Original Article

Determinants of adherence to tuberculosis treatment in Iranian patients: Application of health belief model

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Abstract
Introduction: Adherence to TB treatment is an important issue for TB control, with key health consequences. Identification of the factors associated with that adherence is also important. The objective of this study was to identify factors associated with adherence to tuberculosis treatment, using the health belief model (HBM).
Methodology: Overall 297 TB patients were recruited to the study using the census method. All patients completed a 40-question survey form anonymously. The questionnaire was developed based on the Health Belief Model. Data collection was carried out through interviews and questionnaires, as well as observing medical records and medical cards to be used in medical performance checklists.
Results: The participants comprised 159 men and 138 women with an average age of 56.8 years (range 19-72 years). The results showed that the variables of perceived threat, benefits, barriers, and self-efficacy accounted for 42% of the variance in therapeutic adherence. The strongest predictor of adherence was found to be self-efficacy.
Conclusion: HBM appears to be a suitable model in predicting therapeutic adherence in TB patients. Our results emphasize the centrality of self-efficacy in treatment adherence, that health educators should consider when developing programs to motivate patients to adhere to treatment.

Key words: adherence; behavior; health belief model; tuberculosis.

Introduction

Despite the availability of effective treatment since the 1980s, tuberculosis (TB) is still considered a globally serious public health problem [1]. It is one of the leading causes of illness and death for millions of persons each year and ranks second as leading causes of death from an infectious disease around the world [2]. The fight against TB continues but it is not yet eradicated, and is still common particularly in developing countries [2,3]. It is of concern in much of the developing world [4], and is where it is responsible for 26% of preventable adult deaths [3]. A WHO estimate in 2012 reported 8.7 million new cases [2]. Based on the document "Administration of Tuberculosis and Leprosy Control" of the Ministry of Health in Iran, in 2015, 10,044 cases of TB were identified in Iran [3]. The risk of increasing prevalence of TB in Saveh City is high, because of the immigration of people from Afghanistan [5].

Previous studies have shown that one key factor in effective management of TB is patient adherence to the recommended treatment program [6]. In Iran, several reports have documented the problem of low treatment adherence [7-9]. Patient adherence behavior has the potential to make a tremendous impact on disease control efforts [10].

Adherence to TB treatment has been recognized as an essential element in TB control programs, and poor adherence is an important risk for their success. Non-adherence to therapy can cause relapse, continued transmission, and the increase of extensive drug resistance [11]. Previous studies indicated that a number of variables may contribute to patient adherence. These include awareness about TB and its management; socioeconomic variables such as age, literacy, job, change of residential place; and behavioral factors including perceived barriers about TB treatment, beliefs about TB treatment, perceived

stigma, perception about disease and its treatment, and social support [11,12].

The Health Belief Model (HBM) describes the influences such as knowledge, attitudes, beliefs and perceptions, that affect the individual behavior of patients, such as adherence to treatment [13]. HBM is suggested as a valuable model to describe these behaviors and treatment adherence to guide planning for control programs [6,7,14].

A review of research on TB therapy and patient adherence showed that despite the importance of adherence to treatment in TB patients, little is known about it and its related factors in Iranian patients. However, a good understanding of the process of TB treatment adherence and identification of the factors determining it are the cornerstone of treatment success. Hence, the purpose of this research was to identify factors associated with adherence to TB treatment via HBM in Saveh, Iran.

Methodology

Study setting and population

This cohort study was performed from January 2010 to December 2016, and surveyed 297 TB patients (159 males and 138 males) who came to Saveh Tuberculosis Control Center, and were selected for this study using census method. All identified TB patients are treated based on national TB treatment guideline and treatment is free of charge.

The inclusion criteria in this study included being TB patients who had received a treatment folder during the period of the survey; exclusion criteria were lack of informed consent and lack of inclination to participate in the survey. The data collection was carried out through interviews and questionnaires, as well as observing medical records and medical cards used in medical performance checklists.

Questionnaire

The design and construction of the questionnaire were done by the research team, after studying previous researches [6, 7, 15] and consulting experts in Tuberculosis and in Health Education using the HBM as a basis. The final questionnaire had 40 questions and was structured, with the following parts:

- First part: 10 questions about demographic factors (age, gender, marital status, literacy level, employment status, diagnostician, disease type, treatment month, past infection history, and family infection history);

- Second part: 10 questions about TB awareness e.g. "How many months should a TB patient take prescribed medications?" In this part, 2 points were considered for

the correct answers to the awareness questions, 1 point for the "no idea", and 0 points for the incorrect answers;

- Third part: 25 questions about the HBM constructs (perceived benefits and barriers, perceived threat, and perceived self-efficacy) e.g. "Timely use of anti-TB drugs will lead to my optimal recovery and health." The points in this part ranged from 1 to 5 for the questions on perceived threat (perceived susceptibility and severity), self-efficacy, and perceived benefits and barriers, and they were assigned to the questions as follows: 0 points for the "completely disagree" through to 5 points for the "completely agree";

- Fourth part: a checklist with 5 questions assessing the patients' therapeutic adherence performance. In this part, 2 points were considered for performing and 0 points for not performing an item.

