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Default Risks in Home Tuberculosis Patients Regarding Japanese DOTS (Directly Observed Treatment Short-Course)

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Abstract

Background: A default risk assessment is conducted on home-care tuberculosis patients in Japan to prepare an individual plan of nursing care and to work on DOTS. The purpose of this study is to clarify appropriate default risk items.

Methods: Data on tuberculosis patients who finished treatment during 2013 to 2015 at public health centers in four prefectures was separated into completion and failure and interruption, and conducted X^2 test. Furthermore, logistic regression analysis was conducted to examine the relationship based on the evaluation results as the dependent variable.

Results: 470 subjects consisted of 439 patients (93.4%) whose treatment was completed and 31 patients (6.6%) whose treatment was interrupted. When X^2 test was conducted in regards to 15 common risk items, a significant difference was observed in occurrence of side effects and history of treatment interruption. Analysis after excluding patients in facilities as well as patients under 20 years old also indicated the same results (n=417). When the 15 risk items were considered by excluding patients in facilities as well as patients under 20 years old with multiple logistic regression analysis, risk items included latent tuberculosis patients (OR: 2.59, 95% CI confidence interval: 1.11-6.02) in regards to the affected areas (pulmonary tuberculosis+extrapulmonary tuberculosis group=1), occurrence of side effects (OR: 7.5, 95% CI 3.33-16.92), and history of treatment interruption (OR: 10.57, 95% CI:1.81-61.90). When patients whose medicine intake was directly confirmed were further excluded (n=395), risk items included affected areas (OR: 3.13, 95% CI: 1.28-7.68), occurrence of side effects (OR: 10.46; 95% CI: 4.39-24.93), and no understanding of side effects (OR: 8.19, 95% CI: 2.03-33.14).

Conclusion: As a result of narrowing down the subjects, there were eventually 15 default risk items, among which four strong risk items were suggested, including affected areas, occurrence of side effects, no understanding of side effects, and history of treatment interruption.

Keywords: Tuberculosis patients; Dots (Directly Observed Treatment Short-Course); Risk assessment sheet; Public health nurse

Background

Prevalence of tuberculosis in the world varies significantly depending on the region [1]. The number of newly registered tuberculosis patients in Japan was 17,625 in 2016 and the incidence rate was 13.9 (compared to the population of 100,000), i.e., it is decreasing every year; however Japan is still a moderately prevalent country in comparison with the incidence rate of tuberculosis in the advanced countries (2014) [2-4]. In order to decrease the incidence rate of tuberculosis in the future while moving toward to a country of low tuberculosis prevalence, tuberculosis patients under treatment need to complete medication with no recurrence. In Japan, measures to prevent tuberculosis have been taken under the law regarding infectious diseases, and DOTS system unique to Japan called the "21st Century Japanese DOTS Strategy" (hereafter "Japanese DOTS Strategy") was created in 2003. Since then, flexible efforts have been promoted in Japan, mainly in public health centers in each region. [5].

Japanese DOTS has been supporting hospitalized and unhospitalized patients as called "Nyuin DOTS" and "Chiiki DOTS", respectively in Japanese [6]. Chiiki DOTS provide medication assistance to patients mainly through public health centers where patients reside. However, patients continuously fail to take medications. Recurrence results from failure to ensure medication, leading to appearance of multidrug-resistant tuberculosis (MDR-TB). It is important to ensure medication for complete cure of tuberculosis [7-11].

Regarding default risk items in Japan, the Japanese Society for Tuberculosis suggests what needs to be considered as default risks, based on which each public health center establishes its own default risk items. Then, they use the default risk assessment sheet to establish an individual patient support plan that fits each patient and to provide medication assistance. However, each public health center establishes unique items in the default risk assessment sheet and appropriateness of risk items is not verified under the current situation. Although influential risk factors are suggested in previous literature regarding factors of default risks [12,13], the scope of influence has not been clarified. Furthermore, TB patients are unevenly distributed in Japan between large cities and rural areas, and many public health centers establish different risk items considering characteristics of each region [14-18] and no integrated

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and evidence-based item is observed. Regarding various risk items established by each public health center, only the items common to all public health centers are important to be noted as default risks.

