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Health-related quality of life of inpatients and outpatients treated for tuberculosis in rural Malawi

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Abstract

Introduction.—Patients being treated for tuberculosis (TB) may suffer reductions in health-related quality of life (HRQoL). This study aims to assess the extent of such reductions and the trajectory of HRQoL over the course of treatment in rural Malawi.

Methods.—We collected patient demographic and socioeconomic status, TB-related characteristics, and HRQoL data (i.e. EQ-5D and a visual analogue scale, VAS) from adults (≥18 years old) being treated for TB in 12 primary health centers and one hospital in rural Thyolo District, Malawi from 2014 to 2016. Associations between HRQoL and patient characteristics were estimated using multivariable linear regression.

Findings.—Inpatients (n=197) consistently showed lower median HRQoL scores (EQ5D and VAS: 0.79, 55 vs. 0.84, 70) and suffered more severe health impairments during hospitalization compared to outpatients (n=156). Longer treatment duration was associated with higher HRQoL among outpatients (EQ5D: 0.034 increase per two months, 95% confidence interval 0.012–0.057). We found no substantial associations between patients' demographic and socioeconomic characteristics and HRQoL in this setting.

Conclusion.—HRQoL scores among patients receiving treatment for TB in rural Malawi differ by clinical setting and duration of treatment, with greater impairment among inpatients and those early in their treatment course.

Keywords

health-related quality of life; Malawi; tuberculosis; hospitalization

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Introduction

Tuberculosis (TB), with one third of the world's population infected, is a leading cause of morbidity globally.(1) TB impairs respiratory physiology and functional ability, potentially resulting in diminished patients' well-being in physical, mental, social aspects both in short and long terms. Patients with tuberculosis also suffer from social isolation, stigma, lack of support and economic constraints.(2) TB disease and treatment – taking at least 6 to 9 months to complete, with serious risks of adverse reactions (3, 4) – have important negative effects on patients' quality of life.(5, 6)

Health-related quality of life (HRQoL) is a multidimensional concept that includes domains related to physical, cognitive, emotional and social functioning.(1) The assessment of HRQoL, as a reflection of an individual's perception of their well-being in the context of their community's respective culture and value systems, is an important consideration in estimating the population-level burden of TB disease and its effects on individual patients. (1) Furthermore, accurate estimation of HRQoL and health utility can be important to evaluating the cost-effectiveness of interventions that seek to reduce morbidity and mortality due to TB.

To date, only a few studies(7, 8) have examined the HRQoL of patients being treated for TB and the trajectory of HRQoL over the course of treatment. This is particularly true in rural low-income settings, where both access to care and quality of available data are often limited. We therefore sought to describe the HRQoL of patients being treated for TB in the inpatient and outpatient settings in rural Malawi.

Methods

Study Setting & Population.

Malawi has the eleventh highest burden of HIV-associated TB in the world, with a TB incidence of 181 per 100,000 in 2018; 49% of this burden (88 per 100,000) occurred among people living with HIV. Thyolo is a rural district in southern Malawi with a population of 721,456 people in 2018.(9)(10) Between January 2014 – December 2016, we collected data on HRQoL from 12 primary health centers and one inpatient hospital in rural Thyolo District, Malawi as part of the CHEPETSA study, a cluster-randomized trial comparing 2 point-of-care TB screening strategies among newly diagnosed HIV-positive individuals (11). We enrolled consecutive adult (≥18 years old) patients, irrespective of HIV status or participation in CHEPETSA: (a) receiving outpatient treatment for active TB at the 12 CHEPETSA clinics; and (b) undergoing inpatient TB treatment at Thyolo District Hospital, the only public inpatient hospital serving the district. Criteria for inpatient admission included clinical severity (at discretion of the treating physician) or mandatory two-month admission for patients with recurrent TB to receive injectable medication. Given the limited hospital capacity and remoteness of clinics in this area, most patients with non-recurrent TB are treated entirely as outpatients. Data from medical charts were not available for this study, but the percentage of TB that was rifampin-resistant or multidrug-resistant TB in Thyolo District at the time of this study was less than 1%.(11)

Procedure.

