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Research Article

Assessment of Adherence to Direct Observed Treatment, Short Course and Factor Affecting Patient's Adherence to Direct Observed Treatment, Short Course among Tuberculosis Patients in Dilla University Hospital

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Abstract

Background: Tuberculosis (TB) is a major contributor to global burden of disease and has received considerable attention in recent year, particularly in low- and middle-income countries where it is closely associated with HIV/AIDS. Defaulting from treatment remains challenge for most TB control program, it may increase the risk of drug resistance, relapse and prolonged infectiousness. Poor adherence to treatment is common despite various intervention aimed at improving treatment completion. Lack of comprehensive and holistic understanding of barrier and facilitator of treatment adherence is a major obstacle to finding effective solution.

Objective: Assessment of adherence to DOTS and factor affecting patients' adherence to DOTS among TB patients in DURH.

Methods: Cross-sectional study will be carried out from April 1- May30, 2008e.c to assess factors that affects adherence to DOTS among TB patients. A total of 80 TB patients will be used no sample size determination and sampling technique is required because all TB patients attending the health facility for DOTS service during data collection period and fulfilling inclusion criteria will be included in the study. Data will be collected using structured questionnaires. Data will be analyzed and processed by using SPSS version 20. The result will be present by using frequency, tables, and graphs.

Work plan and budget breakdown: This study will be done from April1-May30/2008 E.c; and a total budget of 13000.00 birr will be required to conduct this study.

Keywords: Tuberculosis; Adherence to Direct Observed therapy; DOTS strategy; DURH

Introduction

Background information

Tuberculosis (TB) is one of the leading causes of death from infectious disease worldwide and it kills around 1.7 million people each year. TB can be successfully treated but the treatment course is long (at least 6 month). Non-adherence or defaulting from treatment may increase the risk of drug resistance, relapse and death, and may prolong infectiousness [1]. In 1995 the world health organization (WHO), set up direct observed treatment (DOT) as international strategy for TB control. One of the main elements of

DOTS involves the use of standard course of drug treatment with recommendation that trained observers watch people take their treatment. This step prevents people from failing to complete their course of treatment and the world organization set a target level of 85% for treatment success. However, people do often have problem sticking to treatment and the reasons for this are not clearly understood. Factors such as access to care and personal, social and economical situations might affect whether an individual sticks to their prescribed treatment [2].

In resource constrain setting where the health care services are not well developed, delayed presentation for treatment and defaulting from treatment are the two major challenges that TB program face [3]. The idea of DOT evolves from the need to improve treatment adherence. However, the role of DOTS in maintaining treatment adherence appears to be surrounded by controversies. Reports from many countries favor DOT as a key component in DOTS strategy, a global strategy recommended by the world organization for the prevention and control of TB [4], ensuring successful treatment supervision of drug intake [5].

TB continues to be a major public health problem in Ethiopia which ranks 7th by estimated number of cases among the 22 high burden countries [6]. Before the introduction of DOTS in Ethiopia, 82% of TB patients were reported to have failed to complete treatment [7]. DOTS In southern region of Ethiopia was introduced in 1996. An early study on the impact of DOTS in the region reported significantly declining trend in treatment non-completion from 38% to 18% over six years during 1994-2000 [8].

However, one in five patient still continued to default from treatment, and most of the factors associated with treatment non-completion, apart from the patient age and level of education, are those related to physical access to health-care services: distance from home to treatment center, rural residence, and a need to use public transport for ambulatory care because of low socio-economic status, displacement due to famine, drought and war, HIV/AIDS, and patients satisfaction with the care provided may influence treatment adherence. In an effort to reach the global target of 85% treatment success, it was completing to identify, describe, and deal with factors determining treatment adherence to DOTS. The aim of this study is to identify factors that affects patient's adherence to DOTS in DURH.

Statement of the problem

Globally, DOT, short course strategy has been recognized as the best cost-effective approach to TB control, to reduce the disease burden and to reduce the spread of infection. DOTS are the only means by which cure can also be ensured. The challenge is to expand the coverage of DOTS so that the most patients get effective treatment [8].

