

An Innovative Method to Enhance the Modified DOTS for TB Patients

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Background: Nowadays establishing communication and educating patients to enhance their knowledge regarding disease and treatment process at home is one of the most important principles in providing patient care.

Materials and Methods: A semi-experimental study was done on 57 patients with active pulmonary tuberculosis in two care groups namely professional – family mix directly observed treatment short- course (PFM-DOTS) and family based-DOTS (FB-DOTS). The patients were referred to the tuberculosis and lung diseases research center for diagnosis and treatment of pulmonary tuberculosis. Both the patient and a family supervisor were evaluated regarding their level of knowledge of the disease and the treatment regimen.

Results: A significant difference between the degree of knowledge of groups of patients and the groups of family relatives before and after the intervention was indicated, with a higher increase in PFM-DOTS group than in F-B-DOTS group ($P < 0.001$). In PFM- DOTS group 100% of the patients, and in the FB-DOTS group 86.8% of the patients followed the recommended drug regimen ($P < 0.001$).

Conclusion: According to the treatment recommendations by the World Health Organization (WHO) for appropriate implementation of DOTS project combating TB, it seems the PFM-DOTS implementation is a more suitable method with greater effects on correct care and treatment of tuberculosis patients.

Key words: Tuberculosis; Directly observed treatment short-course (DOTS); Knowledge; Patients

INTRODUCTION

Tuberculosis is still considered one of the important factors of mortality in the world. Almost one third of the world's population are infected by *Mycobacteria* (1). However, the clinical signs of active tuberculosis are seen only in one out of ten patients and the infection remains in a latent form in the rest of them (2). Tuberculosis and HIV co-infection are still major global problems (3) due to acid

fast bacilli. The increasing types of resistance to therapy can be a potential hazard for different countries in the world (4,5). Thus, a strong need is seen in developing methods of combating and managing the disease. The incorrect and irregular use of drugs or/and not adhering to the appropriate treatment regimen are considered the most prevalent causes of failure in treating patients with TB. (6,7).

Taking care of patients in their residence sometimes creates problems regarding drug usage. To overcome the problem, health authorities have to explain the general side effects of the drugs to the patients, and to continue their drugs until the end of the therapy (8). As the process of treatment takes at least six months, it is very important that the therapy supervisors establish an appropriate and constant communication with the patients and detect the signs of the disease (9). Providing services at home is being conducted in some countries (10). Direct supervision of the physician can provide valuable results (11). However, with several limitations on the way, the studies on the subject indicate that prevention can become possible through complementing the supervisory and educational programs. The family contribution can play a major role in treatment. The aim of this study was to evaluate the degree of knowledge of the patients and the family about tuberculosis, and the effects of education on their awareness of the disease and meeting the prescribed drug regimen.

MATERIALS AND METHODS

We sought to compare simultaneous effects of two kinds of educating and providing care for TB patients who had come to the tuberculosis and lung diseases research center in Tabriz, Iran for treatment in 2011-2012. The first patient from each group of PFM- DOTS and F.B. DOTS was selected by simple randomization if they had the inclusion criteria. The rest of the patients were included in the therapy groups by random allocation. From 118 pulmonary TB patients, 57 had the inclusion criteria, 24 in PFM-DOTS and 33 in F-B-DOTS therapy group.

The inclusion criteria included all new patients who had:

- 1) A direct sputum smear positive for acid fast bacilli and the chest X ray changes confirming the disease.
- 2) A direct positive sputum smear and also one case of positive sputum culture on Lowenstein-Jensen medium (Hi-Media, Bombay, India).

- 3) At least two direct positive smears associated with acid-fast bacilli.

The exclusion criteria were: all extrapulmonary tuberculosis patients, patients under recurrent treatment, addicts and HIV-positive persons. A researcher designed questionnaire was employed to collect the data regarding knowledge score. The validity of the questionnaire was confirmed by eight experts in infectious and pulmonary diseases. The knowledge questionnaire's reliability ($\alpha= 0.78$) was confirmed by Cronbach's alpha.

The number of questions assessing knowledge was 18 and the range of knowledge score was from 0 to 18 (0-18). The average and standard deviations of knowledge scores for two stages before and after the study were reported among the patients and the supervisors. The knowledge score was assumed as the main variable and the drug regimen was considered as the second variable. All information about the patient and the family was kept confidential. The care method was completely explained to the patients, and those who desired to contribute to the study filled the consent forms and entered the study groups.

In F-B-DOTS group, one family member was chosen as supervisor and the patients obtained the therapy regimen to follow at home. The health authority explained the regimen to the supervisor thoroughly. The health authority followed the process of therapy once in a month through phone calls, and the necessary training was given.

In PFM-DOTS group the health authority paid visits to the residential areas of the patients and through phone calls reminded the patient and his/her family members of the correct way of medication usage once a week in the first and second months of therapy, once in every fifteen days in the third and fourth months of therapy and once a month in the fifth and sixth months of therapy and controlled the conditions of the patients by reviewing their treatment identification card.