Trained study staff conducted face-to-face interviews using a structured questionnaire including items on demographics (age and sex), socioeconomic status (education, employment, and income), TB-related characteristics (estimated dates of symptom onset and treatment initiation), and HRQoL. We measured HRQoL using the Chichewa version of the EQ-5D-3L (12); this instrument asks participants to rate their level of impairment (none, moderate, or extreme) in five dimensions: Mobility, Self-care, Usual activities, Pain/Discomfort and Anxiety/Depression. We also recorded patients' self-rated health on a 20-cm vertical visual analogue scale (VAS) with endpoints (0; 100), labeled 'the best health state you can imagine' and 'the worst health state you can imagine'. Since standards from Malawi were not available, the EQ-5D utility scores for the health states were derived using the Zimbabwean EQ-5D tariff set but we also used UK EQ-5D tariff set to compare the results. (13, 14) (15) We compared EQ-5D health utility estimates to a population reference of individuals being tested for HIV in Blantyre, Malawi, the nearest large city.(16)

Analyses.

Descriptive statistical analysis was used to describe patients' characteristics, HRQoL, and health utility estimates. Differences between categorical variables were assessed with an uncorrected chi-square test. Univariate and multivariable linear regression were used to evaluate associations with HRQoL. A set of candidate variables for the regression analyses was identified based on measured variables having known associations with HRQoL in other settings, including: (1) patient characteristics (gender, age, education, employment and income); and (2) duration from treatment initiation to the date of interview, as reported by the patient. Collinearity was assessed using variance inflation factors. Given the left-skewed nature of the EQ-5D values, we tested log Gaussian transformation and tobit censoring regression models; however, these did not materially influence our primary findings (data not shown) and are therefore not discussed further, as coefficients from the linear regression models are more interpretable. All statistical analyses were conducted using R version 3.6.2 (The R Project for Statistical Computing, Vienna Austria).

Ethical Considerations

The CHEPETSA trial is registered on ClinicalTrials.gov (NCT01450085). This study was approved by the institutional review boards of Johns Hopkins Medicine, the London School of Hygiene and Tropical Medicine, and the Malawi College of Medicine.

Results

We interviewed a total of 197 inpatients and 156 outpatients between the years of 2014 and 2106. Inpatients and outpatients did not differ substantially according to age, gender, and education (Table 1). Most patients were age 20–59 (91% of inpatients and 88% of outpatients), unemployed or working in the informal sector (75% of inpatients and 85% of outpatients), and earned weekly incomes of less than $20 (83% of inpatients and 81% of outpatients). The time between self-reported symptom onset and treatment initiation was slightly longer for outpatients (median: 3.4 months, interquartile range [IQR]: 1.7 – 5.8 months) than inpatients (median: 2.5 months, IQR: 0.8 – 4.2 months). We interviewed

outpatients and inpatients a median of three months (IQR: 2–5 months) and eight days (IQR: 4–14 days), respectively, after treatment initiation. The median self-reported length of hospitalization was 18 days (IQR: 14–59).