In many countries globally the adoption of DOTS has been associated with reduced rate of treatment failure, relapse and drug resistance. However, its impact in reducing TB incidence has been limited by non-compliance to DOT, which occurs when patients do not turn up for treatment as the facility, or community DOT point [9]. In countries where DOT has little impact on TB control, poor or non-compliance to self-administered TB treatment is common and has been as an important cause of failure of initial treatment lead to relapse [10]. High defaulter rate observed and documented in Namibia [11] are of concern, especially when it is known that defaulters are a harbinger for drug resistance TB(DR-TB) [12]. While few studies on the factor associated with poor compliance and defaulting have been carried out globally and sub-Saharan Africa [13].

For the last decade (1999-2008), Ethiopia registered a total of 372,427 new smear positive TB cases and 1,166,863 new all forms of TB cases. Though these cases were registered, case detection rate (CDR) remained within the range of 31-38% for the last 10 years. Whereas the TSR of smear positive TB patients had increased steadily up to 84% during the same period, only 1% of the global target [14]. The HIV pandemic presents a massive challenge to the control of TB at all levels. The synergy between TB and HIV/AIDS is strong. In high HIV prevalence TB is the leading cause of morbidity and mortality, and HIV is driving the TB epidemic in many countries, especially in sub-Saharan Africa [15]. WHO estimated that three million people had both HIV and TB infection in 1990 of which 78% occurring in Africa. This association is responsible for fueling of the incidence of TB [16]. In 2004, Ethiopia started TB/HIV collaborative activities. According to the data from the routine report, the co-infection rate of TB/HIV in Ethiopia is declining from 31% in 2007 to 20% in 2009 whereas, in Addis ababa,2008/09 performance TB/HIV co-infection rate was 33% [17].

MDR-TB is manmade problem, during the 1990s', it emerged as a treat to TB control [18]. Approximately among 440,000 cases of MDR-TB that co-occurred in 2008; only 7% were identified and reported by WHO in 2006 of these cases, only a fifth was treated according to WHO standards [19]. In Ethiopia, a study conducted from 1994 to 1995(n=338) in Hariri region showed that the overall prevalence of resistance to one or more anti-TB was 37.3%, initial and acquired resistance were 32.5% and 51.2% respectively. MDR was detected in 3.5% of cases who had previously history of treatment [20]. The study conducted from 1984-2001, in Ethiopia, showed that the initial resistance to isoniazid rages from 2%-21% and initial resistance to streptomycin ranges from 2-20%. MDR-TB was also reported in about 1.2% of new and 12% of re-treatment cases [21]. Inadequate, incomplete treatment and poor treatment adherence to MDR-TB drugs have led to a newer form of drug resistance known as extensively drug resistance tuberculosis (XDR/TB) [22].

IN 2008, XDR-TB reported as many as 49 countries. In 2007, two countries have confirmed XDR-TB cases in Africa: south Africa (approximately 391 cases) and Mozambique (two cases). However, there is no official report of XDR-TB in Ethiopia [23]. The best way to ensure adherence to treatment and there by diminished the risk of transmission, relapse/reactivation and drug resistances is for health care worker to monitor patients each dose of anti TB medication [24] DOT considered to be the most effective strategy available for controlling the spread of TB (WHO 2005a) [25].

Literature Review

Tuberculosis control program in the world has developed between 1948 and 1963 (the classical TB control periods), the new realistic TB control program had been launched in 1964 (the realistic TB control period,1964-1990). However, TB did not decrease as expected, and the simple and clear TB control program we aiming at 85% or more cure rate, later by DOTS strategy (DOTS period,1991-1999) and to expand and strengthen TB control program more and more, the stop-TB partnership has been started in 2000 (the stop-TB period,2000) [28].

