Comparison of tuberculosis treatment outcomes by method of treatment supervision in the Fiji Islands

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Setting: The National Tuberculosis Programme (NTP) in Fiji.

Objective: To determine anti-tuberculosis treatment outcomes stratified by method of treatment supervision (i.e., self-administered treatment [SAT] vs. supervision by a family member).

Design: A retrospective descriptive study of all tuberculosis (TB) patients registered with the NTP in Fiji between January 2011 and June 2013.

Results: Of 563 TB patients registered, information on the type of treatment supervisor was available for 470 (83%). Of these, most ($n = 401$, 85%) had their treatment supervised by a family member, while 69 (15%) elected SAT. SAT patients had a treatment success rate of 79.4% compared to 88.5% in those supervised by a family member; the difference was statistically significant ($P = 0.0374$).

Conclusion: Anti-tuberculosis treatment outcomes were more likely to be successful in patients who were supervised by a family member than in SAT patients. As this method of treatment supervision is not likely to be resource-intensive, we recommend that it continue in Fiji. Further prospective operational research could be carried out to determine patient preferences for anti-tuberculosis treatment supervision in Fiji, to promote a patient-centred approach.

In the Pacific Islands region, which covers a vast area of 22 countries and territories in the Pacific Ocean, tuberculosis (TB) remains an important health problem, resulting in a significant burden of morbidity and mortality for both individuals and populations. Approximately 16500 cases of TB are notified in the region annually.^{1,2} While most patients are treated successfully, the estimated mortality rate remains unacceptably high, at an estimated 40 cases per 100000 population.¹

Fiji, a Pacific island nation in the central Pacific Ocean, is the second most populous country in the Pacific region and is currently categorised as a low TB burden country, with an estimated TB case notification rate of 24 cases/100000 (2012 data; 95% confidence interval [CI] 21–27).¹ Approximately 150 patients are notified with TB annually.¹ In recent years, the TB case notification rate in Fiji has been on the increase, mainly due to the introduction of interventions aimed at actively detecting and diagnosing people with TB.²

The Fiji National Tuberculosis Programme (NTP) was established in 1951 and the World Health Organi-

zation (WHO) recommended DOTS strategy was introduced in Fiji in 1997.³ As part of the DOTS strategy, anti-tuberculosis medications are taken by patients under the direct supervision of a health care worker or family member, thereby ensuring that the correct medications are taken at the right doses, and that patients are supported throughout treatment.^{3,4} The goals of directly observed treatment (DOT) are to support patients throughout anti-tuberculosis treatment, ensure a successful treatment outcome and prevent drug resistance.⁴

The need for a strategy to enhance anti-tuberculosis treatment support has been reinforced by studies that show that, even in industrialised countries and among knowledgeable and educated individuals, at least 40% of patients do not take their medications as prescribed and may stop treatment when they feel better, before the end of the 6 months of treatment.^{5,6} Other studies on medication adherence predict that up to 50% of individuals do not adhere to a medication regimen as prescribed.^{7,8}

In Fiji, the Global Fund to Fight AIDS, TB and Malaria (The Global Fund), provides support for NTP activities and the reinforcement of the health system. This grant has been in place since April 2010, with the Fiji Ministry of Health as the principal recipient. The grant provides financial support to the NTP for DOT, ensuring that selected TB patients have their treatment supervised. The revised national TB guidelines state that TB patients should be provided DOT throughout treatment if sufficient resources are available.³ Some TB patients receive treatment supervision in Fiji, while others who do not; this is largely determined by patient preference and available resources. DOT has not been evaluated in Fiji, and no information on the impact of type of supervisor on anti-tuberculosis treatment outcomes has been published.

The aim of the present study is to describe and compare anti-tuberculosis treatment outcomes in TB patients on self-administered treatment (SAT) compared to those whose treatment is supervised by an immediate family member in Fiji (i.e., DOT). Findings from this study will be used by the NTP to improve patient care and to ensure that the NTP achieves acceptable treatment success rates and low levels of drug resistance.