Inpatients consistently reported lower HRQoL than outpatients, whether measured as EQ-5D health utility (median 0.79, IQR 0.70–0.86, versus 0.84, 0.77–1) or using the VAS (55, 50–70 versus 70, 60–80). In the inpatient setting, HRQoL was not higher among those reporting longer treatment duration (0.00 per 2 weeks of treatment, 95% confidence interval [CI]: −0.02 – 0.01; see left panels in Figure 2). By contrast, the HRQoL scores of outpatients were higher among those treated for longer periods of time; for example, patients treated for 5–6 months had an estimated median EQ-5D health utility score of 1 (IQR: 0.84 – 1), compared to 0.78 (IQR: 0.70 – 0.87) among patients treated for 0–1 months (Figure 1). After adjusting for potential confounders, each two months of outpatient treatment was associated with 0.034 (95%CI: 0.012–0.057) higher EQ-5D utility score (Figure 2). This trend was not seen with VAS scores (2.2 higher per two months of treatment, 95%CI: −0.5 – 4.9). Overall, 152 of 197 (77%) inpatients and 105 of 156 (67%) outpatients reported impairment in at least one of the five EQ-5D health domains. (Figure 3) The most frequently reported impairments were in the domains of usual activities (55% of inpatients and 37% of outpatients) and pain (50% of inpatients and 33% of outpatients) while anxiety was relatively infrequent (14% inpatients and 17% outpatients). Other than time since treatment initiation among outpatients, no other measured variable was consistently and significantly associated with higher HRQoL on both EQ-5D and VAS in either the inpatient or outpatient setting (Figure 3). There was no substantial difference in the results of regression analyses and HRQoL scores trajectories over time since treatment initiation between inpatient and outpatient groups, based on the UK EQ-5D tariff.

Discussion

This cross-sectional survey of 197 inpatients and 156 outpatients being treated for TB in rural Malawi shows that HRQoL scores differ by clinical setting (inpatient vs outpatient) and duration of treatment. Inpatients consistently showed lower HRQoL scores and reported more severe health impairments compared to outpatients. Furthermore, whereas HRQoL scores were not higher among inpatients who had been treated for longer periods, HRQoL of outpatients was higher with longer treatment and was similar to the reported HRQoL of members of the general population of a nearby city who were tested for HIV (EQ-5D: 0.84, VAS: 70 among all outpatients in this study; EQ-5D: 0.84, VAS: 75 among all people tested for HIV; EQ-5D:0.86, VAS: 80 among people testing negative for HIV).(16) This description of the HRQoL trajectory over the course of TB treatment, including inpatient and outpatient treatment, can help to inform estimates of TB burden and the cost-effectiveness of interventions that aim to reduce that burden in rural Sub-Saharan Africa.

Several recent studies have measured HRQoL among people undergoing treatment for TB, but few have directly compared HRQoL over the course of treatment across different clinical settings (e.g., inpatient versus outpatient)(17), and in rural low-income settings where access to care may be particularly poor. The substantial lag time between symptom onset and treatment initiation in our data speak to limited access to care, particularly among people

who present with such severe disease as to warrant inpatient hospitalization. These patients were also the ones who had notable and persistent impairments in HRQoL. Future studies of the burden of TB morbidity should account for differential access to care under different epidemiological and economic conditions and also consider the possibility that improved access to care and/or earlier diagnosis and treatment initiation could avert a substantial burden of preventable morbidity.

As with other studies (2, 18–20), we noted a discrepancy between EQ-5D utility estimates and VAS scores, reflecting the different nature of the questions and calculations (e.g., preference weights for EQ-5D utility estimates based on time-tradeoff).(21) In this rural setting, participants reported impairments primarily in the domains of usual activities and pain; both inpatients and outpatients reported these as their primary impairments, and these were also the domains for which outpatients reported fewer impairments than inpatients (Figure 3). In many other studies (including one study in Malawi)(5, 22, 23), impairments in pain and anxiety were most frequently reported by TB patients, suggesting that residents of rural Malawi being treated for TB may experience greater impairments in usual activities and fewer impairments in anxiety than might otherwise be expected. VAS scores were also quite low in this population, particularly among inpatients (median score 55). For example, the overall EQ-5D scores in this study (median 0.83, IQR: 0.74–0.9) were higher than scores reported by patients being treated for TB in Thailand (0.69, IQR:0.57–0.77)(22) and Pakistan (0.65, range: 0.43–0.88)(24) (which may have included more severe/ hospitalized patients) and similar to scores reported in South Africa (0.8, IQR: 0.6–0.9) and the United States (0.86, range: 0.69–0.92)(8). On the other hand, the overall VAS score (median: 65, IQR: 50–80) was much lower in this setting than in other countries including Thailand (80), Brazil (74)(25), and South Africa (80).