The global detection rate of new smear positive cases by DOTS programs increased from 11% in 1995 -45%in 2003 and could reached 60% by 2005. More than 17 million patients were treated through DOT program between 1994 and 2003, with an overall treatment success rate of more than 80% since 1988. In 2003 an overall reported treatment success was 82% [29]. MDR-TB treatment requires the use of second line drug that are lon complex and costly and has a considerable rate of adverse effect than first line drug [30]. Drug resistance exists in most African countries as a result of under investment in basic control; poor management of anti-TB drugs and virtual absence of infection control measures [31]. The emergence of DR-TB presents significant challenge to global TB control with an increase in incident cases reaching 489,000 MDR-TB cases by 2006, representing a 65% increase since 2000 [32]. Research has shown that failure to adhere to principle of TB control causes the development of almost all the DR-TB, and poor or non-compliance to TB treatment is the main predisposing factor for an individual to develop DR-TB. This leads to treatment failure and subsequently may lead to death and further spread of DR-TB [33].

A study in turkey in 2005 to assess patient's adherence to TB treatment revealed that a higher rate of adherence was observed among female than males (79.2 versus 58.4%, respectively), older patients were more non-adherence. The adherence rate in non-smoker was significantly higher than that of smokers (81.4 and 52.4%, respectively), patients with pulmonary TB (65%), while patients with extra-pulmonary TB had the lowest adherence rate (45.5%). The presence of cough was significantly associated with adherence. A significantly higher adherence rate was observed in patients with hemoptysis [34].

A study conducted on barriers to utilization of public sector TB service In India, revealed that, out of 4310 patients with TB were 16 years of age or older. From person utilizing RNTCP services, about one-third is women. Among the reason for not completing the process of diagnosis of TB, health provider related barriers were cited most frequently (45.9), followed by improvement in symptoms. Health provider related barriers were also cited most frequently (40.4%) by those who had completed the process of diagnosis but did not start treatment in the RNTCP facility. On multi-variate analysis, the odds of not completing the treatment of TB were significantly higher for men, those who were ever married, those who were not informed that TB was curable, those who were not informed of the duration of treatment at the time of starting treatment, those who were dissatisfied with the DOTS provider, and those who had health facility staff had as the DOTS provider compared with those who had an health worker. Medicine related barriers were cited most frequently by patients who had defaulted in the intensive (37.1%) or continuation (23.1%) phases of treatment. study suggested the need to adopt a patient centered approach to improve utilization of the RNTCP services [35].

A study conducted on the treatment compliance in DOTS for TB, revealed that 93 % of study population was compliant to the DOT. The traditional risk factors for non-compliance like socio-demographic factors, timing, travel, cost of investigation and cost of therapy and long waiting period; were not major hurdles for treatment adherence. The toxicity of drugs was the major reason for defaulting from treatment and compliance of DOT was significantly high among those who have good knowledge about various aspects of disease. Still major hurdle is the inadequate health education [36]. In the Malaysian study, cost and time of traveling to the treatment center were major contributory factor associated with compliance to treatment, as a non-compliance patients paid significantly more for transport than those compliant [37]. A prospective cohort study in southern Ethiopia to determine factor predicting treatment adherence among smear positive pulmonary TB patients found that among 404 TB patients on treatment ,20%defaulted from treatment. In addition 91% of all treatment interruption occurred in the continuation phase, when the patient felt better and had higher cost of transport to a treatment facility [38].

A study conducted among patients with TB on the DOT regimen in jimma zone to determine rate of defaulting and factors associated with it, showed that overall rate of defaulting was 6.7%.the default rate from the DOTS regimen was found to be quite low when compared to the rate of defaulting from the standard regimen in jimma zone. Socio-economic factors including distance of patient's residence from the health institution, lack of money for paying

transportation and poor awareness about the disease were the major reason contributing to poor compliance and defaulting [39].

The study interviewed health workers and Tb patients (male and female) also concluded that stigma and discrimination of TB and HIV patients result I patients delaying seeking testing and treatment and thus poor health outcome. Stigma therefore may result in delays in seeking treatment or taking treatment consistently and correctly. In most African society, TB and HIV are associated with immoral behaviors and patients suffering from this condition would be hesitant to disclose their status to their family members, a situation which may result in this patient not complying with their treatment as they do not want to be seen taking the medicines [40].

