patient		
New	2820	86
Previously treated	468	14
HIV status		
Declined	13	0.5

Not done	180	5
Negative	1810	55
Positive	1285	39
Cotrimoxazole Preventive Therapy		
No	3	0.5
Yes	1281	99.5
ART treatment		
No	57	4
Yes	1222	96

Table 2 present demographic characteristics and treatment outcomes. Public and private sectors had the same TSR (87%) and death rate (9%). Female had slightly higher TSR (88%) than men (87%) but death rate in both sex was similar (9%). Age category 15-24 years had highest TSR (93%), while the lowest TSR was observed in age category >45years (84%). Age category >45years had the highest death rate (12%). Age categories 25-29years and 40-44years had high death rates of 10% respectively. The rate of other adverse outcomes (lost to follow up and transferred out) ranged between 3-6% across all demographic variables.

Table 2

Demographic characteristics and treatment out comes among notified TB patients, 2012-2015 in Vihiga County

Characteristic	**Successful treatment** (%)	**Died** (%)	**Other Adverse outcomes** (%)	**Overall**
Sector				
Private	417 (87)	45 (9)	16 (3)	478
Public	2448(87)	254 (9)	108(4)	2810
Sex				
Female	1167(88)	125 (9)	35 (3)	1327
Male	1698(87)	174 (9)	89 (4)	1961
Age group				
15-24	473 (93)	21 (4)	15 (3)	509
25-29	316 (85)	37 (10)	18 (5)	371
30-34	396 (89)	33 (7)	17 (4)	446
35-39	417 (86)	43 (9)	24 (5)	484
40-44	619 (86)	71 (10)	26 (4)	716
>45	641 (84)	94 (12)	24 (3)	759
Zone				
Emuhaya	630 (87)	75 (10)	16 (2)	721
Hamisi	887 (86)	83 (8)	62 (6)	1032
Sabatia	452 (89)	40 (8)	15 (3)	507
Vihiga	896 (87)	101 (10)	31 (3)	1028

Table 3 shows clinical characteristics and TB treatment outcomes among notified patients in Vihiga County. Patients with BMI less than 15Kg/M2 had TSR of 80% and death rate of 15%, while patients with BMI more 25Kg/M2 had TSR of 92% and death rate of 7%. Patients who had a positive sputum result during initiation of treatment had higher TSR (89%) and lower death rate (6%) than those without sputum result, TSR (85%) and death rate (13%) respectively. PTB patients had higher TSR (88%)and lower death rate (8%) than EPTB patients who had TSR of 85% and death rate of 13%. Patients who declined a HIV test had lowest TSR (69%) and highest death rate (23%). Although they had higher death rate (14%), HIV positive patients had a better TSR (83%) than patients without a HIV test (80%). TSR was higher (91%) among HIV negative patients.

Table 3.

Clinical characteristics and treatment out comes among TB patients notified between 2012-2015 in Vihiga County

	Successful treatment (%)	Died (%)	Other Adverse outcomes (%)	Overall (%)
BMI				
<15	188 (80)	36 (15)	10 (4)	234(8)
15-18.4	976 (86)	115 (10)	50 (4)	1141(39)
18.5-24	1211(90)	89(7)	50 (3)	1350(47)
>25	147 (92)	11 (7)	2 (1)	160(6)
X-ray				
N	2139(87)	209 (9)	109(4)	2457(75)
Y	726 (87)	90 (11)	15 (2)	831(25)
Sputum exam month 0				
Not done	581 (85)	88 (13)	18 (2)	687(21)
Negative	916 (87)	112 (11)	30 (3)	1058(32)
Positive	1368(89)	99 (6)	76 (5)	1543(47)
Type of TB P/EP				
EPTB	514 (85)	77 (13)	16 (2)	607(19)
PTB	2351 (88)	222 (8)	108 (4)	2681(81)
Type of patient				
New	2499 (89)	241 (8)	80 (3)	2820(86)
Previously treated	366 (78)	58 (12)	44 (9)	468(14)
HIV Status				
Declined	9 (69)	3 (23)	1 (8)	13(0.5)
Not done	145 (80)	21 (12)	14 (8)	180(6)
Negative	1644 (91)	99 (5)	67 (4)	1810(55)
Positive	1067 (83)	176 (14)	42 (3)	1285(39)
ART Treatment				
N	46 (81)	9 (16)	2 (4)	57(5)
Y	1018 (83)	166 (14)	38 (3)	1222(95)

Figure 1 highlights yearly treatment outcomes among patients managed for TB in Vihiga County, 2012-2015. TRS ranged between 85-88% across all the years while death rate was 8%, 10%, 10% and 8% for 2012, 2013, 2014 and 2015 respectively. There was a steady decrease of transfer outs from 2.5% in 2012 to 0 in 2015. Lost to follow was ranged 2-4% during review period.