When the overseas environment surrounding tuberculosis was considered, the issue in countries of low tuberculosis prevalence such as various European countries and the U.S. relates to immigrants from a country of high tuberculosis prevalence seeking economic income who enter a country as potential TB patients and develop tuberculosis in the destination country, influencing the TB incidence rate [2,7,19]. The main goal in a country of low tuberculosis prevalence includes measures on immigrants who appear to be potentially affected by tuberculosis rather than confirmation of patient's medicine intake. However, items listed as default risks are different depending on each country [20-27].

The purpose of this study is to clarify the default-related factors as well as the most influential default factors among them, at the present time when Japan is becoming a country of low tuberculosis prevalence.

Operational definition of terms

Treatment failure: The culture specimen collected after the fifth month from treatment commencement is confirmed positive.

Default: Treatment interruption for 60 consecutive days or two consecutive months, or insufficient treatment period for standard treatment.

Interruption: Treatment interruption by self-judgement without physician's instruction.

Methods

Subjects

Data for analysis includes risk assessment data on tuberculosis patients for whom involvement with DOTS ended during 2013 to 2015 at public health centers in four prefectures of the Tokai District (attributes of subjects, risk assessment items, treatment evaluation results, and the method to confirm medicine intake).

Data collection

Chiiki DOTS risk assessment sheets actually used at 57 public health centers in four target prefectures of the Tokai District (Aichi, Gifu, Mie, and Shizuoka) were collected in January to February 2016 to summarize risk assessment items established at each health center (collection rate: 96.5%). A total 34 items were established as risk items at public health centers that responded. These items were categorized into the "condition of tuberculosis," "background of living", "DOTS" "understanding of tuberculosis," and "mental and physical conditions" to prepare a survey sheet of risk items.

In addition to this survey sheet of risk items, matters relating to patients (age, gender, occupation, affected area), method to confirm medicine intake (confirmation frequency, place, method, person), and treatment evaluation results were surveyed.

The survey was conducted during June to September 2016. Regarding the survey procedure, approval for the survey was obtained from the department that governs tuberculosis at each prefecture, followed by mailing of letters to request cooperation to each public health center. For data collection, the researcher visited public health centers that gave consent and transcribed the information on the questionnaire, or staff at a public health center transcribed it on the survey sheet and returned it to the researcher.

15 out of 34 risk items were common to each public health center surveyed. In regards to categorization of analysis targets, the "condition of tuberculosis" included "occurrence of side effects," "complications," and "MDR-TB;" the "background of living" included "trouble/difficulty upon hospital visit," "solitary living," "financial issues," and "no fixed address;" "understanding of tuberculosis" included "no understanding and acceptance of disease," "no understanding of the need to take medicines," and "no understanding of side effects;" and the "mental and physical conditions" included "physical disability," "disability in mind, memory, and cognition," "anxiety about medicine intake," "alcohol/drug dependency," and "history of treatment interruption."

Data analysis

Treatment outcomes were categorized in accordance with the criteria of tuberculosis registrant information system at the Tuberculosis Surveillance Center of the Research Institute of Tuberculosis in Japan. Cure and completion were considered as "completion" and treatment failure and interruption were considered as "default" to examine the relationship with default risks. In regards to patients treated for longer than 12 months, final evaluation (medication completion/default) was used for determination and latent tuberculosis patients were also categorized in the same way.

For analysis, risk items common to all health centers were divided into completion and default to conduct X2 test between two variables of each risk item and evaluation item. Next, logistic regression analysis (stepwise method) was conducted with evaluation results as the dependent variable to calculate relative risks of default, etc. SPSS Windows24.0 (IBM Japan) was used as the statistical package and the significance level was set at 5%.

