Code and Title of the research project

Estimation of the risk factors associated with multidrug resistance tuberculosis in Sudan [18-13]

Country - Sudan

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- Reporting Period: May – December 2019

- Objectives of the study:
  - General:

To estimate the causal effect of risk factors associated with MDR-TB occurrence among patients infected with tuberculosis in Khartoum, Sudan

  - Specific:

. To estimate the causal effect of the treatment interruption on the MDR-TB

2- To determine the association between contact with MDR-TB patient and the MDR-TB

3- To assess the causal effect of the of the previous treatment of TB on the MDR-TB

4- To estimate the causal effect of the HIV infection on the MDR-TB

5- To determine the association between poor adherence to DOTs and the MDR-TB

6- To estimate the causal effect of the type -2 Diabetes on the MDR-TB

INTRODUCTION:

Human tuberculosis is caused by Mycobacterium tuberculosis Bacilli which known as Mycobacterium tuberculosis complex, which includes Mycobacterium tuberculosis, Mycobacterium africanum, and M. bovis. The bacteria basically infect lung (pulmonary TB) but can affect other sites as well (extra-pulmonary TB) (1). Multidrug resistance is defining as simultaneous resistance to at least rifampicin and Isoniazid (2). In 2014, the estimation of the new cases of MDR-TB was 480 000 (range: 360 000–600 000) worldwide. Furthermore, 190 000 (range: 120 000–260 000) deaths are due to the infection with MDR-TB (3). The emerging of multidrug resistance tuberculosis is complicating the control efforts in TB programmes all over the World (4).

Previous studies indicated that association risk factors such as treatment interruption, diabetes, smoking and development of MDR-TB have not been assessed. MDR-TB patients need long treatment time (approximately two years), high treatment costs, and other complications which make MDR-TB more complex disease. There is a big financial burden for MDR-TB patients especially those who responsible of their families. So, MDR-TB is not only a biological disease but it has financial and social impact (5). A case control study was conducted in Ethiopia in Oromia Region found that contact history, HIV infection, previous known TB history, and previous TB treatment outcome were predictors of MDR-TB (6). In a separate case control study investigate the risk factors of MDR-TB in Amhara region in Ethiopia, TB treatment failure , contact with MDR-TB patients , and young age were significantly associated with MDR-TB (7). In another case control study performed to find the determinants of MDR-TB in patient who underwent first line treatment in Addis Ababa, Ethiopia the interruption of treatment of at least a day, and duration of treatment between 2 and 7 months were significantly associated with the occurrence of MDR-TB (5). In study conducted in Port Sudan, Eastern Sudan 2006-2007, among 100 tuberculosis patients, resistance to rifampicin was 8% and resistance to isoniazid was 13% (8). In a different study conducted also in Kassala, Eastern Sudan 2007 to 2009, and included 53 isolates from pulmonary tuberculosis patients indicated that the the prevalence multidrug resistance was 9.4% (9). In a recent study conducted to estimate multi drug resistance among tuberculosis patients in Sudan, the prevalence of at least resistance rifampicin and isoniazid was 38% by using DST and 37.3% by using LPA in 2016 (10).

Sudan is bordered by a high TB burden country, Ethiopia and there is no any restriction in the people movement between the two countries. The risk factors associated with the drug resistance tuberculosis may vary from country to others. The study can help in identifying person with high risk factors of multi-drug resistance tuberculosis. Furthermore, the study will contribute to fill the gap in literature about contributed factors of multi-drug resistance tuberculosis in Sudan.

METHODOLOGY:

Study design:

A case control study design

Study population:
- Case-definition: Patient resistant to both Rifampin and Isoniazid was considered as MDR-TB
- Control definition: Patients who had completed first-line anti-TB treatment (for 6 months) and were registered as cured

Sample size:

Total number of 450 cases and controls were included in the study

Sampling method:
For each case two controls were selected

Data collection:

Designed Questionnaire was used to collect primary data from study participants. Secondary information regarding cases and controls was selected from national tuberculosis program registration books. Demographic information such as age, sex, and area of residence were collected. Other variables include the following; history of TB treatment, Smoking status, Type -2 diabetes, Living conditions (number of persons per room), Contact with TB patients. In addition, type of care provider (public – private), HIV infection, and total time of the previous treatment for at least one month were included in the data collection tools

Face-to-face interview was used to collect data from study participant. After the selection of the study participant randomly, informed consent was obtained before collecting the data. This procedure is not only data collection and procedures, but also setting up appointment for interview or visit to data collection sites.

- Case-definition: Patient resistant to both Rifampin and Isoniazid will be considered as MDR-TB cases and will be included in the study. Cases should be confirmed by the reference TB lab by either conventional culture or molecular techniques such as line probe assay (LPA).

- Control definition: Patients who had completed first-line anti-TB treatment (for 6 months) and were registered as cured

Collected data was checked to maintain high quality data. Quality assurance before conducting the research and quality control during the running of the research will be maintained.

Data analyses :
Data were entered in the statistical package for social sciences (SPSS) version 20. We described data by calculating the frequnecies of different variables.

Ethical considerations:

Ethical approval was obtained from the National ethical committee at the Ministry of Health Sudan (NO.FMOH/rd/1/104).Written informed consent was handed to participants who were able to read and their signature was taken. For those who were not able to read the information in the inform consent was read out by the interviewers. Objectives of the study were explained in separated sheet which was attached in the questionnaire and read and explained to participants not able to read.

Results:

A total number of 450 participants including 150 cases and 300 controls were collected. This number includes 314 (69.8%) males and 136 (30.2%) females. The mean age of study participants was 35.5±14.9. Regarding education level, 82 (18.1%) participants have university education, 128 (28.4%) have secondary education, 119 (26.4%) have primary level, 32 (7.1%) have Khalawa education (informal education) , and 89 (19.8%) they are without education.

The study found that 117 (78.0%) of cases had history of previous tuberculosis treatment, whereas 10 (3.3%) in control group indicated that they had history of previous treatment. In the same way, 55 (36.7%) cases indicated that they stop treatment during their course of treatment at least one time. On the other hand, only 3 (1.0%) controls indicated that they stopped tuberculosis treatment. Regarding contact with MDR-TB patients, 32 (21.3%) cases reported that they had contact with MDR-TB patients. Contrary, only one (0.3%) control mentioned that they have contacted MDR-TB patients.

On the other hand, HIV was very low and reported in 2 (1.3) cases and 6 (2.05) controls. Moreover, 13 cases (8.7%) mentioned that they have type-2 diabetes mellitus, while 15 controls (5.0%) reported the same condition. In addition, a total number of 43 (28.7%) cases, and 19 (6.3) controls were smock cigarette. Moreover, 61 (40.7%) of cases and 51 (17.0%) controls smoke water pipe,

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