Previous studies have consistently shown that the HRQoL of patients treated for TB is lower than that of healthy individuals; many studies have also shown that HRQoL improves during TB treatment.(5, 26) In terms of factors associated with HRQoL, some studies found associations with patients' characteristics including age(1, 22, 27), sex(28), income(26), education(28), employment(28) and ART treatment(29)/ CD4+ count(28). In contrast to these studies, we did not find that individuals being treated for TB in the outpatient setting had markedly lower HRQoL than individuals selected for HIV testing in a nearby city (16); however, this may reflect greater impairment in HRQoL in the comparator population rather than less illness in our study population. We also did not find any substantive associations between patient sociodemographic characteristics and HRQoL, consistent with some other studies (26, 30). These findings suggest that the HRQoL experience of people treated for TB in rural Malawi may be somewhat unique, in that these patients have substantial impairments in usual activities and pain, similar EQ-5D score to a local comparator population (that also reports major impairments), and similar HRQoL experiences across patient groups as defined by sociodemographic characteristics.

This study had several important limitations. We did not have access to longitudinal data and were thus unable to quantify the long-term effects of TB after treatment. Our cross-sectional design should not be interpreted as identifying causal effects. Our participants included registered patients in the only hospital and several outpatient clinics across a rural district;

our findings among inpatients are therefore likely representative of hospitalized adults in this district but may not generalize to individuals being treated for TB in urban or higher-income settings. Our ability to see differences in HRQoL over time since treatment initiation was limited among inpatients, of whom only 16% had received more than three weeks of treatment at the time of the interview. Similar to other studies using EQ-5D, scores may be limited by the ceiling effect (i.e. the score distribution tends to be skewed to the left).(1) The differences in HRQoL score between inpatients and outpatients we report might not be a direct result of improved health status by TB treatment, but could result in part from other unmeasured differences such as HIV clinical status (CD4 count or ART adherence), other underlying co-morbid conditions besides TB, or the side effects of treatment (especially as many participants were hospitalized explicitly to receive injectable therapy). Disentangling the association between delays in treatment initiation and reductions in quality of life is both important and challenging. Since patients progress in their TB disease at different rates, longer duration from symptom onset to treatment initiation may imply a slower disease course rather than a delay in care-seeking. We did not have IRB approval to access medical charts and were therefore unable to assess smear status, drug resistance status, or radiological results.

Nevertheless, our study highlights the importance and complexity of measuring and evaluating the trajectory of HRQoL over the course of TB treatment. We also illustrate the usefulness of assessing the profile of HRQoL among patients being treated for TB across different clinical settings, using different measurement tools, and across the full spectrum of treatment duration. Future studies could expand and strengthen these investigations using a longitudinal cohort design. A better understanding of HRQoL profiles can help guide better patient support that could be tailored to the specific impairments reported in this population. More comprehensively measuring different aspects of patients' well-being that are affected by disease and treatment will ultimately facilitate more effective and patient-centered public health interventions and more appropriate evaluation thereof.(5)

In conclusion, this cross-sectional study of patients being treated for TB in rural Malawi revealed consistently lower HRQoL among inpatients and evidence of higher HRQoL with increasing duration of outpatient treatment. The findings emphasize the importance of efforts to improve access to care in this highly resource-constrained setting, which may reduce the number of people who present at a late stage of disease (requiring hospitalization). They also highlight the unique HRQoL experience of patients in this rural low-income setting. Measurement of HRQoL over the course of TB treatment in this population may help to improve estimates of local TB burden, inform analyses of interventions' effectiveness and cost-effectiveness, and motivate patient-centered interventions for TB case finding and treatment support.