The questionnaire was validated using the Content Validity Index and Content Validity Ratio methods. To determine the content validity index, the questionnaire was presented to 10 experts who had great experience and expertise in the fields of Health Education and Promotion, and behavioral and infectious diseases. They were asked about the simplicity, clarity, and relevance of each item based on a 4-point Likert scale; the items with values over 0.75 were kept and those with lower values were omitted. Also, to determine the content validity ratio, the experts' opinions on the necessity of each item were collected using a 3-point Likert scale (necessary, useful but unnecessary, unnecessary); items with values below 0.62 were omitted based on Lawshe's table measurement. The reliability of the questionnaire was also evaluated in terms of internal consistency and stability. Cronbach's alpha was measured for 25 patients in order to determine the internal consistency. The mean Cronbach's alpha coefficient was 0.81. The test-retest method was run to examine the stability of the questionnaire. To this aim, 25 participants answered the scale's questions for a second time over a period of two weeks, and Pearson's correlation coefficient was calculated as 0.79.

Data analysis was done with the Statistical Package for the Social Sciences (SPSS, version 16.0.). Descriptive factors are stated as frequency, mean, and minimum and maximum. Scores for knowledge, therapeutic adherence and constructs of the HBM, including perceived, threat, benefit, barriers and self-efficacy were also compared based on demographic variables using one-way analysis of variance (ANOVA) and independent sample T-Test. A multiple linear regression analysis was performed to identify the predictive power of the HBM constructs on therapeutic

adherence of the TB patients. The normality of data was evaluated via the Kolmogorov-Sminov test.

Ethics

The ethics committee of the Saveh University of Medical Science approved the research (ethics approval number IR.SAVEHUMS.REC.1395.42). Before enrolment in the research, all patients provided verbal informed consent.

Results

The average age of the participants in this study was 56.8 years, with a standard deviation of 12.5 and a range from 19 to 72 years. Of the 297 participants, 53.5% of them were males and 46.5% females. In addition, 59% of the samples were Afghan nationals and 41% Iranian. Regarding disease type, 54% of the males and 49% of the females had smear-positive pulmonary tuberculosis, 25% of the males and 19% of the females had extra-pulmonary tuberculosis, and the rest were smear-negative pulmonary tuberculosis. Most of the extra-pulmonary cases were related to lymph nodes (48%) while bones, joints, digestive system, and genital system came next respectively.

In terms of literacy, most participants (61%) were illiterate; 19%, 13% and 7% had primary, secondary (6-11 years of education) education and high school diploma, respectively. The average time from the emergence of the symptoms in smear-positive patients until the diagnosis was 3.4 months. The males showed more therapeutic adherence than the females. The

independent t-test showed significant differences between the mean score of the HBM constructs and the therapeutic adherence of the males and females ($p < 0.05$). The analysis of variance test revealed significant differences between the disease type (smear-positive, smear-negative, or extra-pulmonary) and the therapeutic adherence: patients who were smear-positive showed better therapeutic adherence than those who were smear-negative, and extra-pulmonary. In addition, smear-positive patients had higher scores for perceived threat and perceived benefits, as well as better therapeutic adherence. The analysis of variance test demonstrated that patients with higher literacy levels showed lower perceived barriers to treatment, higher perceived threat to improper treatment, perceived benefits to therapy, and self-efficacy as well as better therapeutic adherence to therapy than patients with lower literacy levels (primary) and the illiterate ($p < 0.05$) (Table. 1).

Multiple liner regression analysis was used to evaluate the predictive power of the HBM constructs on therapeutic adherence. The results of the model showed that the independent variables of awareness, perceived threat, perceived benefits, perceived barriers, and self-efficacy accounted for 42% of the variance in therapeutic adherence. Among these variables, perceived self-efficacy, benefits, threat and barriers were respectively the strongest predictors of therapeutic adherence, while the variable of perceived awareness was not a significant predictor (Table 2).

Table.1. Distribution of mean and standard deviation scores of therapeutic adherence and model constructs based on demographic variables.

