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Assessment Treatment Outcomes of Directly Observed Treatment Short Course Programme among Tuberculosis Patients in Al-Najaf Governorate, Iraq

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Abstract: OBJECTIVES: to evaluate the detection rate and treatment outcomes among TB (tuberculosis) patients in Al-Najaf TB center and compare these outcomes with WHO (World Health Organization) targets. METHODOLOGY: Cohort study was conducted during the period between January 2012 to December 2012, for patients attending TB center in AL-Najaf Province. The collected data were analyzed for treatment and retreatment outcomes, treatment and retreatment success rates. RESULTS: 162 TB cases were enrolled in the present study, and the patients were distributed according to age into seven age groups. The young and middle age groups (15-24 and 25-34 years interval) showed higher frequencies of cases (20.4% and 23.5%, respectively) than other age groups. The male to female ratio was 1.7:1. The case detection rate was 34.6% as only 56 out of 162 cases were sputum-smear positive for AFB (acid-fast bacilli), and they were followed in the present study. Treatment outcomes—cured, completed treatment, defaulter, treatment failure, died and transfer out of 56 patients are 69.6%, 9%, 16%, 3.6%, 0.0% and 1.8%, respectively, whereas retreatment outcomes—cured, completed treatment, defaulter, treatment failure, died and transfer out are 50%, 0.0%, 50%, 0.0%, 0.0%, 0.0%, respectively. The DOTS (directly observed treatment short course) treatment success rate 75% and the retreatment success rate was 49%. CONCLUSION: All the estimations of detection rate, success rate of treatment and retreatment outcomes were lower than that of WHO targets. RECOMMENDATIONS: Improving success rate through overcoming obstacles that prevent regular drug supply, execution regular surveys to evaluate the performance of DOTS programme, community-based health education programmes about the role of DOTS strategy in improving treatment success rate.

Key words: Tuberculosis, DOTS programme.

1. Introduction

TB (Tuberculosis) is a major global health problem. It causes illness among millions of people each year and ranks as the second leading cause of death from an infectious disease worldwide, next to HIV (human immunodeficiency virus) infection. According to the WHO (World Health Organization) 2012 report, almost 9 million new cases and 1.4 million TB deaths occur worldwide by the year 2011 [1]. Effective treatment of TB requires adherence to a minimum of 6 months treatment with multiple drugs [2].

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Tuberculosis is an infectious disease caused by *Mycobacterium tuberculosis*, which is a facultative intracellular parasite that is easily ingested by phagocytes, however, it is resistant to intracellular killing [3]. It affects primarily lungs causing pulmonary tuberculosis, it can also affect meninges, bones, lymph glands and other tissues in body [4].

Globally speaking, one-third of population is asymptomatically infected with tuberculosis, of whom 5%-10% will develop apparent clinical features [5]. The great majority of new cases and deaths occur in developing countries where infection was acquired during childhood [6]. The disease still causes a public health problem. During the year 2013, it was found 9

million newly developed cases, 56% of them occur in Asia, whereas 29% in Africa, 13% (1.1 million) of these were HIV positive [7]. It was found that 1.5 million people died of tuberculosis, of whom 360,000 where HIV positive and 210,000 were due to MDR-TB (Multidrug Resistant TB) [8], out of those newly diagnosed cases only 6.1 million cases were reported to WHO, of these only 5.7 million were newly diagnosed, the total number of missed cases during this year were three million, either undiagnosed or diagnosed but not treated [9].

Regarding classification of tuberculous cases according to drug resistance, the most important type is MDR-TB, where TB is resistant to at least both isoniazid and rifampicin [10]. The MDR-TB infection is more prevalent in developing countries, which could be due to poverty, economic causes, malnutrition, overcrowding, or there is a defect in the application of national tuberculosis control programmes, which hamper the achievement of high cure rate [11].

In 1991, a WHA (World Health Assembly) had set "a global target of cure of 85% of sputum-positive patients under treatment and detection of 70% of cases by the year 2000". However, it had become apparent that the targets would not be met by the specified date; in 2000, the fifty-third WHA therefore postponed the target year to 2005. The Stop TB Partnership has found that the achievement of these impact targets globally requires sustained progress in implementation [12, 13]. That is, national control programmes around the world must reach at least 70% case detection and 85% treatment success [14, 15].

WHO had set strategy called DOTS (Directly Observed Treatment, Short course) Chemotherapy to ensure cure by providing the most effective drugs and confirming that is taken. It is the only programme which has been proved to be effective against TB infection [8]. DOTS strategy has a central role in the approach for tuberculosis control, which is now presented as Stop TB Strategy. The target of DOTS programme is successful treatment or cure rate of 85% of newly cases with positive sputum smear, and detection of 70% of such cases [16].