Figure 1:

Yearly treatment outcomes among patients treated for tuberculosis in Vihiga County, 2012-2015

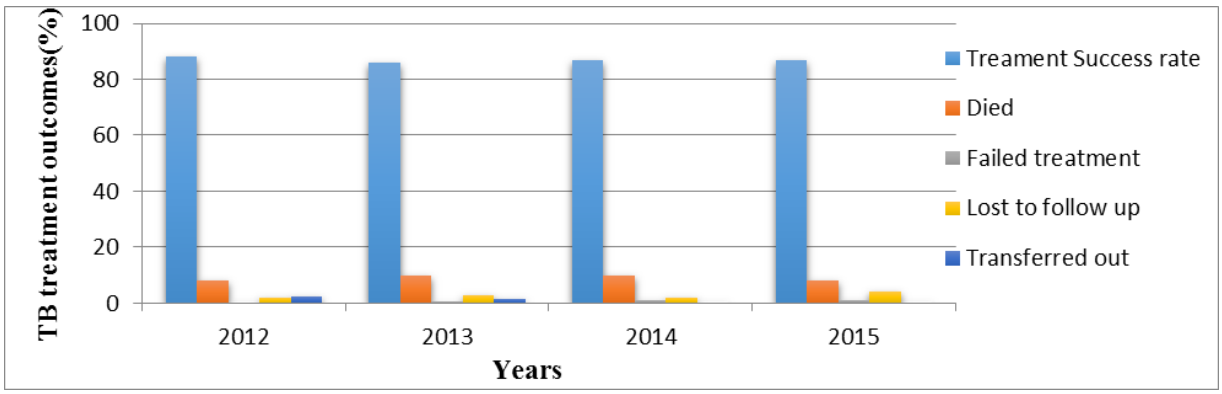

Table 4 presents all-cause mortality among patients managed for TB, 2012-2015. On multivariate analysis, factors associated with increased risk of TB related death were age more than 45years (odds ratio, OR=3.3), age 40-44 (OR=2.58) and previous TB treatment (OR=1.68). Factors associated with reduction in risk of death were BMI 18.5-24 Kg/M^2 (OR=0.38), BMI >25Kg/M^2 (OR=0.39), positive sputum result during initiation of treatment (OR=0.48) and PTB (0.75). After adjusting for the effect of confounders, patients aged 45 years or more were almost 3 times more likely to die (Adjusted Odds Ratio (AOR)=2.96, Confidence Interval (CI)= 1.73-5.07, P-Value, <0.001) compared to age 15-24 years. HIV positive patients were two and a half times more likely to die (AOR= 2.58, CI=1.93-3.47, P-value<0.001) while patients without HIV test results were two times more likely to die (AOR=2.11, CI=1.21-3.68, P-value 0.008). Previously treated TB patients were almost two times more likely to die (OR=1.78, CI=1.27-2.49, P-value<0.001) than new TB patients. Patients with a BMI 18.5-24 Kg/M^2 were 63% less likely to die (AOR=0.37, CI=024-0.58, P-value<0.001) and those with BMI >25Kg/M^2 were 67% less likely to die (AOR=0.33, CI=0.16-0.68, P-value 0.003) compared with those with BMI less than 18.5 Kg/M^2. Patients with positive sputum result before initiation of treatment were 32% less likely to die (AOR=0.68, CI=0.50-0.94, P-value 0.018) than the negative sputum cases. Also, patients with PTB were 37% less likely to die (AOR=0.63, CI=0.48-0.83, P-value<0.001) compared to EPTB patients.

Table 4

All-cause mortality among notified tuberculosis patients in Vihiga County from 2012-2015

	Died (%)	Crude OR (95% CI)	Adjusted OR (95% CI)	P value
Gender				
F	125(42)	1	1	
M	174(58)	0.96(0.691.34)	1.03 (0.77-1.37)	0.853
Age group				
15-24	21(7)	1	1	
25-29	37(12)	2.64(1.7-2.9)	1.68 (0.90-3.15)	0.104
30-34	33(11)	1.88 (1.07-3.3)	1.48 (0.81-2.73)	0.206
35-39	43(14)	2.32 (1.36-3.98)	1.55 (0.86-2.79)	0.146
40-44	71(24)	2.58 (1.56-4.27)	1.76 (1.02-3.06)	0.044
>45	94(31)	3.3 (2.03-5.38)	2.96 (1.73-5.07)	<0.001
Body Mass Index				
<15	36(12)	1	1	
15-18.4	115(39)	0.62 (0.3-0.72)	0.61 (0.40-0.93)	-
18.5-24	89(30)	0.38 (0.25-0.58)	0.37 (0.24-0.58)	<0.001
>25	11(4)	0.39 (0.19-0.79)	0.33 (0.16-0.68)	0.003
HIV status				
Negative	99(33)	1	1	
Not Done	24 (8)	0.43 (0.11-1.73)	2.11 (1.21-3.68)	0.008
Pos	176(59)	0.49 (0.13-1.85)	2.58 (1.92-3.47)	<0.001
Type of TB patient				
New	24(81)	1	1	
Previously treated	58 (19)	1.64 (1.21-2.23)	1.78 (1.27-2.49)	<0.001
Sputum examination at treatment initiation				
Negative	88(29)	1	1	
Not done	112(38)	0.81(0.6-1.09)	1.22 (0.86-1.71)	0.262
Positive	99(33)	0.48 (0.35-0.65)	0.68 (0.50-0.94)	0.018
Type of TB				
EPTB	77(26)	1		
PTB	222(74)	0.75 (0.35-0.97)	0.63 (0.48-0.83)	<0.001

