Drug adherence and efficacy of smear microscopy in the diagnosis of pulmonary tuberculosis after 2 months of medication in North-western Tanzania

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A B S T R A C T

Objectives: The study aimed at assessing the Tuberculosis (TB) medication adherence level and the efficacy of smear microscopy in the diagnosing pulmonary TB at month 2.
Methods: A prospective study was conducted at the four sites located in the Northern-western Tanzania. New smear positive, pulmonary TB patients were followed up and their adherence to TB medication assessed after 2 months of the treatment. In addition, the acid fast bacilli (AFB) smear microscopy was performed after 2 and 5 months of the treatment. All smear positive samples were subjected to geneXpert (MTB/RIF) assay and culture on the Lowenstein Jensen (LJ) media.
Results: A total of 331 smear positive, newly diagnosed patients with pulmonary TB were enrolled. The median age was 36 [Interquartile range (IQR): 28–45] years and males formed the slightly majority, 187 (56.5%) of the participants. A total of 105 (31.7%) patients were infected with HIV. Out of 331 patients, 36 (10.9%) were still AFB smear positive at the end of two month. Of these 19 (52.8%) were positive on GeneXpert MTB RIF and none was Rifampicin resistant. Of note, only 13 (31.1%) were culture positive (viable). None of the patients was positive at month 5. Poor adherence to TB medications in the first 2 months of treatment was observed in 56/331 (16.9%) [95% CI = 12.9–21.0] of the patients.
Conclusion: Over two thirds of smear positive patients are wrongly put in one month extension of the intensive phase treatment; this may cause increased costs and drug toxicity. Culture should be advocated to confirm smear positivity after 2 months of medications. TB treatment drug adherence in our setting is good and is associated with successful cure. No multidrug resistant tuberculosis (MDR-TB) was observed. Continued surveillance and emphasizing of TB drug adherence should be kept upbeat in order to control tuberculosis in developing countries.

Introduction

Tuberculosis (TB) is a major public health problem. The number of TB cases with poor outcome (failure, relapse, death) following first line TB treatment is increasing in the sub-Saharan Africa (Dye et al., 2008; World Health Organization, 2016). The MDR-TB globally is reported to be 3.9% and 21.0% among newly diagnosed and previously treated cases respectively (World Health Organization, 2016). In Tanzania 1.1% of all new TB cases are MDR-TB (Chonde et al., 2010). Furthermore, unfavourable treatment outcomes as high as 14.2% has been reported in TB re-treatment cases (Ministry of Health and Social Welfare, 2011) and the treatment success rate for new and relapse cases TB was 90% (World Health Organization, 2016).

Optimal adherence to TB treatment is a key to successful outcome. Several factors such as the patient's related and health

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care related factors have been found to contribute to MDR-TB. There is paucity of data regarding drug adherence and factors associated with poor adherence to TB medications in North-western Tanzania. Most studies have documented that poor adherence is a key parameter that can predict poor treatment outcome (Hirpa et al., 2013) and there is a clear link between poor adherence and MDR-TB. Therefore it is important to follow up patients taking anti-tuberculosis medication to ensure optimal adherence in order to control TB. To achieve this, the WHO recommends all countries to practice direct observed therapy strategy (DOTS). The current study determined the efficacy of smear microscopy in the detection of pulmonary TB after 2 months of treatment and assess the level of TB drug adherence and associated factors. These findings are useful for designing interventions to promote optimal adherence to anti-TB treatment so as to reduce the magnitude of MDR-TB in this setting. Furthermore, findings from this study provide proper explanation for acid fast bacilli (AFB) positive follow up regarding their viability.

Patients, materials and methods

Study site and population

The study was conducted in the city of Mwanza, North-western Tanzania. The city has a population of >0.7 million and TB and HIV prevalence of 9.8% and 7.2% respectively (National Bureau of Statistics (NBS) and Office of Chief Government Statistician (OCGS) Zanzibar, 2013; Tanzania Commission for AIDS (TACAIDS) et al., 2013; Ministry of Health and Social Welfare, 2014). The target population was newly pulmonary TB patients who were about to start anti-TB. The target population was sampled from presumptive TB patients attending four clinics, namely the Bugando Medical Centre, Sekou-Toure Regional Hospital, Nyamagana District Hospital and Buzuruga.