The health authority gave necessary recommendations through phone calls every three days in the first and the second months (20 times all together), and once a week in

the third and fourth months (8 times) and once a month in the fifth and sixth months (2 times). In the beginning and at the end of therapy, the knowledge score of the patient and his/her family members was compared in the two groups separately. The average score of knowledge (standard deviation) was calculated for the quantitative variables in both groups of PFM-DOTS and F-B-DOTS, separately. Normality of the data was checked using Kolmogorov-Smirnov test and was confirmed. The normality for knowledge variable was not confirmed so logarithmic conversion was used. To evaluate the average difference of knowledge score between the two groups, the dependent t-test and Man-Whitney test were used prior to the intervention. Intervention factors like demographic characteristics of the patients such as age, occupation, gender, and level of education were evaluated in the research process and were moderated by co-variance analysis following the logarithmic conversion of variables.

To analyze the study variables, $P < 0.05$ was considered significant and the results were analyzed using SPSS (version 11.5; SPSS).

RESULTS

There was no significant difference in gender distribution, age, education, and occupation between the patients in the two groups of PFM-DOTS and F-B-DOTS. There was no significant difference in gender distribution,

age, education, and occupation between the supervisors in the two groups of PFM-DOTS and F-B-DOTS. In the study 3 men from PFM-DOTS group, and one man and 2 women (3) from F-B-DOTS died (due to non tuberculosis diseases) and were excluded from the study. From 21 patients who remained in the study in the PFM-DOTS group, all patients (100%) used their medication regularly without any interruption. From 30 patients in F-B-DOTS group, 26 (86.6%) used the medication regularly, but 4 (13.3%) used the medication irregularly and had an interruption of 10 to 60 days throughout their course of therapy.

The statistical analysis was conducted on the knowledge results of the two groups of patients and supervisors independently (Table 1). There was a significant difference between the score of knowledge before the intervention [PFM-DOTS: 5.4762(4.26168)] and [F-B-DOTS: 5.7692(4.28306)] and after the intervention [PFM-DOTS: 16.4286(1.77684)] and [F-B-DOTS: 9.7692(3.50209)] and also adherence to the drug regimen after the intervention. In PFM- DOTS group 100% of the patients, and in the FB-DOTS group 86.8% of the patients followed the recommended drug regimen ($P < 0.001$).

The enhancement of knowledge in PFM-DOTS group was higher than in the F-B-DOTS group. Comparison of the knowledge score between the two groups before the intervention did not show any significant difference ($P = 0.816$ for patients) and ($P = 0.523$ for supervisors).

Table 1. The score of knowledge of tuberculosis patients and their supervisors before and after the intervention.

Groups	Methods	N	Mean	Std. Deviation	Std. Error Mean	**P Value	*P Value	
Patient's Knowledge	(Before intervention)	PFM-DOTS	21	5.4762	4.26168	0.92997		
		F-B-DOTS	26	5.7692	4.28306	0.83998	0.816	0.001
	(After intervention)	PFM-DOTS	21	16.4286	1.77684	0.38774		
		F-B-DOTS	26	9.7692	3.50209	0.68682		
Supervisor's Knowledge	(Before intervention)	PFM-DOTS	21	5.7143	4.24432	0.92619		
		F-B-DOTS	26	6.4231	3.30058	0.64730	0.523	0.001
	(After intervention)	PFM-DOTS	21	16.4762	1.07792	0.23522		
		F-B-DOTS	26	10.1923	3.35880	0.65871		

DISCUSSION

In the studies done all over the world, the outcomes of tuberculosis in DOTS by health worker-, family- member- or self- administrated treatment (SAT) have been different. A ten-year study (1991-2000) on more than 90% of tuberculosis patients in China (12) indicated that the failure in treatment of TB patients diminished through proper implementation of DOTS by health care workers. This strategy has also been a great help in diagnosis of new TB cases. In a similar study conducted in India by Balasubramanian et al. (13), the treatment outcome was more optimal. The results of some studies (14,15) rejected the superiority of DOTS versus SAT in general, and did not find any significant difference between these two methods. The results of most of the studies prefer DOTS rather than SAT. The most important thing that must be taken into consideration is the route of implementing DOTS, and this study has approached it in a careful and unique manner.

Newell and colleagues in Nepal (16) evaluated the degree of success of DOTS by family members (89%) against community DOTS (DOTS by health workers) (85%). According to the WHO's recommendations (17), implementing DOTS seems to be of great importance. However, the proper implementation should be conducted to enhance the efficiency and outcomes of the method, otherwise the optimal results would not be achieved (6). This study was a combination of the two methods of DOTS by health worker and DOTS by family- members, and the results were compared with just the DOTS by family- members. Throughout this combined strategy, the health worker paid periodic home visits to the patient and the family member who acted as a supervisor and attempted to enhance their knowledge about the disease and treatment process. Enhancement in quality of life among tuberculosis patients can improve persistence to anti-tuberculous therapy (18). Obviously the presence of the health worker in the patients' home can be of great benefit, provided it remains confidential.

