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Treatment Supporters and Their Impact on Treatment Outcomes in Routine Tuberculosis Program Conditions in Rawalpindi District, Pakistan

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Background: Tuberculosis (TB) is a major cause of mortality affecting millions of people in third world countries. In DOTS monitoring of patients is facility-based and treatment supporter-based; by these two ways patients' compliance to treatment is monitored. The aim of this study was to evaluate the role of treatment supporters and their impact on patients' treatment outcomes.

Materials and Methods: The study was a cross-sectional survey in the routine TB control program operational context. All sputum smear positive TB patients that were diagnosed and registered by the public sector in the urban and rural diagnostic centers in 2008 with available outcomes were included in the study. Data of 451 patients were collected during August-October 2010 from 15 health facilities.

Results: The majority of patients (89.6%) were provided with treatment supporters. Of 404 (89.6%) cases with treatment supporters, in 203 (50.2%) the supporters were lady health workers, in 46 (11.4%) were community health workers and health facility workers, and in 155 (38.4%) were family members and community volunteers. A total of 384 (85.1%) were categorized as "treatment success", 31 (6.9%), as "transferred out", 17 (3.8%), as "expired", 16 (3.5%) as "defaulted" and three (0.7%) as "treatment failure". The treatment success rates in patients supervised by Lady health workers, community health workers and health facility workers, and family members and community volunteers were 93.1%, 89.1% and 73.5%, respectively.

Conclusion: We found a significantly higher treatment success rate (93.1%) in patients supervised by lady health workers compared to others. The overall treatment success rate was 85.1%.

Key words: Outcomes, Treatment supporter, Tuberculosis, Pakistan

INTRODUCTION

Tuberculosis (TB) is a contagious, airborne disease and remains a major global public health hazard. TB is a major cause of mortality and is affecting millions of people in low income and middle income countries. Worldwide one person out of three is infected with the *Mycobacterium tuberculosis* (MTB). Each year about 9.4 million people develop TB globally and 1.7 million die of this disease (1).

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. According to the World Health Organization (WHO), more than 80% of the new TB cases have been detected in 22 high burden countries, with Asia having 55% and Africa 30% of cases (1). Along with the new cases, a significant number of re-

treatment cases are being noticed. The factors associated with the resurgence of TB are low economic conditions (malnutrition, poverty, poor sanitation and homelessness), overcrowding, stress, alcohol, acquired immunodeficiency syndrome (AIDS), diabetes mellitus, immune deficiency states, and corticosteroid therapy (2).

Pakistan ranks number eight among the high burden countries. Directly observed treatment short-course (DOTS) is an internationally recommended treatment strategy for TB patients and for their continuous follow-up during the treatment (3). DOTS relies on self referral of symptomatic individuals to health facilities, called "passive case finding". WHO has set the millennium development goals (MDGs) to control TB with 70% case detection rate and 85% cure rate in the DOTS program. The national TB control program of Pakistan achieved countrywide DOTS coverage in 2005.

There are many tasks involved in providing treatment support for the patients which is mainly carried out by the treatment supporters (4). A suitable and acceptable treatment supporter for the patient is the key to success for DOTS and is mandatory at least for smear-positive patients in intensive phase and for the whole duration of treatment for re-treatment cases. The available treatment supporter options include: health facility-based workers (HFW) i.e. health staff members working at the selected treatment centers; community health workers (CHW) i.e. any person formally associated with the health services and living close to the patient's place; community volunteers (CVT) like a decent person selected from the community e.g. teachers, religious leaders, neighbors, co-workers, friends, etc; and lady health workers (LHW) i.e. a women formally working with the national program for primary health care and family planning (PHC & FP) (5,6). A family member (FM) or any person who is willing to help and is accepted by the patient and answerable to the health services can also be a treatment supporter (5).

This study aimed to evaluate the role of treatment supporters and their impact on the treatment outcomes in

district and sub-district hospitals and rural health centers in Rawalpindi district, Pakistan.

MATERIALS AND METHODS

This cross-sectional survey was conducted during August to October 2010 in a routine TB control program operational context. A quantitative research method was used to achieve the objectives of the study. Data were collected from 15 health facilities: one district hospital, 4 sub-district hospitals, and 10 rural health centers covering 98 basic health units in the Rawalpindi district. A total of 451 sputum smear positive TB patients diagnosed and treated in public sector, urban and rural diagnostic centers during the year 2008 were registered.