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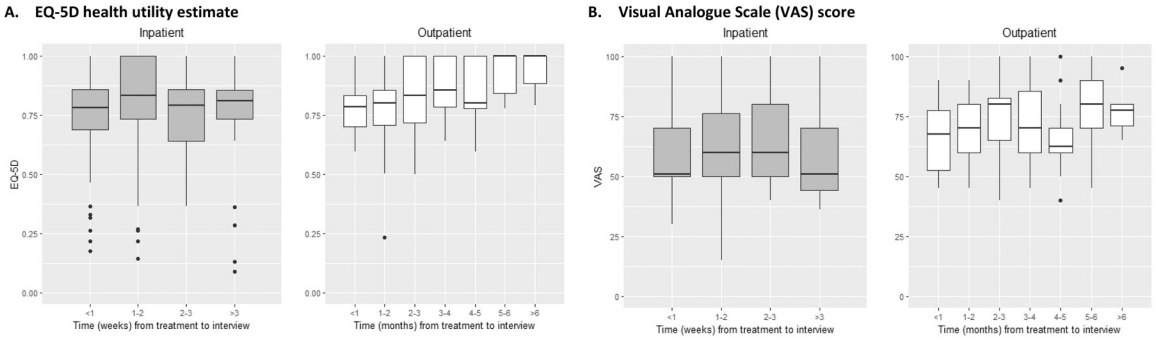

Figure 1. EQ-5D health utility scores of adults treated for tuberculosis in inpatient and outpatient settings in rural Malawi, by the duration of treatment at the time of interview.

The box plots illustrate the trajectory of health utility estimates according to the self-reported duration from treatment initiation to interview among adults in rural Malawi being treated for tuberculosis (TB) in inpatient and outpatient settings. Panel A represents EQ5D utility scores and Panel B represents VAS scores among inpatients (grey boxes on the left) and outpatients (white boxes on the right). Horizontal lines correspond to the median value, boxes to the interquartile range, whiskers to the 5th and 95th percentiles, and dots to outlying observations falling outside that range. Since inpatients generally reported a shorter duration of treatment than outpatients, inpatients were grouped by weeks from treatment initiation to interview, whereas outpatients were grouped by months.