CONCLUSION

Since tuberculosis can be transmitted easily, and the period of the therapy is long (6 months at least), the medication should be taken regularly to prevent the probability of drug resistance. Taking care of the needs of the patients and educating them in their residence can help. The results of the present study revealed the enhancement of the score of knowledge through educating the patients and their family, which made the patients follow the drug regimen. The weekly visits of the health worker in the patient's home in PFM-DOTS method had a positive effect. The degree of awareness and adherence to the therapy regimen were higher in PFM-DOTS than F-B-DOTS. This led to the recovery in the expected time. So it seems that the PFM-DOTS method probably has been one of the most appropriate methods in managing the tuberculosis and enhancing the knowledge of the patients and their family members.

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REFERENCES

1. Asgharzadeh M, Kafil HS, Roudsary AA, Hanifi GR. Tuberculosis transmission in Northwest of Iran: using MIRU-VNTR, ETR-VNTR and IS6110-RFLP methods. *Infect Genet Evol* 2011;11(1):124-31.
2. Rashedi J, Asgharzadeh M, Moaddab SR, Sahebi L, Khalili M, Mazani M, Abdolalizadeh J. Vitamin d receptor gene polymorphism and vitamin d plasma concentration: correlation with susceptibility to tuberculosis. *Adv Pharm Bull* 2014; 4(Suppl 2):607-11.
3. Molaeipoor L, Poorolajal J, Mohraz M, Esmailnasab N. Predictors of tuberculosis and human immunodeficiency virus co-infection: a case-control study. *Epidemiol Health* 2014; 36:e2014024.

4. Asgharzadeh M, Rashedi J, Moaddab SR, Ansarin K, Mirgasemi Z, Shirazi S. Foki Polymorphism, Vitamin D Receptor Gene Start Codon and Its Association with Tuberculosis. *Urmia Medical Journal* 2014;25(9):778-83.
5. Rashedi J, Asgharzadeh M, Moaddab SR, Amani M, Mazani M. Apal Polymorphism of Vitamin D Receptor Gene and Association with Susceptibility to Tuberculosis. *Journal of Ardabil University of Medical Sciences* 2013;13(4):379-87.
6. Rashedi J, Mahdavi Poor B, Rafi A, Asgharzadeh M, Abdolalizadeh J, et al. Multidrug-resistant tuberculosis in north-west of Iran and Republic of Azerbaijan: a major public health concern for Iranian people. *J Res Health Sci* 2015;15(2):101-3.
7. Sabzevari S, Mohammad-Alizadeh S. A survey of knowledge and attitude in medication controls of Tuberculosis patients referring to Zahedan anti TB centers in 1999. *Journal of Kerman University of Medical Sciences* 2001; 8(3):153-60.
8. Nikpour B, Ainparast A, Faraji F. The care at home.1st ed. Tehran; Tebb and Tazkieh: 2003.
9. Kyani F. Physical problems due to TB from the perspective of Patients in the city of Zahedan and Zabol and its relationship with some of the their demographic pro-file. *Journal of Zanjan University of Medical Sciences* 2001;9(1):20-5. [In Persian].
10. Fallahi Khoshnab M, Khankeh H, Mohammadi F, Hosseini M, Rahguy A, Ghazanfari N. Home care effectiveness in preventing rehospitalization of acute schi-zophrenic patients. *Iran J Nurs Midwifery Res* 2009; 4:59-66. [In Persian].
11. Nasehi M, Mirhagani L. National Directory for Combating TB. 1st ed.Tehran. Andishmand Press;2010.
12. Xianyi C, Fengzeng Z, Hongjin D, Liya W, Lixia W, Xin D, et al. The DOTS strategy in China: results and lessons after 10 years. *Bull World Health Organ* 2002;80(6):430-6.
13. Balasubramanian VN, Oommen K, Samuel R. DOT or not? Direct observation of anti-tuberculosis treatment and patient outcomes, Kerala State, India. *Int J Tuberc Lung Dis* 2000;4(5):409-13.
14. Zwarenstein M, Schoeman JH, Vundule C, Lombard CJ, Tatley M. Randomised controlled trial of self-supervised and directly observed treatment of tuberculosis. *Lancet* 1998;352(9137):1340-3.
15. Walley JD, Khan MA, Newell JN, Khan MH. Effectiveness of the direct observation component of DOTS for tuberculosis: a randomised controlled trial in Pakistan. *Lancet* 2001;357(9257):664-9.
16. Newell JN, Baral SC, Pande SB, Bam DS, Malla P. Family-member DOTS and community DOTS for tuberculosis control in Nepal: cluster-randomised controlled trial. *Lancet* 2006;367(9514):903-9.
17. World Health Organization (WHO). Global tuberculosis control- surveillance, planning and financing: Russian Federation. Geneva: WHO; 2005.
18. Mamani M, Majzoobi MM, Ghahfarokhi SM, Esna-Ashari F, Keramat F. Assessment of Health-related Quality of Life among Patients with Tuberculosis in Hamadan, Western Iran. *Oman Med J* 2014;29(2):102-5.