DISCUSSION

Our study found that men bear a heavy burden of TB. This may be due to biological factors and risks men engage in like cigarette smoking, alcohol intake and overcrowding (5). The results also indicate that PTB is more common and mostly affects people more than 45years. This may be attributed to reducing immunity and increased incidence of co-morbidities in advancing age, this play a vital role in reactivation of latent TB infection or progression of primary TB infection(17). Similar results were demonstrated in the Kenya TB prevalence survey(5).Across all the years under study, death was the modal unfavorable outcome followed by lost-to-found. Failure of treatment among notified patients was significantly low across the study period. We also observed a steady decrease in transfer outs from the year 2012.This phenomenon may have resulted from programmatic interventions which require SCTLCs to seek and declare treatment outcomes for all patients they notify. Despite strengthened effort in tracing of treatment interrupters by community health volunteers lost to follow up remains one of the main unfavorable TB treatment outcomes. This may have resulted from a court ruling that barred imprisonment of TB patients refusing to take medication(16). In 2016, a circular directed county governments to come up with inpatient facilities to take care of these patients. However, this has not been effected in Vihiga County.

Risk of death among patients was independently associated with increase in age, being HIV positive, not having HIV result during treatment initiation and being a previously treated TB case. Our study has indicated that population >45 years not only bear heavy TB burden but also have increased risk of death from it. A study should be undertaken to establish causality and establish whether this group can benefit from TB prophylaxis. HIV infection is known to promote rapid progression of TB due to decline in immunity among cases leading to death(15). Patients who have not tested for HIV may in fact have the infection and because of unknown HIV status, these patients may not benefit from ART and CPT(18). These findings concur with a study which indicated that knowledge of HIV status among TB patients improves management of these patients hence improving treatment outcomes(2). Among previously treated cases, mortality may be attributed to complications arising from previous TB disease or drug resistance(11,18).Decrease in the risk of death among notified patients was associated with higher BMI, having pulmonary TB and having a positive sputum result during treatment initiation. PTB and bacteriologically confirmed TB patients had better TB treatment outcome than those without sputum results and EPTB cases. This is probably so because some clinically confirmed TB patients may not in fact have TB.

A study done in South Africa to establish cause of death in patients on treatment for patients on TB treatment who die do not have TB(10). Additionally, lack of bacteriological confirmation may have a negative impact on drug adherence leading to poor treatment outcome. We found that patients with higher BMI have less risk of death: malnutrition and TB have a complex synergetic relationship, leading to rapid progress of both conditions(19).This finding may be elaborated by the Kenya TB prevalence survey-2016 which demonstrated that 80% of symptomatic participants and 67% of prevalent TB cases did not seek health care services, because they did not perceive their symptoms as being serious(5). This perception is likely to delay diagnosis and treatment of TB leading to severe malnutrition and poor treatment outcome. Similar findings were demonstrated studies done in Surin province, Thailand and rural health facilities in South Africa(7,10).

FUNDING/ ACKNOWLEDGEMENT STATEMENT

This research was conducted through the Structured Operational Research and Training Initiative (SORT IT), a global partnership led by UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) based at the World Health Organization The model is based on a course developed jointly by the International Union Against Tuberculosis and Lung Disease (The Union) and TB in a rural South African hospital indicated that more than a third of This study did not include data from children under 15years and this may limit inference of the finding to all TB patients. Nevertheless, inclusion of this age group may not have skewed results considering that the proportion of children on TB treatment is low. This study has strength of adhering to the STROBE guidelines in reporting. Also, the TIBU database has internal consistency checks to ensure that data entry errors are minimized.

In conclusion, this study found mortality rate among notified TB patients to be higher than the national rate. Advancing age, being HIV positive, being a previous TB case were associated with death while higher BMI and bacteriologically confirmed TB cases were associated with reduced risk of death. We recommend accurate and early detection of TB cases through facility based active case finding and more involvement use of community health volunteers in TB case finding.

Conflict of Interest: None

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