Effectiveness of Directly Observed Therapy Short Course (DOTS) in Patients with Tuberculosis Registered at Federal General Hospital, Islamabad

M. Sajid Abbasi, Sarah Nisar, M. Tahir, Rukhsana Manzoor, Muhammad Shafique Arshad

Abstract

Objective: To determine the effectiveness of DOTS in TB patients at Federal General Hospital.

Study Design: Cross section study

Place and Duration: The study was conducted in Medical department and TB DOTS center National TB Control Program (NTP) at Federal General Hospital Chak Shahzad Islamabad from Jan 2015 to Dec. 2015.

Methodology: Using consecutive sampling technique, 148 confirmed TB patients presenting to medical OPD were enrolled in study and were registered with DOTS program. After taking informed consent, a validated questionnaire was used to gather information including demography, clinical characteristics, details on compliance and outcome status. Data was analyzed using SPSS software.

Results: Total 148 TB patients were enrolled. Male to female ratio was 0.94:1. Mean age was 36 years (±SD 2.8). The most frequent age group was 15-<50 years (106, 72%). Out of total 148 cases, 126 (85%) had pulmonary tuberculosis, 21 (14%) had extrapulmonary TB while one was (1%) was cryptogenic. 130 patients (89%) were newly diagnosed whereas 18 (11%) were relapse cases. Except for 15 cases (9 lost to follow up and 6 deaths), rest 133 complete d treatment with 94% cure rate.

Conclusion: DOTS is a very effective strategy to treat tuberculosis patients. Good counseling of the patients by the doctors and TB healthcare worker can further minimize the risk of treatment default.

Key Words: Tuberculosis, DOTS program, treatment default, Islamabad, lost to follow up.

Introduction

TB is a communicable disease caused by a bacterium called Mycobacterium tuberculosis, spread through droplet infection. It is one of the top 10 killer infectious diseases in the world and it has become a pandemic. According to WHO, 10.4 million people suffered from TB and 1.8 million died in 2015. Over 95% of TB deaths occur in low- and middle-income countries and South-East Asia contributes about 60% of the total TB burden in the world.

TB is endemic in almost every part of the world. However, 58% of new cases globally occurred in the South-East Asia and Western Pacific Regions during 2014. Compared with the global average of 133 TB cases per 100
Pakistan is among the high burden TB countries and ranks 6th globally. About 44% of tuberculosis patients in the Eastern Mediterranean Region are from Pakistan. For sputum-positive TB cases, the incidence is 80/100,000 per year in Pakistan and the disease accounts for 5.1% of the total national disease burden.  

In March 2000, 20 high burden countries of world issued the Amsterdam Declaration to accelerate action against TB through WHO-recommended strategy to combat tuberculosis Directly Observed Therapy Short-course (DOTS), providing for at least 70% detection of infectious cases by the year 2005  

Providing free first-line anti-TB medication in all high burden TB countries. 

According to WHO, an estimated 480,000 people developed multidrug-resistant TB (MDR-TB) globally in 2015. In Pakistan according to the National Drug resistance (DR) survey (2012-13), the DR-TB incidence is estimated to be at 3.7% among notified new pulmonary cases and 18.1% among retreatment patients. Among many identified risk factors for the development of MDR, non-adherence to therapy and lack of directly observed treatment, limited or interrupted drug supplies are the major reasons. Ministry of Health Pakistan declared TB a national emergency in March 2001 and formulated a policy to adopt WHO-recommended DOTS strategy. To achieve the goal, National TB control program was launched in Pakistan. 

In DOTS program, patients are given anti-tuberculosis medications directly by healthcare workers and it is assured that patient has taken the medicines. Further proper time and dose of medicine is also assured. 

Many studies have evaluated the DOTS program where TB health workers were involved. This is a different study in which we have evaluated a cohort of people using DOTS through a hospital setup. The objective of this study was to evaluate and find out the effectiveness of DOTS strategy program among the TB patients visiting the FGH for treatment.