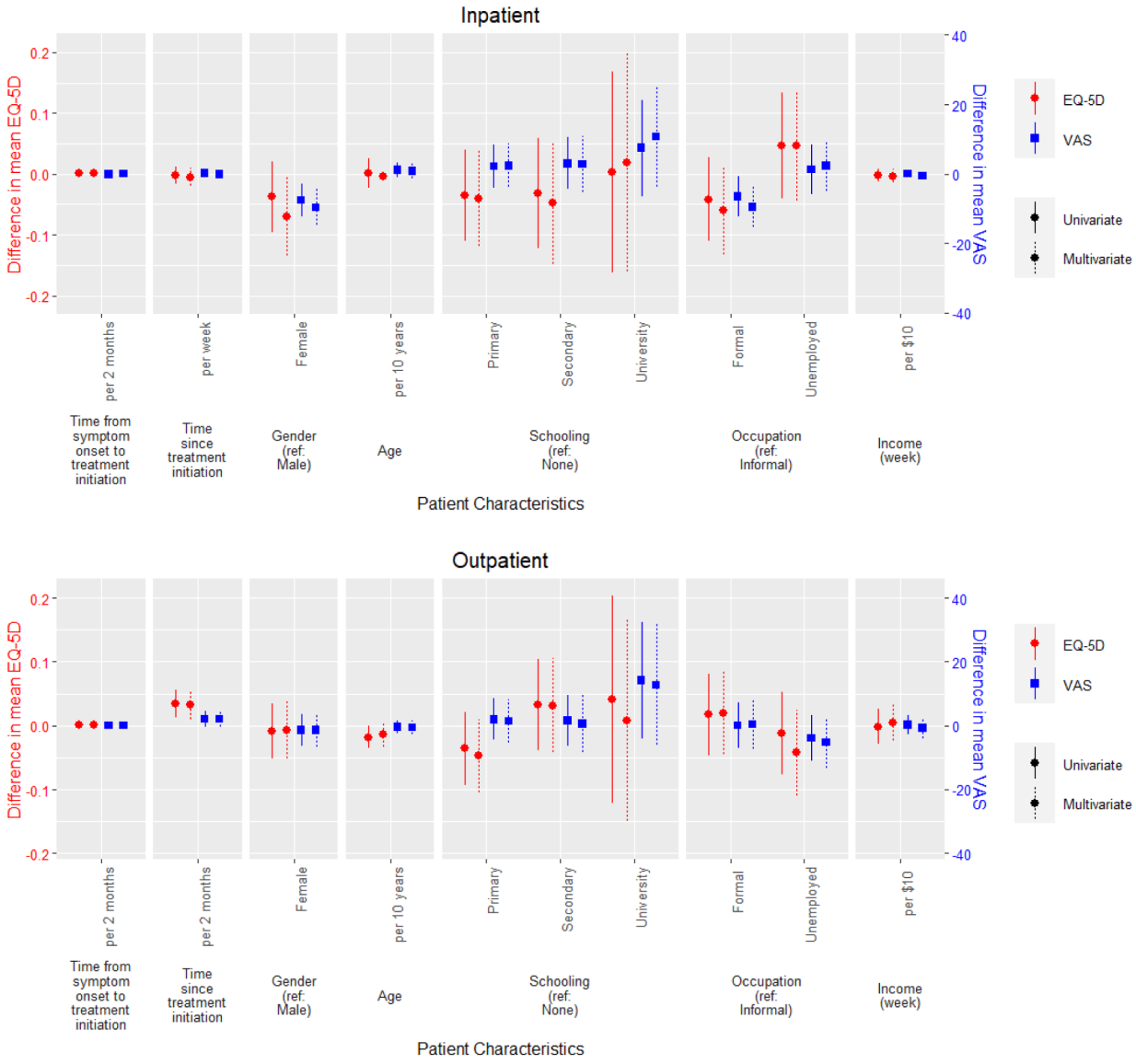

Figure 2. Associations between patient characteristics and health-related quality of life among adults being treated for tuberculosis in rural Malawi

The figure illustrates the change in the mean value of health-related quality (HRQoL) scores for inpatients and outpatients by patients' characteristics. Red bars (circular markers) represent the difference in mean EQ5D utility scores, and blue bars (rectangular markers) represent the difference in mean visual analogue scale (VAS) scores, among patients with each reported characteristic compared against the reference group listed on the x-axis. Solid lines indicate 95% confidence intervals of univariate linear regression analyses, and dashed lines indicate 95% confidence intervals of multivariable linear regression analyses. Lines that cross the horizontal line corresponding to zero difference suggest associations that are not statistically significant at the $p<0.05$ level.