Ethical clearance

This study was conducted upon obtaining consent from the Research Ethics Committee of Aichi Prefectural University (28 Ai-Ken-Daigaku-Jo No. 6-10). Information that can identify individual participants was not collected, and personal information on public health nurses who carried out an assessment was not obtained either. No disadvantage by participation as well as no problem relating to protection of human rights was explained to obtain cooperation.

Furthermore, this research was conducted as part of the research grant to the School of Nursing of Gifu Shotoku Gakuen University and of the basic research program with the grant-in-aid to fund the academic research for 2017 to 2019 (C) (task number 17K12601). The relevant university is not affiliated with the study and there is no conflict of interest.

Results

Characteristics of tuberculosis patients

Data was collected from 588 people, and after excluding the deceased and missing values, analysis was possible for 470 people, among whom 433 people completed medicine intake and 31 people defaulted it, ages (average ± standard deviation) 58.8 ± 23.0 and 60.1 ± 19.7, respectively. 239 males and 200 females completed medicine intake, and 16 males and 15 females defaulted it. When the ages of subjects were divided into five sections including 0-19, 20-39, 40-64, 65-79, and 80 and older, ages 0-19 completed medicine intake at the highest proportion, i.e., all 25 people completed it (Table 1).

Regarding categorization of occupations, the most subjects had no

job, i.e., 219 people (46.6%), and the proportion of the elderly was high; therefore, the proportion of the unemployed was also high. Patients engaging in occupations in relatively close contact with the general public such as the entertainment business, nurses/public health nurses, doctors, other health professionals/caretakers, teachers/kindergarten teachers, etc. consisted of 15.8%.

Relationship between risk items common to each public health center and evaluation results

Items of default risks for all subjects: X^2 test was conducted to see the relationship between patients who completed and defaulted medicine intake in regards to 15 risk factors common to each public health center. Patients who defaulted were significantly more than patients who completed in regards to two out of 15 items: occurrence of side effects categorized in the "condition of tuberculosis" (p=0.00) and history of treatment interruption categorized in the "mental and physical conditions" (p=0.01) (Table 2).

Items of default risks in the case of selected target patients (excluding patients in facilities and patients under 20 years old): X^2 test was conducted on 417 people after excluding patients in facilities where the facility staff is able to assist medicine intake (welfare facilities as well as patients admitted for another disease) and patients under 20 years old as there was no one who defaulted under control of parents or guardians. As a result, a significant difference was recognized in two items in the same way as the results of all subjects: occurrence of side effects (p=0.00) and history of treatment interruption (p=0.00) (Table 3).

Risk items with multiple logistic regression analysis

Relationship after excluding patients in facilities and patients under 20 years old from target patients: 417 subjects were analyzed. A significant difference was observed in affected areas (pulmonary tuberculosis+extrapulmonary tuberculosis and latent tuberculosis), and latent tuberculosis had a higher default risk in comparison with pulmonary tuberculosis+extrapulmonary tuberculosis (OR: 2.59, 95% CI: 1.11-6.02). A significant difference was also recognized in occurrence of side effects (OR: 7.51, 95% CI: 3.33-16.90) and history of treatment interruption (OR: 10.57, 95% CI: 1.81-61.9) (Table 4).

Risk items after excluding patients in facilities, patients under 20 years old, and direct confirmation of medicine intake (as confirmed by public health nurses): 395 subjects were analysed after excluding people whose medicine intake was confirmed every day by public health nurses who determined high possibility of default, in addition to people in facilities and people under 20 years old. There was a significant difference in three items: affected area (OR: 3.13, 95% CI: 1.28-7.68), occurrence of side effects (OR: 10.46, 95% CI: 4.39-24.93), and understanding of side effects (OR: 8.19, 95% CI: 2.03-33.14) (Table 5).