METHODS

Study design and setting

This was a retrospective descriptive study conducted in Fiji, involving a comparative analysis of informa-

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tion from TB patient records, TB registers, in-patient and out-patient folders, TB treatment cards and doctors' notes. Fiji is an upper middle-income island nation⁹ in the south-west Pacific.¹⁰ It comprises 332 islands, of which one third are inhabited. Viti Levu and Vanua Levu are the two main islands.¹⁰ Fiji's Human Development Index (a composite indicator comprising indicators of life expectancy, educational attainment and income)¹¹ in 2009 was 0.702; this assigns the country a rank of 96 among 187 countries with comparable data.¹² Fiji's population in 2007 was 837 271, comprising 57% *i-Taukei* (indigenous Fijians), 37% Fijians of Indian ethnicity and 6% from other ethnic groups.¹³

TB control in Fiji benefits from a positive legal environment: TB is a notifiable disease, and TB diagnosis and treatment are provided free of charge. TB care is predominantly funded by the government, and anti-tuberculosis medicines are only available through the NTP. As part of the NTP, three DOTS centres have been established at the three Divisional Hospitals in Fiji: the P J Twomey Hospital in Suva for the Central and Eastern Divisions, Lautoka Hospital in the Western Division and Labasa Hospital in the Northern Division. All three DOTS centres, along with the Colonial War Memorial Hospital in Suva, provide TB microscopy services. All TB patients are diagnosed using sputum smear microscopy and/or clinical and radiological findings as determined by a physician.³ The Xpert® MTB/RIF assay (Cepheid, Sunnyvale, CA, USA) has recently been introduced in Fiji to identify *Mycobacterium tuberculosis* in clinical specimens and determine rifampicin resistance. Antimicrobial drug resistance is not common in Fiji; no cases of multidrug-resistant TB have been detected, and no cases of drug resistance were observed in the latest reporting period (2010–2011).¹⁴ All TB patients are tested for human immunodeficiency virus (HIV) as part of routine TB care, and eight HIV cases have been diagnosed since TB-HIV testing was introduced in 2010.^{1,3} TB patients are also routinely tested for diabetes mellitus and are counselled about tobacco cessation if they smoke.¹

TB case finding and treatment efforts have been boosted by fruitful partnerships with non-governmental and volunteer-based organisations such as the Fiji Red Cross Society, which has implemented advocacy, communication and social mobilisation activities designed to empower communities to seek TB care and to encourage TB patients to complete anti-tuberculosis treatment.

Once a diagnosis of TB has been made, the NTP recommends that all TB patients be offered DOT. This is partly achieved during the intensive phase, as the Fiji NTP hospitalises many of its TB patients. However, DOT is generally not provided throughout the continuation phase due to limited resources. This situation is changing with the increase in funding for TB patient support. In our study, those who received DOT in the continuation phase were asked if they would prefer a family member to supervise their treatment or if they preferred SAT; DOT in the continuation phase was therefore self-selected.

Study population

Our study population comprised all TB patients registered with the NTP and enrolled on TB treatment from the three divisional DOTS centres (i.e., Central, Western and Northern Divisions) for the period from January 2011 to June 2013, with the exception of two TB patients whose records could not be located (treatment outcome indicated 'transferred out'). In this study, the definition of DOT included the entire duration of anti-tuberculosis treatment (i.e., into the continuation phase).

Data collection and analysis

The following data were collected from patient folders using a data collection proforma designed for the study: TB patient registration number, year of TB registration, age, sex, ethnicity, marital status, employment, geographical location (by Division), type of TB, category of TB, supervisor type and treatment outcome. The type of TB, category of TB (i.e., registration group) and treatment outcomes are designated in Fiji according to the definitions in the national TB guidelines, which are consistent with the WHO anti-tuberculosis guidelines.¹⁵ When a TB patient completes anti-tuberculosis treatment in Fiji, one of six treatment outcomes is assigned: cured, treatment completed, died, treatment failed, defaulted or transferred out.

Data were double entered into EpiData Entry, version 3.1 (EpiData Association, Odense, Denmark), and verified and validated before analysis. Analysis was carried out using EpiData Analysis, version 2.2.2.178. Descriptive analysis was performed by calculating frequencies, and treatment outcomes were analysed in relation to patients on SAT compared to those supervised by an immediate family member. Outcomes were compared between the two groups using odds ratios (ORs) and the χ^2 test with 95% CIs. Differences at the 5% level were regarded as significant.

