

Multidrug resistant tuberculosis conversion rate after initiation on standardised short regimen: Retrospective study

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Abstract

Background Multi Drug Resistance (MDR) Tuberculosis (TB) is a global risk. Several suboptimal results were noticed which resulted to introduction of a standardised short regimen of 9-12 to optimise favourable outcomes. This new intervention has not been evaluated for effectiveness since inception in the Eastern Cape Province. **Objective:** To evaluate multidrug resistant tuberculosis conversion rate following initiation on short regimen.

Methods A retrospective study using a descriptive design was used to collect data from conveniently sampled 71 documents at Nkqubela TB and Duncan Village Day hospitals. Data were collected using a self-designed structured questionnaire and analysed using Statistical Packages for Social Sciences (SPSS) version 24.

Results Sixteen percent (n=19) of 71 records had no consecutive smear results. Demographic findings showed that the majority of the affected age group was between the ages of 36-45 years in both genders (34.7%, n=47) with males being highly affected more than females. The majority of participants were unemployed (51.7%), people living with HIV/AIDS (62.7%), use alcohol and smoking. Conversion rate was 68, 5%.

Conclusion There is a need to review EDR web to accommodate sputum results irrespective of TB treatment start date. An extensive, ongoing counselling, support and health education needs to be provided for patients and families until the completion of treatment to emphasize the importance of monthly sputum collection and importance of treatment adherence. Clinicians need to strengthen their counselling and education skills. The introduction of short regimen to treat MDR has shown an improved sputum conversion rate in RR/MDR TB.

Introduction

Multidrug-resistant tuberculosis (MDR-TB) is defined as resistance to at least two key first-line drugs: isoniazid and rifampicin ^[1]. This MDR-TB treatment is a lengthy regimen using mainly bacteriostatic which are too many, less effective, more toxic drugs, and thus is poorly tolerated by clients. Consequently, adherence is extremely difficult especially to infected clients who stay very far from the clinic and unemployed. Tuberculosis is an epidemic disease and it remains a global challenge. Tuberculosis is regarded as the tenth leading cause of death in the world, with estimated 580 000 new MDR cases ^[2]. Africa is known to be carrying the greatest burden of TB and accounts for the largest proportion of TB/HIV cases worldwide ^[3,4]. Patients diagnosed with RR/MDR-TB are treated for 18-24 months depending on the conversion date. Short regimen of 9-12 months was recommended in May 2016 ^[5] and introduced in January 2017 in South Africa. The short regimen was recommended to shorten the time for TB treatment and to reduce lost to follow up clients on treatment. This study was conducted to examine RR/MDR-TB sputum outcomes after the introduction of a short regimen. Sputum conversion plays an important role in the management of tuberculosis because it determines response to TB treatment ^[6,7].

Prognosis of the patient is determined by negativity or positivity of the sputum results. The overall duration for the current treatment regimen for MDR-TB is 20 months or more, requiring daily administration of drugs that are more toxic and less effective than those used to treat drug-susceptible TB and are costly [8,9]. Unfavourable outcomes such as non-conversion of sputum culture are often produced at the end of intensive phase. Sputum conversion within the first two months serves as the predictor of treatment success in MDR TB patients.

The chances of achieving treatment success or even sputum and culture conversion are largely suboptimal in MDR/XDR-TB clients due to contributory factors. Factors such as use of alcohol and smoking affect sputum conversion during management of MDR/XDR-TB [10,11,12]. Therefore, with use of alcohol and smoking sputum conversion and good response to treatment is less likely.

Therefore, this study was conducted to assess multidrug resistant tuberculosis conversion rate following initiation of short regimen between January 2017 and July 2017.