Alcohol and substance abuse have often been cited as a reason for poor compliance to medication in general. The altered behavior under the influence of alcohol and other substance is believed to be the reason for such observations. When one is under the influence of alcohol, one is likely to forget to take the medicine, and even if not the chance of developing side effects that may subsequently lead to poor compliance are high [41].

A study conducted among patients registered at the Addis Ababa TB center in Ethiopia to determine the rate of defaulting from treatment and factors associated with it, a high rate of defaulting,82% was found. The rate of defaulting were higher in males, in the older age group and in those living near to the TB centers. Social problems and feeling of improvement were the top two reasons for patients to default. Inadequate knowledge, low educational level, nearer distance and negative attitude toward the TB center were found to be statistically significant predictors for defaulting $p<0.0001$, $p<0.001$,$p<0.001$,and $p<0.05$ respectively [42].

Significant of the Study

Correct treatment of tuberculosis aims at curing the patient, interrupting transmission of tuberculosis to other persons and preventing bacilli from becoming drug resistant. These aims are not achieved in many regions of the world even when anti tuberculosis drugs are available [27]. The main reasons are death of the patients during treatment, default before the scheduled end of treatment or resistance to the drugs prescribed.

Ethiopia ranks 15th of high MDR-TB countries with more than 500 estimated MDR-TB countries reported in 2006 [26]. A national survey conducted from DST between 2003 and 2006 showed that level of MDR-TB are:1.6% and 11.8% in new and re-treatment cases of TB patients respectively [27]. MDR-TB is major public health problem which is the challenge for TB control program. The main importance of this study is to identify factors that affects patient's adherence to DOTS in DURH, was given insights into the reason of low treatment success rate. In general, it helps to take active intervention to increase patient adherence to DOTS and TB treatment at all. The study will benefit for current and future as findings may be used to formulate strategies to improve the quality of care. This study also provides base line information for future studies. In addition, recommendation could then be made to the national TB control program (NTCP) on how TB treatment compliance could be improve in DURH and subsequently improve TB control in this area.

Objective

General objective

Assessment of adherence to DOTS and factor affecting patients' adherence to DOTS among TB patients in DURH.

Specific objectives

I. To assess the status of adherence to DOTS among TB patients in DURH.

II. To identify factors that affects patient's adherence to DOTS.

Methodology

Study area and period

The study will be conducted in Dilla hospital, which is referral hospital in dilla town, SNNPR, Ethiopia, the hospital has the weather condition of woinadega according to data collected by a hospital administrative (2005 E.c). Dilla town is found 369 km south of Addis Ababa and 90 km south of Hawasa (capital city of SNNPR). Dilla is the administrative center of gedeo zone in SNNPR and longitude and latitude of 6^0 24'3^0N 38^0 18'30^0E respectively with an elevation of 1520 m above sea level (Internet). The hospital has 676 workers,486 of which are administrative and supportive contract workers, the rest 190 are health care workers which are serving the hospital in different departments. This hospital has four major departments such as internal medicine, surgery, pediatrics and gynecology and obstetrics. The hospital has also other departments like radiology, psychiatry, laboratory ART and TB clinic, environmental health, dentistry and ophthalmology. the hospital provide a medical service for a population within their catchment area and the hospital mainly provided by ministry of health .in the hospital DOTS and ART introduce in 1998 E.c and now 100% availability of DOTS for TB patients. The hospital providing TB diagnosis treatment and case management on newly diagnosed TB cases are required to be registered in the hospital TB clinic and reported to upper level of health authority. TB clinic have been operating for many years in the hospital and ART clinic were established in 1998e.c as a part of the expansion of HAART provision (according to data collected hospital administrative).

The present study will be conducted from May 1 –may 30/2008 E, c.

Study design

Cross sectional study will be conducted from April 1- May 30,2008 E.c in DURH to assess factors affecting adherence to DOTS among TB patients.

Populations

Source population: All TB patients registered In TB clinic at DURH will be the source population.