Variable		N (%)	Awareness	Perceived threat	Perceived benefits	Perceived barriers	Self-efficacy	Therapeutic adherence
			Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Gender	Male	159 (53.5)	15.6 (2.1)	24 (4.7)	11 (1.8)	9.1 (2.2)	9.5 (2.1)	6.5 (1.4)
	Female	138 (46.5)	13.2 (2.3)	21 (3.8)	8.7 (2.2)	11.4 (2.6)	7.7 (1.8)	4.1 (1.6)
			0.04	0.001	0.001	0.01	0.001	0.01
Nationality	Afghan	175 (59)	10.1 (2.8)	15 (5.1)	6.5 (2.5)	10.9 (2)	6.7 (1.9)	3.6 (1.7)
	Iranian	122 (41)	16.4 (1.9)	28 (4.2)	12.6 (2.2)	8.5 (2.8)	11.4 (1.1)	7.8 (1.2)
P			0.001	0.001	0.001	0.001	0.001	0.001
Disease type	Smear-positive	153 (51.5)	13.8 (3.2)	23 (4.4)	11.8 (2.1)	9.1 (1.7)	8.4 (1.2)	7.6 (1.1)
	Smear-negative	67 (22.5)	14.1 (2.9)	18 (3.9)	7.2 (2.9)	12 (2.1)	8.2 (1.1)	4.5 (1.5)
	Extra-pulmonary	77 (26)	13.9 (2.8)	21 (4.2)	7.9 (2.3)	10.4 (1.7)	8.5 (1.2)	5.9 (1.2)
P			0.26	0.01	0.001	0.001	0.001	0.001
Literacy level	Illiterate	181 (61)	11.5 (2.7)	14.9 (5.6)	6.6 (3.0)	11 (1.6)	6.1 (1.8)	3.6 (2.4)
	Primary	56 (19)	13.4 (2.5)	18.1 (4.8)	7.4 (2.6)	10.2 (2.3)	7.5 (2.0)	4.2 (2.3)
	Secondary	39 (13)	14.3 (3.1)	19 (4.1)	9.2 (1.9)	7.2 (3.2)	9.3 (1.2)	7.1 (0.9)
	Diploma	21 (7)	16.2 (1.9)	24 (3.5)	12.1 (2.4)	7 (2.4)	11.6 (0.9)	7.3 (1.8)
P			0.001	0.001	0.001	0.001	0.001	0.02

Table 2. Results of multiple regression analysis of HBM on therapeutic adherence.

Variable	Unstandardized coefficients		Standardized β	p value
	B	**SE**		
Awareness	0.16	0.08	0.21	0.07
Perceived threat	0.35	0.15	0.22	0.02
Perceived benefits	0.30	0.13	0.25	0.03
Perceived barriers	-0.11	0.05	-0.15	0.05
Perceived self-efficacy	0.45	0.16	0.41	0.006
Model R^2		0.42		0.001

Discussion

The results of this study revealed that HBM constructs were able to explain 42% of the variance in patients' behavior, in other words, these results provide experimental support for the idea that HBM constructs might contribute to predicting therapeutic adherence in TB patients. This result is in line with previous studies, which have shown that HBM is a useful model to explain healthy behaviors including treatment adherence, that patients should practice. For example, Tola *et al.* showed that TB patients in educated group based on HBM were 0.31 times more likely to adhere to treatment [6]. Similarly, Llongo reported that HBM was a useful model to explain treatment adherence in tuberculosis cases in New York City [15]. In another study by Brownlee-Duffeck, HBM constructs could explain 52% of the variance in adherence to metabolic control among patients with diabetes [16]. Among our patients, HBM could only explain less than half of the variance in therapeutic adherence. One possible explanation could be that adherence may also be correlated with the patients' tolerance to the complexity of the therapy, with many anti-TB drugs used, isolation conditions, and methods for early diagnosis. Also the follow up and evaluation of response to therapy could play a role. Additional reasons for incomplete accounting of treatment adherence by HBM could be poor association between healthcare professionals and patients, low literacy, cultural factors, poor social support, and unhelpful attitudes or beliefs [6,12,15]. All of this points to the need to study other factors that were not accounted for by HBM.

In previous studies, perceived self-efficacy has been demonstrated as a prerequisite skill for treatment adherence [17]. Similarly, our study indicated that among the HBM constructs, self-efficacy played a key role in therapeutic adherence in TB patients, which highlights the centrality of self-efficacy in treatment adherence. This result has reported in studies on other diseases. For instance, Mancuso *et al.* reported a significant relationship between self-efficacy and asthma patients' abilities to self-manage [18]. Nokes *et al.*, found support for perceived self-efficacy as the strongest predictor for adhering to antiretroviral therapy among people living with HIV [19]. Indeed, the results of these studies highlight the importance of self-efficacy in adherence behavior. If it can be confirmed that perceived self-efficacy is a facilitator to behavior adherence, then medical interventions to improve self-efficacy will lead to patients receiving greater benefit from existing treatments.