Parameters		Mean	S.D.
Age		58.9	22.8
Parameters		**(n)**	**(%)**
Gender	Male	255	54.3
	Female	215	45.7
Affected area	Pulmonary tuberculosis	229	48.7
	Extrapulmonary tuberculosis	91	19.4
	Latent tuberculosis	150	31.9
Occupation category	Entertainment business	15	3.2
	Health/welfare-related occupation	53	11.3
	Elementary/junior high/high school and college students, teachers/kindergarten teachers, etc.	25	5.4
	Other full-time workers	82	17.4
	Other temporary workers	32	6.8
	Other self-employment/freelance occupation	15	3.2
	Children before school age	11	2.3
	Unemployed/homemakers	234	49.8
	Others/unknown	3	0.6
Method to confirm medicine intake (multiple answers allowed)	Direct confirmation of medicine intake	45	9.6
	Confirmation of empty bags	153	32.6
	Confirmation of remaining drugs	109	23.2
	Confirmation of medication notes	178	37.9
	Confirmation by hearing	227	48.3
	Others	1	0.2
Place to confirm medicine intake (multiple answered allowed)	At home	228	48.5
	Hospital outpatient clinic	29	6.2
	Visit to public health center	32	6.8
	Pharmacy	7	1.5
	Contact (by phone)	194	41.3
	Others	47	9.8

Table 1: Characteristics of TB patients.

			All subjects n=470		
			Completion	Default	*p* value
			n=439	N=31	
Condition of tuberculosis	Occurrence of side effects	Yes	56 (77.8%)	16 (22.2%)	0**
		No	383 (96.2)	15 (3.8)	
	Complications	Yes	223 (93.7)	15 (6.3)	0.85
		No	216 (93.1)	16 (6.9)	
	Drug resistance (INH or RFP)	Yes	5 (83.3)	1 (16.7)	0.34
		No	434 (93.5)	30 (6.5)	
Background of living	Trouble/difficulty upon hospital visit	Yes	29 (90.6)	3 (9.4)	0.46
		No	410 (93.6)	28 (6.4)	
	Solitary living	Yes	91 (93.8)	6 (6.2)	1
		No	348 (93.3)	25 (6.7)	
	Financial issues	Yes	54 (91.5)	5 (8.5)	0.57
		No	385 (93.7)	26 (6.3)	
	No fixed address	No	439 (93.4)	31 (6.6)	—
Understanding of tuberculosis	No understanding and acceptance of disease	Yes	39 (88.6)	5 (11.4)	0.2
		No	400 (93.9)	26 (6.1)	
	No understanding of the need to take medicines	Yes	32 (88.9)	4 (11.1)	0.28
		No	407 (93.8)	27 (6.2)	
	No understanding of side effects	Yes	30 (88.2)	4 (11.8)	0.27
		No	409 (93.8)	27 (6.2)	
Mental and physical conditions	Physical disability	Yes	49 (98.0)	1 (2.0)	0.23
		No	390 (92.9)	30 (7.1)	
	Disability in mind, memory, and cognition	Yes	59 (93.7)	4 (6.3)	1
		No	380 (93.4)	27 (6.6)	
	Anxiety about continuing medication	Yes	22 (88.0)	3 (12.0)	0.22
		No	417 (93.7)	28 (6.3)	
	Alcohol/drug dependency	Yes	6 (85.7)	1 (14.3)	0.38
		No	433 (93.5)	30 (6.5)	
	History of treatment interruption	Yes	5 (62.5)	3 (37.5)	0.01*
		No	434 (93.9)	28 (6.1)	
	*p<0.05, **p<0.01		χ^2 test(Fisher's exact test)		

Table 2: Relationship between risk items common to each public health center and evaluation results (All subjects).