Ethics

Ethics approval was obtained from the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France, and the Fiji National Research Ethics Review Committee, Suva, Fiji.

RESULTS

A total of 563 TB patients were registered for anti-tuberculosis treatment during the period from January 2011 to June 2013; 326 (58%) were male and 456 (81%) were of *i-Taukei* ethnicity. Information on the type of treatment supervisor was available for 470 (83%). Patient characteristics are shown in Table 1. Of the 470 TB patients with patient information available on the treatment supervisor, the majority ($n = 401$, 85%) had their TB treatment supervised by an immediate family member and 69 (15%) selected SAT (Table 1). Of the 401 TB patients supervised by a family member, the relationship of the family member was recorded for 320 (80%); the spouse was the most common supervisor ($n = 117$, 37%), followed by an aunt or uncle ($n = 92$, 29%) (Table 1).

Table 2 shows patient characteristics stratified by

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TABLE 1 Characteristics of patients enrolled on anti-tuberculosis treatment, Fiji, January 2011–June 2013

Characteristic	<i>n</i> (%) [*]
Sex	
Male	326 (58)
Female	236 (42)
Not recorded	1 (0)
Age group, years	
0–14	47 (8)
15–24	105 (19)
25–34	116 (21)
35–44	85 (15)
45–54	78 (14)
55–64	65 (12)
65–90	67 (12)
Division of residence	
Western	167 (30)
Northern	102 (18)
Central/Eastern	294 (52)
Ethnicity	
<i>i-Taukei</i>	456 (81)
Fijian Indian	76 (13)
Other	31 (6)
Marital status	
Married	332 (59)
Single	181 (32)
Not recorded	50 (9)
Employment status	
Employed	203 (36)
Unemployed	302 (54)
Not recorded	58 (10)
Type of TB	
PTB smear-positive	260 (46)
PTB smear-negative	178 (32)
Extra-pulmonary	122 (22)
Not recorded	3 (1)
Category of TB	
New	539 (96)
Retreatment	20 (4)
Not recorded	4 (1)
Treatment supervision	
SAT	69 (12)
Supervised by family member	401 (71)
Not recorded	93 (17)
Total	563

^{*} Some totals do not add up to 100% due to rounding.

TB = tuberculosis; PTB = pulmonary TB; SAT = self-administered treatment.

method of treatment supervision. TB patients who received supervised treatment were more likely to be unemployed than employed (62% vs. 36% respectively, OR 2.91, 95%CI 1.69–5.01) and were more likely to be aged ≥ 40 years (45% vs. 36%, OR 1.75, 95%CI 1.03–2.98) (Table 2). TB patients who lived in the Western and Northern Divisions (combined) were less likely receive supervised treatment than those in the Eastern and Central Divisions (44% vs. 58%, OR 0.57, 95%CI 0.34–0.96) (Table 2).

Anti-tuberculosis treatment outcomes in relation to the type of treatment supervisor are shown in Table 3. For the 469 TB patients with a recorded treatment outcome, the difference in treat-

ment success rate by type of treatment supervisor was statistically significant (Table 3). A treatment success rate of 79.4% was reported among SAT patients, compared to 88.5% in those supervised by an immediate family member ($P = 0.0374$).

DISCUSSION

This is the first study in Fiji to compare anti-tuberculosis treatment outcomes by method of treatment supervision. DOT was formally recommended when Fiji adopted the internationally recommended DOTS strategy in 1997; however, in practice not all patients have been receiving DOT since that date. This has been the case in many resource-limited settings in the Pacific Islands region and elsewhere.¹⁶ We found a clear difference of 9.1% in treatment success rates between the two groups in our study; this difference was statistically significant. The difference in treatment outcomes is also likely clinically significant, and is important for the Fiji NTP, which has been aiming to achieve high treatment success rates.