**Methodology**

It was a hospital-based prospective cohort study carried out from January 2015-December 2015 at Federal General Hospital, Islamabad, the capital city of Pakistan. Islamabad has a population of two million, the 10th largest city of Pakistan. It covers an area of 1,165.5 km² (450 mi²) of which 906 km² (349.8 mi²) is Islamabad proper. 

Islamabad Capital Territory comprises Islamabad city and surrounding rural areas. The national TB program achieved 100% TB DOTS countrywide coverage in all public-sector health facilities in 2005. For FGH, National reference Laboratory is situated within the premises of National Institute of Health (NIH), Islamabad. 

**Recruitment of study participants:** All patients visiting the medical OPD of FGH with suspicion of tuberculosis were followed till the confirmation of TB diagnosis by National Reference lab. Patients with HIV, some other immunodeficiency state and those with the severe comorbid disease were excluded from the study. All TB confirmed cases were briefed about nature and importance of the study. After ethical clearance and receiving consent from participating hospital, data collectors were trained on questionnaire filling. Trained nurses filled the performas by extracting information from TB registers. During the study period, there were 148 eligible confirmed TB cases at FGH, all agreed to participate in the study. These patients were residents of rural Islamabad including Bani Gala, Mohra Noor, Chuk Shershad, Tramri and Chatta Bakhhtawer. All patients coming to a health facility with suspicion of TB were consecutively selected.

**Data collection:** After seeking informed consent from the participants, a validated questionnaire consisting of close-ended questions was used to collect information under five heads including demography, clinical characteristics, details on compliance and outcome status. Data was collected from TB registers (TB registers TB03). Patient charts were used to determine and record their progress. One day training was provided to the nurses involved in the data collection process. Variables included in the questionnaire were gender, age, lab result, TB status, treatment compliance, and treatment outcome. All the patients coming back to FGH with confirmed TB diagnosis were counseled by the treating physician for treatment continuation and results of non-compliance. Patients were also assured that they can come any day to the treating physician in case of any complain or confusion regarding TB treatment.

**Data management and analysis:** Data were entered in excel sheet and was analyzed using SPSS. Data completeness and consistency were checked. For categorical variables, bivariate analyses was done.

**Ethical considerations:** Ethical clearance was obtained from the institutional review board of the Federal General Hospital, Islamabad.
Results

Total 148 confirmed TB cases were enrolled. There were 76 (51%) females and 72 (49%) male patients with male to female ratio of 0.94: 1. The median age was 30 years (±SD 2.8). Patients were divided into 04 age groups. The most frequent age group was 12-32 years (77, 52.3%), followed by 32-52 years (42, 28.3%), 52-72 years (22, 14.8%) and finally 72-85 years (06, 4.06%) showing that disease is more prevalent in younger age groups. (Table I)

<p>| Table I: Demographic Characteristics of TB Patients registered at FGH (n=148) |</p>
<table>
<thead>
<tr>
<th>Age Groups</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 - 32 Years</td>
<td>77</td>
<td>52.38%</td>
</tr>
<tr>
<td>33 - 52 Years</td>
<td>42</td>
<td>28.38%</td>
</tr>
<tr>
<td>53 - 72 Years</td>
<td>22</td>
<td>14.86%</td>
</tr>
<tr>
<td>73 - 85 plus</td>
<td>6</td>
<td>4.06%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>148</td>
<td>100.00%</td>
</tr>
</tbody>
</table>

Main characteristics of study population are given in table II.

| Table II: Clinical Characteristics of TB Patients registered at FGH (n=148) |
| Laboratory Results (Smear) |
| Positive | 64 (43%) |
| Negative | 84 (57%) |
| TB status |
| New | 130 (89%) |
| Relapsed | 18 (11%) |
| TB Site |
| Pulmonary | 126 (85%) |
| Extra Pulmonary | 21 (14%) |
| Cryptogenic | 01 (1%) |
| Treatment Compliance |
| Completed | 133 (90%) |
| Lost to follow-up | 9 (6%) |
| Died | 6 (4%) |

Analysis showed that patients with pulmonary tuberculosis were 3.4 times more likely to complete the treatment than with extrapulmonary TB. (OR: 3.4. CI: 1.2-9.0, P value: 0.01). Among 12-32 years age group, the majority of the patients (66, 86%) were of pulmonary TB. Age and gender did not have any statistical association with treatment outcome.