Data were extracted from the patients' TB treatment cards (TB01) and TB register (TB03) on a pre-designed form.

Inclusion criteria:

All smear positive TB patients registered during year 2008 in public sector district, sub-district hospitals and rural health centers in DOTS program with available treatment outcomes were included.

Exclusion criteria:

1) All smear negative pulmonary and extra-pulmonary cases other than sputum smear positive cases. 2) All private hospitals.

Data were recorded in a pre-designed form and were entered and analyzed by SPSS/PASWstats version 17 software. Descriptive statistics were applied, using frequencies and cross tabulation, and Pearson and Chi-square test (χ^2) were used to compare group differences for categorical variables. The level of significance was set at $P < 0.05$.

RESULTS

Baseline Characteristics:

Table 1 shows the distribution of TB patients according to geographical location, gender and age. Fifty three percent of the patients were males, 53.4% of the registered

patients lived in urban settings, whereas 46.6% of the patients were registered in rural settings.

For data analysis, patients were divided into three age groups (7):

Group 1: Age ≤ 14 yrs (Childhood)

Group 2: Age 15-54 yrs (Productive age)

Group 3: Age ≥ 55 yrs (Older age)

There were 14 (3.1%) patients in the childhood group, 324 (71.8%) in the productive age group and 113 (25.1%) in the older age group.

Table 1. Baseline characteristics of TB patients based on their geographical location

Characteristics	Geographical location	
	Urban n (%)	Rural n (%)
	241 (53.4)	210 (46.6)
Gender		
Male	128 (53.1)	109 (51.9)
Female	113 (46.9)	101 (48.1)
Age group		
≤ 14 yrs	6 (2.5)	8 (3.8)
15-54 yrs	185 (76.7)	139 (66.2)
≥ 55 yrs	50 (20.8)	63 (30)

Treatment Support:

The majority of patients (89.6%) were provided with treatment supporters, which were recorded on the TB01 form. In 404 (89.6%) cases for whom treatment supporters were provided, in 203 (50.2%) the supporters were LHW, in 46 (11.4%) were CHW/HFW, and in 155 (38.4%) were FM/CVT.

Twenty four patients (5.3%) had self-administered treatment (self-support) and in 23 patients (5.1%) treatment support was not documented. The patients in the groups "self support" and "undocumented" were combined in "no treatment support" group.

A total of 53.4% of treatment supporters lived in urban settings and 46.6% in rural areas. Among treatment supporters 129 (63.5%) LHW belonged to rural setting and 112 (72.3%) FM/CVT lived in an urban setting. Among the CHW/HFW, 25 (54.3%) lived in the rural setting. Among the patients with "no treatment support" 34 (72.3%) lived in the urban setting. When comparing the group of patients with "treatment support" by LHW with "no treatment support" patients, we found a highly significant

difference between urban and rural locations ($\chi^2 = 20.03$, $p = 0.0000076$). Similarly when comparing the group of patients with "treatment support" by CHW/HFW with patients with "no treatment support", we found a significant difference between urban and rural locations ($\chi^2=6.852$, $p=0.00885$) (Table 2).

In all registered patients, 237 (52.5%) treatment supporters were males, while 214 (47.5%) were females. Among all the registered patients 203 (45%) were supported by LHW, 102 males and 101 females. In FM/CVT supporters, male and female distribution was 81 (52.3%), and 74 (47.7%), respectively (Table .3).

Table 4 shows that from all the registered patients, 324 (71.8%) belonged to the productive age group (15-54 yrs). Most of them were provided with LHW (137, 67.5%), 34 (73.9%) with CHW/HFW and 118 (76.1%) with FM/CVT, while 35 (74.5%) with "no treatment support" also belonged to this age group. Among the older age group (≥ 55 yrs), 60 (29.6%) were provided with LHW, 10 (21.7%) with CHW/HFW and 31 (20%) were provided with FM/CVT treatment supporters, while 12 (25.5%) were in the "no treatment support" group. There were only 14 (3.1%) cases in the childhood age group (≤ 14 yrs), and all were provided with treatment supporters.

Treatment Outcomes:

Three hundred and eighty four (85.1%) were categorized as "treatment success", 31 (6.9%), as "transferred out", 17 (3.8%), as "expired", 16 (3.5%) as "defaulted" and 3 (0.7%) as "treatment failure".