The findings of other studies comparing DOT with SAT for TB patients are not always consistent with our study. A Cochrane review of 11 trials with 55 609 participants showed no statistically significant difference between DOT and SAT in terms of cure (relative risk [RR] 1.02, 95%CI 0.86–1.2) or cure and treatment completion combined (RR 1.06, 95%CI 1.00–1.13) in individuals receiving treatment for TB.¹⁷ These findings are further supported by Walley et al., who studied 497 adult TB patients in Pakistan; TB treatment success rates were similar in those who received DOT and in those on SAT (67%, 62% and 65% for health care worker DOT, family DOT and SAT, respectively).¹⁸ In another study conducted in Thailand, TB patients were assigned to either DOT by a health care worker or a community or family member or SAT.¹⁹ The treatment success rate in the DOT arm was 84% compared to 76% in the SAT group, and the treatment success rate varied slightly according to the type of supervisor (88% for health care worker supervisors vs. 79% for community member supervisors and 84% in those supervised by a family member).¹⁹ Other studies have also noted higher treatment success rates in people on DOT than in those on SAT.^{20–22} Based on our study findings and those of other studies, we conclude that the relative contribution of DOT as a stand-alone patient support intervention is often difficult to assess, and the nature of the patient-health care worker relationship may be as important as direct supervision of medication taking.^{17,23,24}

One of the strengths of this study is that it was conducted within an NTP setting with a nationally representative sample using two and a half years of treatment outcome data. However, the study has some limitations, some of which reflect the retrospective nature of the study, with routinely collected programme data as its data source. Some of the information required was missing or incomplete; this may have confounded our findings about treatment outcomes or other patient characteristics. The findings of missing and incomplete data will be used to improve recording and reporting within the NTP. In addition, we were unable to verify whether the TB medications were truly directly observed; we assumed that if a patient was marked as having a treatment supervisor that the treatment was in fact directly observed. One study conducted in Thailand found that 35% of family members do not actually directly supervise medication taking.¹⁶ Another study conducted in Brazil highlighted that, in individuals receiving DOT by a family member, the family member can forget to supervise medication taking.²⁵ We were also not able to compare our findings with DOT administered by a health care worker, as has been the case in other studies on DOT;^{26–29} this might have been

TABLE 2 Characteristics of TB patients stratified by type of treatment supervision, January 2011–June 2013

Characteristic	DOT by family member (n = 401)	SAT (n = 69)	OR (95%CI)
Sex (n = 469)			
Male	221 (55)	45 (65)	Reference
Female	179 (45)	24 (35)	0.66 (0.39–1.12)
Age group, years (n = 470)			
0–14	42 (10)	0 (0)	–
15–40	180 (45)	44 (64)	Reference
>40	179 (45)	25 (36)	1.75 (1.03–2.98)*
Division of residence (n = 470)			
Central/Eastern	224 (56)	29 (42)	Reference
Western/Northern	177 (44)	40 (58)	0.57 (0.34–0.96)†
Ethnicity (n = 442)			
<i>i-Taukei</i>	325 (85)	57 (93)	Reference
Fijian Indian	56 (15)	4 (7)	0.41 (0.14–1.17)
Marital status (n = 460)			
Married	253 (64)	24 (37)	Reference
Single	142 (36)	41 (63)	0.96 (0.56–1.65)
Employment status (n = 455)			
Employed	146 (38)	42 (64)	Reference
Unemployed	243 (62)	24 (36)	2.91 (1.69–5.01)‡
Type of TB (n = 469)			
Pulmonary	307 (77)	56 (81)	Reference
Extra-pulmonary	93 (23)	13 (19)	1.30 (0.68–2.49)
Category of TB (n = 467)			
New	388 (97)	68 (99)	Reference
Retreatment	10 (3)	1 (1)	1.75 (0.22–13.91)

*P = 0.0379.

†P = 0.0333.

‡P = 0.0001.

TB = tuberculosis; DOT = directly observed treatment; SAT = self-administered treatment; OR = odds ratio; CI = confidence interval.

TABLE 3 Outcomes of patients undergoing treatment under SAT and DOT by an immediate family member, Fiji, January 2011–June 2013

Treatment outcome	DOT by family member n (%)*	SAT n (%)
Treatment success†	355 (88.5)	54 (79.4)
Cured	139 (34.7)	18 (26.1)
Treatment completed	216 (53.9)	36 (52.2)
Unsuccessful treatment outcome	46 (11.5)	14 (20.6)
Treatment failure	0 (0)	0 (0)
Lost to follow-up	24 (6.0)	6 (8.7)
Died	22 (5.5)	8 (11.6)
Not recorded	0 (0)	1 (1.4)
Total‡	401	68

*Does not total 100% due to rounding.