WHO launched the new Stop TB Strategy in 2006 for the second "Global Plan to stop TB (2006-2015)". The target of this strategy by the year 2006 is to reduce prevalence and death rates to 50% relative to 1990 levels, while the target by the year 2015 is that the global incidence of TB disease will be less than or equal to one case per million population per year [17].

The aim of this study was to evaluate the detection rate and treatment outcomes among TB patients in Al-Najaf TB center and compare these outcomes with WHO targets.

2. Material and Methods

2.1 Time and Place

Current study was a cohort study, conducted in Al-Najaf Province during the period between January to December 2012. The patients who followed in present study were attending TB center in AL-Najaf Governorate either as:

1. Direct attendants whom seek treatment.
2. Referred cases from hospitals, Primary Health Centers (PHCs) or private clinics for diagnosis and treatment.

2.2 Definition of Cases

The following are the WHO standard definitions of cases with modification [18, 19]:

A tuberculosis case is defined as a patient in whom tuberculosis has been bacteriologically confirmed or diagnosed by a clinician [20].

Smear positive patient: Patient with at least two initial sputum smear examinations positive for AFB (acid fast bacilli), or one sputum smear examination positive for AFB plus radiographic abnormalities consistent with active pulmonary tuberculosis as determined by a clinician.

Follow up was restricted to smear positive cases.

The cases are classified according to the presence or absence of history of taking anti TB drugs:

(1) New patient: a patient who had never taken treatment for TB or who had taken anti-TB drugs for less than four weeks;

(2) Retreatment patient: A patient who had taken anti-TB drug for one month or more at any time in the past, and is one of the following:

(a) Treatment Failure: A patient who, while on treatment remained or became again smear-positive five months or later after commencing treatment.

(b) Relapse: A patient who has been declared cured of any form of TB in the past by a physician, after one full course of chemotherapy, then became sputum smear positive.

(c) Defaulter: A patient who interrupts treatment for two months or more, and returns to the health service with smear positive sputum.

2.3 Data Sheet

Two forms of data sheets were designed to accommodate the various data required for the follow up patients:

Data sheet (I) was designed for new cases. It allows documentation of data concerning: age, sex, sputum smear result, chest x-ray, name of treatment unit, follow up investigation and treatment outcomes (cured, completed treatment, defaulter, failure, died and transfer out).

Data sheet (II) was designed for retreatment cases. It allows documentation of data concerning: age, sex, sputum smear result, chest x-ray, case definition (relapse, defaulter, failure), name of treatment unit, follow up investigation and treatment, defaulter, died and transfer out.

2.4 Treatment Outcomes

Treatment outcomes are classified into six groups which are:

(1) Cured: Initially smear positive patient who completed treatment and had negative sputum smear results, on at least two occasions of treatment.

(2) Completed Treatment: Sputum smear positive patient who completed treatment with negative sputum smear results at the end of the initial phase, but with no or only one negative sputum smear result in the continuation phase and none at the end of treatment.

(3) Died: Patient who died during treatment, regardless of cause.

(4) Failure: Smear positive patients who remained or became again smear positive five months or later after commencing treatment.

(5) Defaulter: Patient who, at any one time after registration, had not taken drugs for two months or more.

(6) Transfer out: Patient who has been transferred to another reporting unit and his/her treatment results are not known [20].

2.5 Statistical Analysis

Statistical analysis was performed with the SPSS, Version 20 (statistical Package for Social Sciences), 2011. Data analysis was done using Z-test, P-value < 0.05 was considered as a level of significance.

3. Results

One hundred sixty two newly diagnosed TB cases in addition to a group of retreated cases were enrolled in the present study, and the patients were distributed according to age into seven age groups as shown in the Table 1. The young and middle age groups (15-24 and 25-34 years interval) showed higher frequencies of cases (20.4% and 23.5%, respectively) than other age groups.

The gender variation was very prominent in these age groups. The male to female ratio was 2.45 and 2.66 in the age groups 15-24 and 25-34, respectively. Also, the total male to female ratio was 1.7 among all cases.

Out of 162 referred new pulmonary TB cases, only 56 cases were sputum-smear positive for AFB, and they were followed in the present study. Case detection rate was 34.6% as shown in Table 2.

The results showed that 39 out of 56 new sputum-smear positive patients were cured (completed

Table 1 Distribution of pulmonary TB patients registered for DOTS program according to age and gender.

Age Group	Gender		Total
	Male, *n* (%)	Female, *n* (%)	
0-14	3 (1.9%)	7 (4.3%)	10 (6.2%)
15-24	24 (14.8%)	9 (5.5%)	33 (20.4%)
25-34	27 (16.6%)	11 (6.7%)	38 (23.5%)
35-44	12 (7.4%)	8 (4.9%)	20 (12.3%)
45-54	13 (8.2%)	6 (3.7%)	19 (11.7%)
55-64	12 (7.4%)	9 (5.5%)	21 (13%)
≥ 65	11 (6.7%)	10 (6.1%)	21 (13%)
Total	102 (62.9%)	60 (37%)	162 (100%)

Table 2 Performance indicator of case detection rate* with the WHO target.