Methodology

Research design, setting and population

A retrospective study was done using a quantitative descriptive design to extract data from clients' records who were diagnosed, registered and initiated on MDR TB treatment between January 2017 and July 2017. The study was conducted at Nkqubela TB hospital and Duncan Village Day Hospital both situated at Buffalo City Municipality Metropolitan. Nkqubela TB Hospital is a centralised site and is regarded as the Centre of Excellence in the management of drug resistant tuberculosis whereas Duncan Village Day Hospital is one of the decentralised sites. Population comprised of all patient's records diagnosed, registered and initiated on multi-drug resistant TB treatment. A self-designed structured questionnaire was used to extract information from conveniently sampled 71 records. Inclusion criteria encompassed records of RR/MDR-TB participants who were registered and initiated treatment at Nkqubela TB and Duncan Village Day Hospitals between the period of January 2017 and July 2017.

Inclusion and exclusion criteria

The inclusion criteria encompassed RR/MDR TB participants who were registered and initiated treatment for the first time at Nkqubela TB and Duncan Village Day Hospitals between the period of 26 January 2017 and 31 July 2017. RR/MDR TB participants who are 12 years of age and older and those who have uncomplicated extra-pulmonary TB.

Exclusion criteria involved participants who were not registered and initiated RR/MDR-TB treatment at Nkqubela TB and Duncan Village Day Hospitals and those having complicated extra-pulmonary RR/MDR TB such as disseminated TB, TB of the abdomen.

Data collection tool

A self-made structured data extraction tool was used to extract secondary data from patient files. The instrument consisted of discrete and continuous data. Variables that were extracted were discrete, dichotomous, continuous, ordinal and nominal. Closed questions such as Yes or no and multiple choice questions. The tool entailed the following sections:

Section A: focuses on demographic data.

Section B: entails socio-economic data.

Section C: deals with medical and patient history.

Section D: consists of TB history and diagnosis.

Section E: focuses on TB treatment

Section F: deals with sputum results and TB outcome.

Validity and reliability

The researcher conducted two different pilot studies. The first pilot study was done to 2 patient files and there were issues that needed to be addressed. After reconstructing the data extraction tool, a second pilot study was done to three patient files and it produced desirable results. Files used for pilot study were not used in the study. Two research assistants were trained on the data extraction tool for five working days. This enabled research assistants to understand the content of the tool and ask questions where possible. The same data extraction tool was used for the entire study to increase reliability. Secondary data that already existed in the patient files were used.

ETHICAL CONSIDERATION

Ethical approval was obtained from the University of Fort Hare Research Ethics Committee (Ethical Clearance Number MUP101SSOM01), Department of Health Research Ethics Committee, BCM Health District and two public hospitals.

DATA ANALYSIS

Unique codes were used to ensure anonymity. Data analysis was performed using SPSS version 24.0. MDRTB smear conversion were examined between January and July 2018 at the end of 12 months.

Results

All records of clients diagnosed and started treatment between January to July 2017 were retrieved for analysis. The ages of the participants were ranging between 14 and 89 years with mean age of 41 years, median of 40 years and a mode of 37 years. The age group of 36-45 years was the most affected (34.7%). Males (n=47) were more affected than females (n=24). The majority of affected racial group

was the Africans with 98.3% of the participants. Many participants were from Buffalo City Metropolitan (52, 5%) with Bisho/KWT having high number of participants (27) in the district. Fifty two percent of the participants (n=61) were unemployed. Fifty-one records (72%) showed that the clients were HIV positive and 20 (28%) were HIV negative. Table 1 presents period at which participants had smear conversion.

Table 1: Distribution of smear conversion

Data element	No. converted (%)
Conversion rate in month 1-2	39 (33, 1%)
Conversion rate in month 3-4	8 (5, 1%)
Conversion rate in month 5-6	5 (2, 5%)
No consecutive sputa	19 (16, 1%)
Total	71 (100%)

Out of 71 participants, 48 (68%) converted within month 1 and 6 of treatment. Nineteen participants (16, 1%) did not have consecutive sputa results during the intensive phase.