The majority of the registered patients with treatment success (189) had LHW treatment support with urban and rural distribution of 72 (35.5%) and 117 (57.6%), respectively. One hundred and fourteen patients had FM/CVT as treatment supporters with urban and rural distribution of 75 (48.4%) and 39 (25.1%), respectively. Similarly, among the patients with "no treatment support" 40 were declared as treatment success, with urban and rural distribution of 30 (63.8%) and 10 (21.3%), respectively. When comparing the group of patients with

LHW “treatment support” with “no treatment support” group, highly significant differences were found between urban and rural locations in treatment success ($\chi^2 = 18.2$, $P = 0.00002$). Similarly, when comparing the group of patients with CHW/HFW “treatment support” and the “no treatment support” group, we found a significant difference between urban and rural locations in treatment success ($\chi^2 = 6.958$, $P = 0.008$). The treatment success rate in LHW, CHW/HFW, and FM/CVT was 93.1%, 89.1% and 73.5%, respectively (Table 5).

The majority of the registered patients with treatment success (189) had the LHW “treatment support” with male and female distribution of 91 (44.8%) and 98 (48.3%), respectively. One hundred and fourteen patients had FM/CVT treatment supporters with male and female distribution of 61 (39.3%) and 53 (34.2%), respectively. Among patients with “no treatment support” 40 were declared as treatment success, with male and female

distribution of 23 (48.9%) and 17 (36.2%), respectively (Table 6).

Most patients with “treatment support” by LHW were categorized as treatment success and were distributed in the three age groups as 6 (3%), 130 (64%) and 53 (26.1%) cases, respectively. One hundred and fourteen patients had FM/CVT treatment supporters with 6 (3.8%), 93 (60%), and 15 (9.7%) cases, respectively in the three age groups. Among patients with “no treatment support” 40 were declared as treatment success, with the majority of them (30, 63.8%) being in the productive age group, while the remaining 10 (21.3%) were in the older age group. Interestingly it was noticed that all patients with age ≤ 14 years were provided with a treatment supporter and all were declared as treatment success. Among patients with “unfavorable” and “transferred out” outcomes, the majority belonged to the productive age group (Table 7).

Table 2. Distribution of TB patients based on geographical location and their treatment supporter

Geographical location	Treatment Supporter			
	Treatment Support			No Treatment Support
	LHW (203) n (%)	CHW/HFW (46) n (%)	FM/CVT (155) n (%)	(self support + undocumented) (47) n (%)
Urban	74 (36.5)	21 (45.7)	112 (72.3)	34 (72.3)
Rural	129 (63.5)	25 (54.3)	43 (27.7)	13 (27.7)

Table 3. Distribution of TB patients based on gender and their treatment supporter

Gender	Treatment Supporter			
	Treatment Support			No Treatment Support
	LHW (203) n (%)	CHW/HFW (46) n (%)	FM/CVT (155) n (%)	(self support + undocumented) (47) n (%)
Male	102 (50.2)	25 (54.3)	81 (52.3)	29 (61.7)
Female	101 (49.8)	21 (45.7)	74 (47.7)	18 (38.3)

Table 4. Distribution of TB patients based on age group and their treatment supporter

Age groups	Treatment Supporter			
	Treatment Support			No Treatment Support
	LHW (203) n (%)	CHW/HFW (46) n (%)	FM/CVT (155) n (%)	(self support + undocumented) (47) n (%)
≤ 14 yrs	6 (2.9)	2 (4.4)	6 (3.9)	0 (0)
15-54 yrs	137 (67.5)	34 (73.9)	118 (76.1)	35 (74.5)
≥ 55 yrs	60 (29.6)	10 (21.7)	31 (20)	12 (25.5)

Table 5. Treatment outcomes based on patients' geographical location and their treatment supporters

Outcomes	Geographical location	Treatment Supporter			
		Treatment Support		No Treatment Support	
		LHW (203) n (%)	CHW/HFW (46) n (%)	FM/CVT (155) n (%)	(self support+ undocumented) (47) n (%)
Treatment Success	Urban	72 (35.5)	19 (41.3)	75 (48.4)	30 (63.8)
	Rural	117(57.6)	22 (47.8)	39 (25.1)	10 (21.3)
Unfavourable †	Urban	1(0.5)	1 (2.2)	20 (13)	3 (6.4)
	Rural	9 (4.4)	1 (2.2)	1 (0.6)	0 (0)
Transferred out	Urban	1 (0.5)	1 (2.2)	17 (11)	1 (2.1)
	Rural	3 (1.5)	2 (4.3)	3 (1.9)	3 (6.4)

† Unfavourable: It includes failure, defaulted and expired cases.