† $\chi^2 = 4.332$, P = 0.0374.

‡Excluding TB patient with unknown treatment outcome.

SAT = self-administered treatment; DOT = directly observed treatment.

informative. In addition, our analysis was limited to available programme data, which may not provide adequate insights into patient preferences and behaviour. We were not able to determine why TB patients do not complete the entire course of treatment, nor were we able to determine patient preferences as regards treatment supervision. Both of these questions were beyond the scope of the present study, but could provide important information

complementing our study findings and inform local TB policies in Fiji.

CONCLUSION

In our setting in Fiji, there are significant differences in TB treatment outcomes if patients on DOT are compared to those on SAT. The use of DOT in TB care in Fiji should be maintained. It is reasonable to continue family member DOT if treatment success rates remain high and if it is acceptable to TB patients and their families. Other patient support measures are also important, and may promote a patient-centred approach and improve TB treatment outcomes. Further operational research on TB patient support may help the Fiji Ministry of Health to decide how and where to invest valuable public health resources.

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Contexte: Le Programme National de lutte contre la Tuberculose (TB) (PNT) aux Fidji.

Objectif: Déterminer les résultats du traitement anti-tuberculeux stratifiés par méthode de supervision de ce traitement (soit une auto supervision [SAT] par les patients eux-mêmes, soit la supervision par un membre de la famille).

Schéma: Etude rétrospective descriptive de tous les patients tuberculeux enregistrés par le PNT aux Fidji entre janvier 2011 et juin 2013.

Résultats: Un total de 563 patients tuberculeux ont été enregistrés et pour 470 (83%) d'entre eux, on disposait d'informations sur le type de supervision. Parmi ces derniers, la majorité ($n = 401$; 85%) bénéficiait de la supervision de leur traitement par un membre de la

famille ; 69 (15%) ont reçu SAT. Ces derniers ont eu un taux de succès du traitement anti tuberculeux de 79,4% comparé à 88,5% chez les patients supervisés par un membre de la famille ; ce résultat était statistiquement significatif ($P = 0,0374$).

Conclusion: Les résultats du traitement anti-tuberculeux étaient plus souvent meilleurs chez les patients supervisés par un membre de la famille par rapport à ceux recevant SAT. Cette méthode de supervision du traitement n'exige pas beaucoup de ressources, c'est pourquoi nous recommandons qu'elle soit poursuivie aux Fidji. On pourrait réaliser une recherche opérationnelle prospective afin de déterminer les préférences des patients en matière de supervision de leur traitement anti-tuberculeux aux Fidji dans le cadre d'une approche centrée sur le patient.

Marco de Referencia: El Programa Nacional contra la Tuberculosis (PNT) en Fiji.

Objetivo: Definir los desenlaces del tratamiento antituberculoso en función del método de supervisión (autosupervidado [SAT] o supervisado por un miembro de la familia).

Método: Se llevó a cabo un estudio descriptivo retrospectivo de todos los pacientes registrados en el PNT de Fiji entre enero del 2011 y junio del 2013.

Resultados: En el período estudiado se registraron 563 pacientes con diagnóstico de tuberculosis (TB); de estos, 470 contaban con información acerca del tipo de SAT (83%). En la mayoría de los casos un miembro de la familia supervisó el tratamiento ($n = 401$; 85%) y en 69 casos el tratamiento han recibido SAT (15%). La tasa de éxito

terapéutico en los pacientes que recibieron SAT fue 79,4%, en comparación con 88,5% en los casos supervisados por un miembro de la familia; la diferencia fue estadísticamente significativa ($P = 0,0374$).

Conclusión: Es más probable que el tratamiento antituberculoso sea eficaz cuando la supervisión está a cargo de algún miembro de la familia del paciente que cuando el paciente mismo lo supervisa. Esta estrategia de supervisión del tratamiento de la TB no exige grandes recursos y por ello se recomienda su continuación en Fiji. Se deben adelantar nuevos estudios de investigación operativa con el fin de terminar las preferencias de los pacientes con respecto a la supervisión del tratamiento en el país e impulsar una estrategia centrada en el paciente.