Discussion

Sputum conversion within the first two months serves as the predictor of treatment success in MDR-TB patients [6, 13]. In the first 4 months of the treatment, conversion rate achieved was 38% and is sub-optimal. The factors that could have contributed to this low conversion rate were smoking and alcohol consumption especially in males [14]. Alcohol consumption and smoking have a negative effect in treatment adherence and reduce smear conversion rate at the correct time [15,16].

Another contributory factor was unemployment, which was associated with non-adherence to treatment due to lack of transport fare to go to the clinic [17,18].

According to medical history retrieved from patient files, 80% (n=94) of the participants had other comorbidities and 62, 7% were HIV positive. The mean viral load for all HIV positive participants was between 203183, 0 and 651888, 7 with mean CD4 count of 194, 5- 202, 4. The high number of HIV positive participants (n=74) proved the fact that a weakened immune system has a much greater risk of suffering from TB and if not on ART and the mortality rate ranges between 91 and 100% [19,20,21]. Poor HIV management increases the risk of getting infected with opportunistic infections. Data on comorbidities could not be obtained from two missing patient files.

There is a difference in monitoring TB treatment progress in conventional and short regimens. Conventional regimen is monitored by TB culture results whereas short regimen is monitored by TB smear results. TB culture results predict therapeutic efficacy in MDR-TB treatment as [6] have alluded and in both conventional and short regimen TB culture determines TB treatment outcome. [6] further state that sputum conversion within the first two months serves as the predictor of treatment success in MDR-TB patients. [22] states that the chances of achieving smear and culture conversion are largely suboptimal in MDR cases. The studies conducted by Damien Foundation on a short regimen over a period of 12 years showed that the short regimen achieved sputum culture negativity at the end of the intensive phase of 4 months [5,23]. Sputum smear conversion is a very important factor to predict treatment outcome [24]. Earlier conversion, especially in the first 3 months after initiation of treatment increases the likelihood of successful outcome. In this study, out of 71 participants, 48 (68%) converted within month one and six of treatment, which is a positive predictor that these clients will be cured at 9 months.

Smear conversion rate of 68.5% despite contributory factors mentioned by [6] have made a great predictor of treatment outcome. Therefore, clients on TB treatment need to be educated on use of alcohol and smoking. Clinicians need to strengthen their counselling skills regarding education of the clients on admission. The number of participants who converted might have increased if all participants complied with monthly sputum collection as indicated by Department of Health (2018), out of 19 participants who had no consecutive smear results, 6 of them had a positive outcome [25,26]. Therefore, clients need to be educated about the importance of monthly producing of sputum for early prediction of the outcome.

Conclusions And Implications For Health Policy

Standardised short regimen for treatment MDRTB has shown promising and positive results. The results of the study has shown high success rate if adhered to the guidelines. Conversion rate can be affected by many factors including and not limited to alcohol use, smoking and non-producing of smear when needed for testing. There is a need to review EDR web to accommodate sputum results irrespective of TB treatment start date. An extensive, ongoing counselling, support and health education needs to be provided to patients and families until the completion of treatment to emphasize the importance of monthly sputum collection, duration of treatment, reporting of adverse drug effects and importance of treatment adherence. Clinicians need to strengthen their counselling and education skills to ensure that the clients are well informed. The introduction of short regimen to treat MDR has shown an improved sputum smear conversion rate in RR/MDR TB.

Limitations Of The Study

The researcher was unable to assess perceptions and experiences of the participants due the quantitative method used. Only two institutions that register and initiate drug resistant TB treatment were studied, therefore generalizability will be limited to BCM. The study could not enrol many participants due to time constraints and the duration of treatment the participants had to take.

Declarations

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CONFLICT OF INTEREST

The authors declare that they have no competing interest, financial or otherwise

Author Contributions

NS carried out the design, data collection, participated in data analysis and drafted the manuscript. WM and NGM participated in data analysis and helped to draft the manuscript. All authors read and approved the final manuscript.

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