Discussion

Our study showed that out of 148 TB patients enrolled, 128 were newly diagnosed while 19 were relapsed cases. Except for 15 cases (6 died and 9 loss to follow up) all completed the treatment and 100% cured.

Consistent with previous studies 10,11,12 conducted, our results showed that TB cases are more common among younger age groups, more than half of the TB cases were among 12-32 years (77, 52.3%), the productive group.

Saima et al.12 in their study have shown that 61.2% of patients were women and linked it to prevailing malnutrition and reduced immunity status among women. In the current study, females are more than males (76, 51%) however this difference is not statistically significant nor is the association with treatment outcome.

There are many factors for poor TB control in Pakistan, however, availability of inadequate services and proper treatment counseling on part of treating physicians remains constant. TB DOTS program has addressed both these aspects. In the current study, initial counseling by treating doctor and regular follow up along with taking care of concurrent problems proved in good compliance and cure of patients. A study from Afghanistan reported that even in war, there is increase in number of patients receiving TB treatment under DOTS program (from 9,261 cases in 2001 to 21,851 in 2005), with treatment success rate of 86%.13

After realization by WHO of tuberculosis as a neglected disease in 1991, 148 countries had adopted the WHO DOTS strategy and 27% of the TB patients are treated with DOTS program.14

Another study from Nigeria15 proved the effectiveness of DOTS strategy. There was (100%) compliance among 500 pulmonary patients with 100% cure using both DOT and TB home visitor. These results confirm the effectiveness of DOT and therefore, the cure of tuberculosis. However, in our study, compliance was 94% and may be due to the fact that all TB cases were not pulmonary TB patients and follow up was entirely based on good counseling skills by treating physicians. Even in our study compliance was much better in pulmonary patients as compared to extrapulmonary as was in the study from Nigeria. A study from India has compared the results of treatment outcomes of pulmonary TB patients by assigning them two study groups, in the DOTS-group and in the non-DOTS group. The outcome was 91% of the DOTS group and 53% of the non-DOTS after 6 months of chemotherapy emphasizing the advantage of DOTS over self-administered regimens.16 However contradicted to these findings on effectiveness of DOTS in TB treatment, Walley JD et al reported that TB outcome in...
terms of treatment completed or cure rates achieved was same in three groups namely DOT by health workers, DOT by family members and self-administered therapy (SAT) and concluded further operational research is needed to prove effectiveness of DOT. 17

Our study has also evaluated the effectiveness of DOTS in patients with tuberculosis. Out of 148 patients only 6% (9) patients lost to follow up and 6 (4%) died during the treatment Remaining 133 completed the treatment and were cured, the success rate was 94% excluding 6 deaths. We found DOTS as a very effective treatment strategy to treat tuberculosis and results achieved are above the goal set by WHO. One reason for this high degree of compliance with DOTS was possibly related to effective counseling.

Supervised treatment of tuberculosis patients is one of the most difficult components of DOTS as it requires resources. Sustainability of DOTS is required its revision as the cost of DOT by health workers at health facilities and the huge manpower requirements are high especially in low-middle income countries. In spite of this, DOTS proved to be very effective in tuberculosis control globally.18 In the current study, we face the same implementation problems, as due to limited staff we tried to follow the patients by telephone and rest with health workers as no separate staff is available at FGH for DOTS.

**Conclusion**

We found that DOTS is a very effective strategy to treat tuberculosis and results can be further improved by good counseling of the patients by the doctors and TB healthcare workers.

**References**

5. National Tuberculosis control Program, Pakistan. Available at: http://www.ntp.gov.pk/about.htm