Study population: The study population for this study will be registered TB patients during the study period who have been on DOTS regimen at DURH.

Study units: The study unit is selected registered TB patients during the study period who have been on DOTS at DURH.

Eligibility Criteria

Inclusion criteria: Men and women greater than 18 years of age receiving anti TB treatment at the DOTS center of the hospital.

Exclusion criteria: Being under DOTS treatment and not being a current patient at study site.

Seriously ill and mentally disabled patients will be excluded from the study.

Sample size determination and sampling techniques: All patients on DOTS regimen and currently on follow up at the institution will be included.

Study variables

Dependent variable: Adherence to DOT.

Independent variable: Socio-demographic variables, -age, -sex, Marital status, Educational status, Income level, Health care system related , Distance from health service, Attitude of stuff of TB clinic for the patient, Patient related faced, patient supporter, smoking, alcohol drinking, history of defaulter, Disease and medicine related, Availability of medicine, Presence of co-infection

Data collection

Data collection technique& instruments: A structured questionnaire will be used to interview participants to evaluate level of adherence to anti-TB treatment. The questionnaire recorded demographic and socio-economic characteristics of the study participants; information on treatment adherence and problems associated with non-adherence. Face to face interview technique will be used to collect all relevant information from respondents. And oral language translation will be used by data collector at the time of the data collection. Data will be collected by fourth year health officer students and trained for one day before data collection.

Data processing and analysis: After the collection of data, the researcher will check the completed questionnaires; responses will be coded, cleaned and entered to computer using SPSS version 20 statistical program for analysis. Results of the study will be presented by using tables and graphs. Chi squire test will be determined by entering the dependent and independent variable based on research hypothesis using statistical program. The significance of association will be assessed using 95% confidence interval and p value. Bivariate and multivariate logistic regression analysis will be conducted.

Data quality control

To assure the data quality high emphasis will be given in designing data collection instrument. For its simplicity the questionnaire will be pre-tested prior to the actual data collection on 5% sample size of Dilla health center TB patients to check for understandability and applicability of the instrument, followed by modification. The filled questionnaire will be checked daily and incomplete questionnaire will be discarded.

Operational definitions

A. Adherence: Extent to which the patient take their medication as prescribed by physician.

Patients who missed ≥ 10% of the total prescribed dose were considered nonadherence to TB treatment

B. A defaulter: In this study is a patient who interrupts TB treatment for at least two months after taking the medication for at least four weeks continuously [44].

C. Compliance: Refers to the extent to which the TB patients are adhering to treatment and accepted it. Or the extent to which patients' behavior coincides with medical advice on how to take TB treatment [45].

D. Failure: When patient remain smear positive or become smear positive after adequate therapy for five month or more [46].

E. Therapy: The treatment of TB [47].

Tuberculosis: A disease caused by mycobacterium tuberculin infection [48].

Tuberculosis patients: Refers to the clients who are infected with *M. tuberculosis* and are under treatment [49].

Ethical considerations

Ethical clearance letter will be obtained from Hawassa college of health science institutional review board. The respondents will be informed about the aim of the survey and verbal consent will be obtained before the data collection. The confidentiality will be kept by not writing their names on the questioners.

Dissemination plan: The outcome of this study will be disseminated to Hawassa college of health science and Dilla university hospital.

Work Plan

Declaration

Ethics approval and consent to participate: The ethical review board at Hawassa College of Health Science followed all protocols including the Helsinki Declaration throughout data collection. The ethical review board of Hawassa College of Health Science will gave its approval to the project. The data collector will inform the respondents that participated in the study was fully voluntary and that there would be no negative consequences if they declined. The respondents will be informed about the aim of the survey and verbal consent will be obtained before the data collection. The confidentiality will be kept by not writing their names on the questioners.

Consent for Publication

Not applicable.

Availability of Data and Materials

The paper includes all data.

Competing Interests

There are no competing interests stated by the authors.

Funding

There was no financing available for this project.

Contributions of the Authors

KTT was responsible for the original drafting of the manuscript's conceptualization, Methodology and development.

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