Table 6. Treatment outcomes based on gender and treatment supporter distribution

Outcomes	Gender	Treatment Supporter			
		Treatment Support		No Treatment Support	
		LHW (203) n (%)	CHW/HFW (46) n (%)	FM/CVT (155) n (%)	(self support+ undocumented) (47) n (%)
Treatment Success	Male	91 (44.8)	23 (50)	61 (39.3)	23 (48.9)
	Female	98 (48.3)	18 (39.1)	53 (34.2)	17 (36.2)
Unfavourable	Male	7 (3.4)	1 (2.2)	14 (9)	3 (6.4)
	Female	3 (1.5)	1 (2.2)	7 (4.6)	0 (0)
Transferred out	Male	4 (2)	1 (2.2)	6 (3.8)	3 (6.4)
	Female	0 (0)	2 (4.3)	14 (9)	1 (2.1)

Table 7. Treatment outcomes based on age group and treatment supporter distribution

Outcomes	Age groups	Treatment Supporter			
		Treatment Support		No Treatment Support	
		LHW (203) n (%)	CHW/HFW (46) n (%)	FM/CVT (155) n (%)	(self support+ undocumented) (47) n (%)
Treatment Success	≤ 14 yrs	6 (3)	2 (4.3)	6 (3.8)	0 (0)
	15-54 yrs	130 (64)	29 (63.1)	93 (60)	30 (63.8)
	≥ 55 yrs	53 (26.1)	10 (21.7)	15 (9.7)	10 (21.3)
	≤ 14 yrs	0 (0)	0 (0)	0 (0)	0 (0)
Unfavourable	15-54 yrs	4 (2)	2 (4.3)	10 (6.5)	2 (4.3)
	≥ 55 yrs	6 (2.9)	0 (0)	11 (7.1)	1 (2.1)
	≤ 14 yrs	0 (0)	0 (0)	0 (0)	0 (0)
Transferred out	15-54 yrs	3 (1.5)	3 (6.6)	15 (9.7)	3 (6.4)
	≥ 55 yrs	1 (0.5)	0 (0)	5 (3.2)	1 (2.1)

DISCUSSION

The national TB control program is not in an early stage in our country. The national program achieved 100% TB DOTS country wide coverage in all public sector health facilities in 2005. The TB DOTS program was implemented in the Rawalpindi district in 2003.

Treatment Support:

Our study showed that the most preferred treatment supporters were lady health workers (45%), followed by family members and community volunteers (34.4%) and community health workers and health facility workers (10.2%).

The common practice in NTP in Pakistan for selection of a suitable treatment supporter is that the DOTS facilitator speaks with the TB patients and tries to convince them to accept LHW as their treatment supporter. If the LHW is accessible and accepted by the patient then she is requested to be the treatment supporter. But if the LHW is not available or not accepted by the patient, then the patient is provided with another choice of CHW/HFW, and if CHW/HFW is not accessible or not accepted by the patient then a FM/CVT is selected as the treatment supporter for the patient.

In our study we observed that the treatment supporter selection process was according to the national guidelines, but there were certain important issues that need to be addressed related to the direct observation. These include: better distribution of the treatment supporters in the catchment area of the health facility, updating the treatment supporters' lists periodically and training different types of treatment supporters including LHW, CVT, and CHW.

The most important finding of this study was that a significantly higher number of rural patients preferred LHW as compared to the urban patients who preferred FM/CVT as their treatment supporters. This could be due to the social unacceptability of LHW to the patients or their families and availability or unavailability of the LHW in the urban settings. Another important finding of the study was the higher number (324, 72.8%) of cases in the productive age group (15-54 yrs). We also observed that the patients within the age group ≤ 14 yrs, were all provided with a treatment supporter.