			Subjects after excluding patients in facilities and patients under 20 years old n=417		
			Completion	Default	*p* value
			n=386	n=31	
Condition of tuberculosis	Occurrence of side effects	Yes	54 (77.1%)	16 (22.9%)	0**
		No	332 (95.7)	15 (4.3)	
	Complications	Yes	202 (93.1)	15 (6.9)	0.71
		No	184 (92.0)	16 (8.0)	
	Drug resistance (INH or RFP)	Yes	4 (80.0)	1 (20.0)	0.32
		No	382 (92.7)	30 (7.3)	
Background of living	Trouble/difficulty upon hospital visit	Yes	26 (89.7)	3 (10.3)	0.4
		No	360 (92.8)	28 (7.2)	
	Solitary living	Yes	88 (93.6)	6 (6.4)	0.82
		No	298 (92.3)	25 (7.7)	
	Financial issues	Yes	45 (90.0)	5 (10.0)	0.77
		No	341 (92.9)	26 (7.1)	
	No fixed address	No	386 (92.6)	31 (7.4)	—
Understanding of tuberculosis	No understanding and acceptance of disease	Yes	27 (84.4)	5 (15.6)	0.08
		No	359 (93.2)	26 (6.8)	
	No understanding of the need to take medicines	Yes	21 (84.0)	4 (16.0)	0.1
		No	365 (93.1)	27 (6.9)	
	No understanding of side effects	Yes	19 (82.6)	4 (17.4)	0.08
		No	367 (93.1)	27 (6.9)	

Mental and physical conditions	Physical disability	Yes	36 (97.3)	1 (2.7)	0.51
		No	350 (92.1)	30 (7.9)	
	Disability in mind, memory, and cognition	Yes	43 (91.5)	4 (8.5)	0.77
		No	343 (92.7)	27 (7.3)	
	Anxiety about continuing medication	Yes	21 (87.5)	3 (12.5)	0.41
		No	365 (92.9)	28 (7.1)	
	Alcohol/drug dependency	Yes	6 (85.7)	1 (14.3)	0.42
		No	380 (92.7)	30 (7.3)	
	History of treatment interruption	Yes	4 (57.1)	3 (42.9)	0.01*
		No	382 (93.2)	28 (6.8)	
*p<0.05, **p<0.01					

Table 3: Relationship between risk items common to each public health center and evaluation results (Subjects after excluding patients in facilities and patients under 20 years old).

Risk item		Number of people (%)	Odds ratio	95%CI	*p* value
Affected area	Pulmonary and Extrapulmonary	292 (70.0)	1		
	Latent	125 (30.0)	2.59	1.11-6.02	0.03*
Occurrence of side effects	No	347 (83.2)	1		
	Yes	70 (16.8)	7.51	3.33-16.9	0**
History of treatment interruption	No	410 (98.3)	1		
	Yes	7 (1.7)	10.57	1.81-61.9	0.01**
*P<0.05, **P<0.01					

Table 4: Relationship between patients who completed and default medication observed from the evaluation results of assessment items common to each public health center. After excluding people in facilities and people under 20 years old (Multiple logistic regression analysis - Stepwise method) n=417.

Risk item		Number of people (%)	Odds ratio	95%CI	*p* value
Affected area	Pulmonary and Extrapulmonary	270 (68.4)	1		
	Latent	125 (31.6%)	3.13	1.28-7.68	0.01*
Occurrence of side effects	No	328 (83.0)	1		
	Yes	67 (17.0)	10.46	4.39-24.93	0**
Understanding of side effects	Yes	379 (95.9)	1		
	No	16 (4.1)	8.19	2.03-33.14	0**
*P<0.05, **P<0.01					

Table 5: Relationship between patients who completed and default medication observed from the evaluation results of assessment items common to each public health center. After excluding people in facilities, people under 20 years old, and people whose medication confirmation method was direct confirmation of medicine intake (Multiple logistic regression analysis - Stepwise method) n=395.