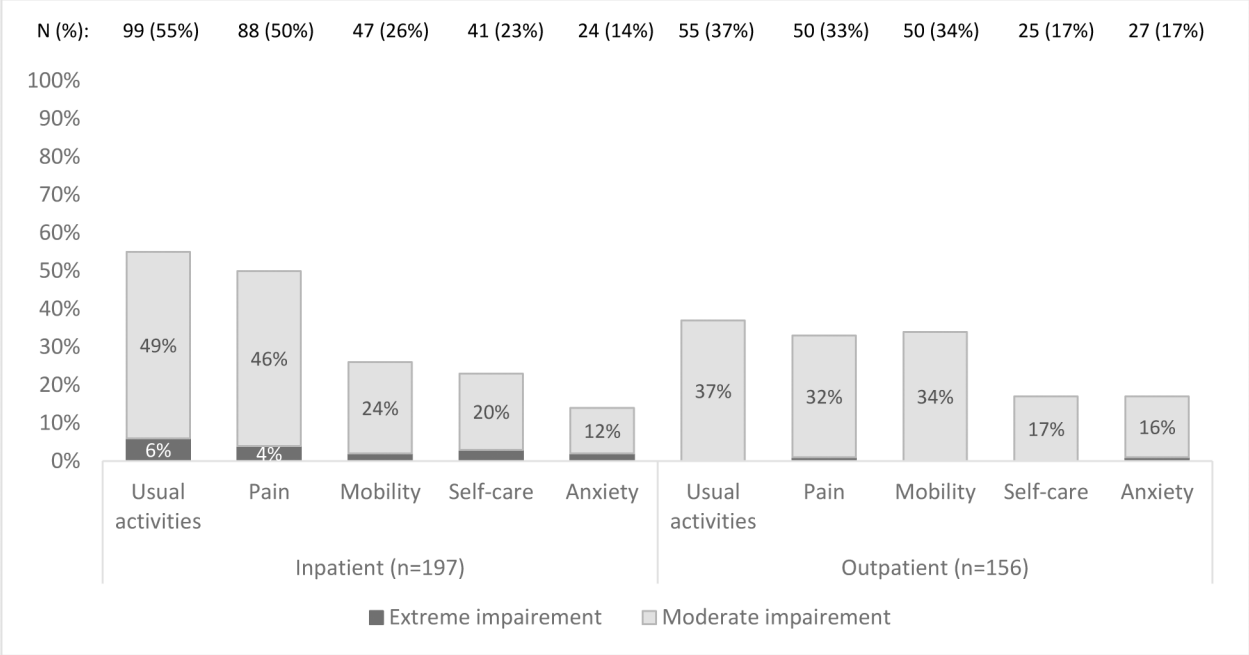

Figure 3. EQ5D Profile for adults being treated for tuberculosis in rural Malawi.

Grey bars denote the percentage of patients reporting moderate impairment in each of the five EQ-5D domains, and black bars denote those reporting severe impairment. The numbers above the bars represent the total number (a percentage) of patients reporting at least moderate disability in each domain.

Table 1.

Characteristics of patients being treated for tuberculosis in the inpatient and outpatient setting in rural Thyolo District, Malawi

		Inpatient (n=197)	Outpatient (n=156)
Gender	Male	93 (47%)	82 (53%)
Age	0–19	8 (4%)	8 (5%)
	20–39	131 (67%)	98 (63%)
	40–59	47 (24%)	39 (25%)
	>60	11 (6%)	10 (6%)
Education	None	41 (21%)	29 (19%)
	Primary	107 (54%)	96 (62%)
	Secondary	42 (22%)	28 (18%)
	University or higher	7 (4%)	3 (2%)
Occupation	Unemployed	25 (13%)	19 (12%)
	Informal[a]	121 (62%)	112 (73%)
	Formal (Gov't/Private)	49 (25%)	22 (14%)
Income (weekly income in 2018 US dollars)	$0-$9	128 (65%)	50 (33%)
	$10-$19	33 (17%)	73 (48%)
	$20-$29	10 (5%)	23 (15%)
	>$30	26 (13%)	7 (5%)
First TB symptom noticed	Cough	100 (51%)	88 (56%)
	Night sweats	38 (19%)	26 (17%)
	Fever	25 (13%)	19 (12%)
	Weight loss	30 (15%)	17 (11%)
Time from symptom onset to interview (months)	1–2	118 (60%)	32 (21%)
	3–4	52 (26%)	71 (46%)
	5–6	17 (9%)	39 (25%)
	>6	10 (5%)	14 (9%)
Time from treatment initiation to interview (weeks)	<1	97 (49%)	N/A
	1–1.9	56 (28%)	
	2–2.9	13 (7%)	
	≥3	31 (16%)	
Time from treatment initiation to interview (months)	1–2	N/A	39 (25%)
	3–4		68 (44%)
	5–6		40 (26%)
	>6		8 (5%)

[a]Informal occupation includes farmer, domestic worker, self-employed; Unemployed includes housewife, student, and unemployed; Employed include formal or government public sector.