Treatment Outcomes:

Several randomized controlled trials have been performed globally to evaluate the impact of treatment supporters on treatment outcomes. In our study, the overall treatment success rate was 85.1%. This seemed to be almost similar to the WHO target rate of 85%. Considering the treatment success rate in patients with

"treatment support" or "no treatment support", no difference was detected as both had 85.1% treatment success rate. The treatment success rate in groups with LHW, CHW/HFW and FM/CVT supporters was 93.1%, 89.1% and 73.5%, respectively. Similar findings have been documented in a study carried out in Southern Thailand; 411 patients were enrolled in the study and 379 (92%) were initially provided with DOT, while 32 (8%) refused DOT (8). The overall treatment success was 85%. In a randomized controlled trial in Pakistan, 497 adult new smear positive TB patients were enrolled (9); 170 were assigned to health workers, 165 to family members and 162 were self-administered. The outcomes were almost similar, with treatment success rates 67%, 62%, and 65%, respectively. This study showed that none of the three strategies was superior to the others. In our study, although the treatment success rate was the same (85.1%) in patient with "treatment support" and "no treatment support", it was higher than in the randomized controlled trial in Pakistan.

A randomized controlled trial was conducted in an urban setting in Tanzania to evaluate the effectiveness of community based DOT by using guardian and former TB patients compared with the hospital based DOT (10). A total of 587 new TB patients including pulmonary smear positive (322), pulmonary smear negative (182) and extrapulmonary (83) cases were enrolled. The treatment success rate among patients under community and health facility based DOT was 85% and 83%, respectively. The findings suggested that both DOT strategies were equally effective for good treatment outcomes.

In a cluster-randomized controlled trial in ten hill and mountain districts in Nepal, 907 new sputum smear positive patients were recruited (11); 549 (61%) were enrolled in the community DOTS in five districts and 358 (39%) were enrolled in family member DOTS group in five districts. The treatment success rate was 85% and 89% in community and family member based DOTS, respectively. Other studies in Malawi, Thailand, Senegal and South-

Eastern Brazil have also shown that family members as supervisors can play an efficient role in DOT in the community (12-15).

A recent study in two rural districts of Southern Ethiopia included 318 smear positive cases (16). The objectives of the trial were to see whether involvement of health extension workers could improve the case detection and treatment success rates. Health extension workers were trained for two days in the intervention group to focus on symptoms and transmission of TB, how to identify suspects, collect, label, store and transport sputum specimens, administer DOT and follow patients during the treatment. Health extension workers in the control group were not trained similar to the intervention group. The treatment success rate was higher in the intervention than in the control group (89.3% vs. 83.1%). In our study the treatment success rate was significantly higher in patients supervised by LHW (93.1%) followed by the CHW/HFW (89.1%) and FM/CVT treatment supporters (73.5%). While in patients with “no treatment support” treatment success rate was 85.1%. The overall treatment success rate was 85.1%.

In our study, the treatment success rate was higher in rural than in urban patients (89.5% vs. 81.3%). This could be due to the social unacceptability to patients or their families and unavailability of LHW, or CHW/HFW in the urban settings. These findings are quite different from those of a study carried out in three districts in Burkina Faso where geographical distance was seen to be a particular challenge for rural patients due to the lack of transport (17). The time and cost are another challenge for poor patients (18, 19). It is observed that daily wagers prefer to seek health care after completing their daily work, by which time all the government health out-patient departments are closed.

In our study the treatment success rate was slightly higher in females than in males (86.9% vs. 83.5%). Similar findings have been documented in studies in Southern Thailand, Pakistan and Southern Ethiopia (8, 9, 16).

CONCLUSIONS

1. Most patients (89.6%) were provided with treatment support by LHW (45%), followed by FM/CVT (34.4%), and CHW/HFW (10.2%).

2. The priorities for type of treatment support are different in urban and rural settings. FM/CVT supporters were found to be the main type of treatment support in urban, while LHW in the rural settings.

3. The treatment success rate was significantly higher in patients supervised by LHW (93.1%) followed by the CHW/HFW (89.1%) and FM/CVT (73.5%) supporters; while in patients with “no treatment support” treatment success rate was 85.1%. The overall treatment success rate was 85.1%.

Ethical Considerations:

The study protocol was approved by the National Bioethical Committee (NBC) of Pakistan,
(Ref: No. 4-87/10/NBC-50/RDC/2429).

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