Discussion

Items of default risks in Japanese DOTS

15 items of default risks that were common to public health centers in the Tokai District were examined in this study. These items are also noted as default risks at public health centers in Japan [28]. A significant difference was recognized only in two out of 15 items in X^2 test: occurrence of side effects and history of treatment interruption. These are the results of vigorous medication assistance suitable for patients after public health nurses engaging in Chiiki DOTS in Japan prepare an individual nursing plan for all tuberculosis patients. In other words, these two items with a significant difference seem to be high-risk items where default cannot be easily prevented even with intervention by public health nurses.

There was no default in subject groups with a high risk: patients in facilities as well as patients under 20 years old. Completion of medicine intake seems to have been accomplished because facilities staff were positioned as supporters of medicine intake to patients in the facilities and were given certain authority and responsibility to manage patients' medicine intake to ensure completion; and in the case of patients under 20 years old, parents were positioned as responsible people to control medicine intake to ensure completion. It seems that DOTS will be successful and contribute to decrease in sources of infection when public health nurses prepare a nursing plan for each patient and provide appropriate support.

Risk items observed with multiple logistic regression analysis

As a result of logistic regression analysis, a significant difference was recognized in four items including occurrence of side effects, no understanding of side effects, affected areas, and history of treatment interruption, while two out of these four items were relating to side effects of drugs.

Default due to a sense of distrust regarding diagnostic treatment as well as to assumption is considered to have arisen from occurrence of side effects [13]. Default resulting from side effects of drugs is reported to be the most frequent not only in pulmonary tuberculosis but also in extrapulmonary tuberculosis [29]. Occurrence of side effects is an important item that can lead to default, which seems to be a risk item that should be noted the most in Chiiki DOTS.

In the case of affected areas, default risks were higher for latent tuberculosis patients in comparison with pulmonary tuberculosis and extrapulmonary tuberculosis. It is considered to be because awareness to treatment is low due to lack of symptoms, there are fewer opportunities to receive education on tuberculosis resulting in insufficient patient education, and treatment is often provided by general medical institutions rather than medical institutions specializing in tuberculosis; and medical staff also seem to lack in professional knowledge [30,31]. Latent tuberculosis does not become a source of infection to other people, while future onset and spread may be possible. In a moderately prevalent country like Japan, it is desired to recommend preventive medication to latent tuberculosis patients who may develop symptoms in the future in order to eliminate the possible source of infection. For this purpose, tuberculosis education to health professionals is essential, and strengthening of administrative control and guidance seems to be the future task.

Regarding the history of treatment interruption, people who experienced treatment interruption include people whose symptoms disappeared in the past, and occurrence of MDR-TB (Multi-Drug Resistant Tuberculosis) and XDR-TB (Extensively Drug-Resistant Tuberculosis) is a future concern [9,32]. It is likely for relapsing patients who defaulted, to repeat the same thing with the erroneous experience of treatment success in the past. Successful DOTS is difficult as these patients seem to be associated with characteristics of patients themselves and feeling of self-efficacy [33,34]. Chiiki DOTS in Japan adopts a network structure where a public health nurse in charge assesses the patient's life of recuperation including these patients and requests medication assistance from a reliable person to receive cooperation. It includes not only family but also nurses at a hospital the patient visits, pharmacists at a drugstore, nursing care staff at a geriatric facility, supervisors at workplace, school staff, etc. for example. This is a system unique to Japan, which seems to be utilizing the characteristics of Japanese people. Support to default of difficult patients seems to improve by further strengthening the network of medication assistance in the future.

In regards to items of particularly high risks among 15 items of default risks, it is necessary to examine and proceed with the individual method suitable for the patient.

Conclusion

It was indicated in this study that there were 15 risk factors in tuberculosis patients who defaulted in Chiiki DOTS in Japan. The risk of four items among them was particularly high: occurrence of side effects, no understanding of side effects, history of treatment interruption, and latent tuberculosis. Appropriate medication assistance needs to be provided for patients to be able to complete medication by paying attention to these four items at a particularly high risk.

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