Performance Indicators	AL-Najaf TB center 2012	WHO Global Target (WHO, 2006)	Z-test
Case detection rate*	34.6%	70%	$P < 0.001$

*Case detection rate = (No. of new smear positive cases/Total No. of new pulmonary TB cases) ×100 (WHO, 1999).

Table 3 Treatment outcomes of new sputum-smear positive patients during the period between January–December 2012 in Najaf.

Treatment Outcomes	Frequency and percentage of cases	
	No.	(%)
Cured	39	(69.6)
Completed Treatment	5	(9)
Defaulter	9	(16)
Treatment Failure	2	(3.6)
Died	0.0	(0.0)
Transfer Out	1	(1.8)
Total	56	100

Table 4 Treatment outcomes of retreatment smear positive patients during the period from January to December 2012 in Najaf.

Treatment Outcomes	Frequency and percentage of case	
	No.	(%)
Cured	2	(50)
Completed Treatment	0.0	(0.0)
Defaulter	2	(50)
Treatment Failure	0.0	(0.0)
Died	0.0	(0.0)
Transfer Out	0.0	(0.0)

Table 5 Comparison of performance indicators with the WHO targets.

Performance Indicators	AL-Najaf TB center 2012	WHO Global Target	Z-test
Treatment Success Rate*	78.6%	85%	$P < 0.05$
Retreatment Success Rate*	50%	85%	$P < 0.001$

*Success rate = (Number of new smear positive TB cases that cured or completed treatment/total *n* of new smear positive TB cases registered for treatment) ×100% (WHO 1996).

treatment and had two sputum negative smears). Other treatment outcomes were listed in Table 3. Particularly, two treatment failures were noticed and one case was transferred out.

Table 4 shows the follow up of retreatment group which revealed that 50% of cases were cured and the

other half of cases was defaulters.

The performance of DOTS among the course of treatment of 162 patients was evaluated according to treatment success rate as indicator of programme performance. The DOTS treatment success rate 75% and the retreatment success rate was 49%.

4. Discussion

Tuberculosis is a transmissible, airborne-illness and remains a major global public health hazard [21]. TB mostly affects subjects in developing countries and it has been reported that more than 85% of TB cases have been noticed in the developing countries. Along with the new cases, a number of re-treatment cases were also being noticed [22, 23].

Little was known to evaluate the outcomes of this programme in Al Najaf Province. The evaluation approach set by WHO depends on treatment outcomes rate and treatment success rates. These criteria give a valid tool to evaluate performance of the programme and can compare the setting in our Province with WHO targets.

The present study revealed that the highest recorded age groups was (15-20) and (25-34), this was probably attributable to the fact that patients in these age groups represent the most active phase of life rendering them at high risk of exposure to infection from patients with open form of disease.

Although male infection in present study was predominant, female ratio could not be representing the actual situation because many women do not attend official health care centers due to fear from social stigma with fear from probable consequence of it like divorce, the present finding is in concurrence with other reports [24, 25] that proposed this ratio could be attributable to biological characteristics and socioeconomic and cultural barriers to access healthcare.

The case detection rate means the proportion of estimated new smear positive cases which are detected (diagnosed and notified to WHO) by DOTS programmes divided by the number of cases estimated for that year, it provides an indication of how effective national tuberculosis programmes are in finding people with tuberculosis and diagnosing the disease. The present data was lower than the goal of global STOP TB strategy. Moreover, the detection rate of new TB cases nationwide that was detected and notified to WHO by Iraqi's Ministry of health was 59% and 57% in 2012 and 2013, respectively [26].

Concerning the success rate of treatment, it was lower than that of countrywide tuberculosis control programme and WHO target. However, it was high than that reported in some Arabs countries like Lebanon (71%), Arab Emirates (76%), Bahrain (44%), and Saudi Arabia (64%) [27].

The lower success rates reflect poor programme performance. The explanation might be due to defects in trained health personnel who was supposed to be responsible for ensuring of taking medicine by patients, or defects in regular drug supply.

Other explanation of lower success rate was probably due to poor compliance with the consequence of poor adherence especially during continuous phase of DOTS programme. Several contributing factor should be considered such as side effects of some anti-TB medicines, unawareness of patients about their conditions and prognosis if drugs was inadequately taken, or presence of defects in supervision by health care personnel.

5. Conclusion

The estimation of treatment and retreatment outcomes using DOTS programme in Al Najaf Province was lower than that of WHO targets.

6. Recommendation

Improving success rate through overcoming obstacles that prevent regular drug supply with regular surveys to evaluate the performance of DOTS programme and performing community-based health education programmes about the role of DOTS and the

role of community participants in achievement of it.

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