In the present study, nearly all patients reported improved health as the major factor for adherence behavior; improving the ability to work was reported as an important reason for over two-thirds of patients. Perceived benefit was the second important factor influencing adherence which means that participants who had good knowledge about the benefit of treatment were more adherent. This is consistent with the report by Li *et al.* in China indicated that perceived benefit was the important predictor of TB care behaviors [20]. Similarly, Rodríguez-Reimann *et al.* found among Mexican Americans that action benefits predicted greater intent to engage in TB health behaviors [21]. In contrast, Tamirat *et al.* found no significant association between perceived benefits and self-care behaviors of diabetic patients in Ethiopia [22]. Improving predicted benefits of healthy behaviors and decreasing predicted barriers has been shown to be important in health promotion and in efforts to develop treatment adherence behavior [7,14]. However, according to the concept of perceived benefit, TB patients must believe that adhering to treatment is important to their TB treatment. Therefore, this construct must be reinforced in the TB control programs.

In this study, patients' beliefs about the seriousness and infectivity of their disease and their anxiety about infecting family members and friends were important factors for treatment adherence. The results indicated that perceived threat was also a significant factor in predicting therapeutic adherence in TB patients. Similar results have been reported in applications of the HBM to the prediction of TB patients' healthy behaviors. For example, a study by Karimy *et al.* in TB patients in Zabol, Iran, suggested that individuals with high perceived threat of the disease were more likely to show

therapeutic adherence [7]. Similar findings were reported by Poss among migrants in the United States [23], and Li *et al.* in China [20], where the perceived threat of TB medical problems predicted increased TB care-seeking behaviors. Indeed, all of these studies demonstrated that patients' attitudes about the seriousness of perceived risk and their beliefs in their susceptibility to those consequences plays a vital role in adherence behavior. That means that using risk messages as a framework to design educational interventions may improve the likelihood of therapeutic adherence.

In the present study, negative associations were found between adherence behaviors and perceived barriers. Our results are in line with those reported by Rodríguez-Reimann *et al* . [21]. Another study by Turner *et al.* reported that more barriers were associated with low adherence in patients [24]. Poss also showed that identifying barriers on an individual basis is important to successful adherence [23]. In addition, our study found that the perception that TB drugs are harmful was one of the major barriers to TB treatment adherence. Joseph *et al*. reported that the opinion that treatment was unsafe was a critical barrier to TB treatment adherence in the US [25]. However, in a meta-analysis of 18 HBM studies (2,702 subjects), benefits and barriers were consistently the strongest predictors of treatment adherence [26]. A body of literature suggests that healthy action is less likely if people perceived more barriers. According to researchers, perceived barriers are both vital and essential factors in behavior change [7,21,23]. These results highlight the importance of identification of strategies to overcome barriers for the design of effective programs for self-management of people with diseases similar to TB.

Our findings suggested that males had more knowledge and better perception of tTB disease and treatment. In this study, the Afghan females and Iranian rural females were less literate, which mean they may have slight knowledge and poor awareness about TB. Agboatwalla reported that rural females in Pakistan tended to view TB as a "punishment from God" [27]. Similarly, a study in YZ County of China found that females, in comparison with males, lacked awareness about TB disease [28]. These results show that patients' awareness about TB, its treatment and effects of treatment non-adherence are associated with successful adherence.

Numerous behavioral and socioeconomic variables were influencing TB adherence. For example, the relationship between education and treatment

adherence has been confirmed in several studies [11,14]. Similarly, our study found a significant association between literacy and TB treatment adherence. Gazmararian *et al* indicated that low literacy was associated with low medication adherence for cardiovascular diseases [29]. Previous studies conducted in Iran have shown that literacy can affect the level of knowledge and produce favorable behaviors and attitudes more than wealth [8,13]. Indeed, patients with more education understand the potential risks of imperfect treatment which promotes motivation to adhere to treatment. A number of limitations of the present research must be acknowledged. Firstly, the data were collected from patients at one university and might not be representative for the country.

Conclusion

The results of our study indicate that HBM is a suitable model in predicting therapeutic adherence in TB patients. To design effective TB prevention interventions, health care workers should target programs to minimize perceived barriers and promote perceived self-efficacy, benefits and threats to achieve improved adherence to treatment. In addition, our results highlight the importance of self-efficacy in TB treatment adherence, which health educators should considered when developing programs on motivation for treatment adherence. However, more research to confirm the variables influencing adherence in these countries (Iran and Afghanistan) would be helpful to design strategies to reduce non-adherence. Similar research would be useful to enhance TB treatment adherence in other developing countries

Authors' Contributions
Study concept and design: Mahmood Karimy; acquisition of data: Nemat Azizi; analysis and interpretation of data: Vahid Naseri Salahshour and Mahmood Karimy.

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