Study design and duration

This was a prospective cohort study that was conducted among smear positive pulmonary tuberculosis patients. Study was conducted from February 2015 to March 2016. Patients starting TB treatment were assessed for overall drug adherence after 2 months of medication (intensive phase treatment). The TB drug adherence was assessed using TB adherence chart from the TB clinic. For the intensive phase treatment, patients had to take 56 doses, and the patients who missed less than 5 doses during the intensive phase treatment were categorized to have the overall TB drug adherence of >90% (good). Patients with the adherence ≤90% (poor) missed 5 or more doses during the intensive phase treatment (Awofeso, 2008; Woimo et al., 2017).

Recruitment procedure

We recruited consecutively all newly diagnosed smear positive TB patients attending TB clinics at four different sites in the city of Mwanza. We recruited and followed up for 5 months patients aged ≥18 years and residence of Mwanza city.

Data collection

A structured questionnaire was administered; socio-demographic data and clinical characteristics were collected. Information collected included age, gender, socio-economic status, HIV status, past medical, co-morbid conditions, weight and height. Adherence to TB medications was verified through TB clinic cards.

Specimen collection and Laboratory analyses

Sputum for acid fast bacilli testing was collected at baseline and after 2, and 5 months. Patients who were still positive after 2 months of the treatment had to continue with the initial phase treatment for one month and thereafter another sputum sample was collected for additional smear microscopy. The sputum samples were processed and interpreted in accordance with the NTLP and WHO guidelines and then subjected to geneXpert (MTB/RIF) assay. Additional sputum samples were processed and cultured on the Lowenstein Jensen (LJ) media as described previously (Kidenya et al., 2013). Blood samples were collected for determining HIV status using two rapid tests done serially as per National AIDS Control Programme Guidelines (United Republic of Tanzania, 2016). The Bugando Medical Centre TB laboratory was used to run all laboratory procedures. At regular intervals, all specimens collected were packed with ice and at each end of the working hours they were transported to the Bugando Medical Centre TB laboratory for further laboratory analyses.

Data management and analysis

Data collected were double entered in EpiData software and then transferred to the STATA for cleaning, completeness and analysis. The outcomes of interest were level of TB medication adherence after 2 months of medication. Descriptive statistics were analyzed to describe the distribution of poor TB medication adherence across relevant strata. Univariate followed by multivariate logistic regression analyses were done to determine potential predictors of poor TB medication adherence. Potential predictors included age, gender, employment status, education level, marital status, being positive at month 2 and HIV status. A final model of multivariate logistic regression analysis was performed with all the predictors with a p-value <0.2 in the univariate analysis controlled for age and sex. Odds ratios with 95% confidence interval (CI) were computed. Factors with a p-value of <0.05 were considered to be of statistical significance.

Quality assurance

Standard operating procedures (SOPs) were developed and strictly followed in all study sites. Prior to data collection, research assistants from the participating sites were trained on the SOPs to promote accuracy and consistency of the study procedures. This was strengthened by regular supportive supervision during the course of the study. Filled forms were examined for completeness and correctness.

Ethical considerations

The ethical approval was sought from the Joint Bugando Medical Centre/Catholic University of Health and Allied Sciences Ethics Review Board. Permission to conduct the study was sought from local authorities where the study was implemented. Information about the purpose of the study, confidentiality, willingness to participate and decision to withdraw was provided to all invitees. Written or thumbprint informed consent was obtained before enrolment.

Results

A total of 331 newly diagnosed pulmonary TB patients were enrolled from 4 sites in the city of Mwanza. The median age was 36 [IQR: 28–45] years and number of males was 187 (56.5%). There were 105 (31.7%) patients who were infected with HIV. Of 331