



# Sputum smear conversion and treatment outcomes for tuberculosis patients with and without diabetes in Fiji

P. Prasad,<sup>1</sup> S. Gounder,<sup>2</sup> S. Varman,<sup>1</sup> K. Viney<sup>3,4</sup>

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**Settings:** Three tuberculosis (TB) treatment centres under the Fiji National Tuberculosis Programme.

**Objectives:** To determine the prevalence of diabetes mellitus (DM) among TB patients for the period 2010–2012, and to evaluate sputum smear conversion and anti-tuberculosis treatment outcomes, comparing patients with and without DM.

**Design:** A retrospective descriptive study using routinely collected data from the TB register and in-patient folders.

**Results:** Of 577 TB patients identified, information on DM was available for 567 (98%), of whom 68 (12%) had DM. Smear status at 2 months was available for 254 (82%) patients with sputum smear-positive pulmonary TB. The sputum smear conversion rate (from positive to negative) was equivalent in TB patients with and without DM (78% vs. 80%,  $P = 0.66$ ). Anti-tuberculosis treatment outcome information was available for 462 patients; the difference in outcome comparing successfully treated patients with those unsuccessfully treated was not statistically significant (91% in TB patients with DM vs. 84% in TB patients without DM,  $P = 0.06$ ).

**Conclusion:** DM is common among TB patients in Fiji. Sputum smear conversion rates were not different in TB patients with and without DM; no difference in treatment success between the two groups was observed.

Fiji is a low tuberculosis (TB) burden country, with a TB incidence rate of 24 cases per 100 000 population and a high treatment success rate of >90% (2012 data).<sup>1</sup> However, diabetes mellitus (DM) is very common in Fiji, and its prevalence is thought to be increasing. The STEPwise approach to Surveillance (STEPS) study conducted in 2002 reported a population prevalence of 16% for DM.<sup>2</sup> A more recent estimate, using a different methodology, gave a DM prevalence among adults in Fiji of 10.9%, with impaired glucose tolerance in a further 11.0%.<sup>3</sup> This remarkably high prevalence of DM is a matter of concern for TB control in Fiji. Published data from other settings have concluded that people with DM have a significantly increased risk of developing TB and worse treatment outcomes, with a higher risk of mortality and treatment failure during anti-tuberculosis treatment than among patients without DM.<sup>4–6</sup> In response to this evidence, the Fiji National Tuberculosis Programme (NTP) introduced random blood glucose (RBG) testing to screen for DM in all registered TB patients in 2011.<sup>7</sup>

A recent local study reported DM in 14% of TB patients in Fiji.<sup>8</sup> It has been noted by local clinical and public health staff that sputum smear-positive TB pa-

tients with DM take longer to convert to smear-negative than TB patients without DM, and that they thus require longer periods of hospitalisation. However, this observation has not been verified empirically, and there are no published data from Fiji reporting sputum smear conversion or treatment response in TB patients with and without DM.

In the present study, we aimed to evaluate treatment outcomes and sputum smear conversion in TB patients with DM and compare these indicators in TB patients without DM.

## METHODS

### Study design

This was a retrospective descriptive study using routinely collected data from the TB register and in-patient folders from three TB treatment hospitals in Fiji.

### Setting

Fiji is an island nation, located in the Pacific Ocean, classified as an upper middle-income economy.<sup>9</sup> It comprises 332 islands, of which 110 are inhabited. The population of 837 231 comprises 56.8% *i-Taukei* (indigenous Fijians) and 37.5% Fijians of Indian descent; the remaining 5.7% are from other ethnic backgrounds.<sup>10</sup>

The Fiji NTP is largely funded by the government, and TB diagnosis and treatment are provided free of charge. Three government hospitals provide TB services for the entire country; the private sector is not involved in TB control. All patients diagnosed with TB are registered as TB cases and treated at one of the three TB treatment centres. The majority of TB patients are admitted for the 2-month intensive phase of treatment, during which they receive anti-tuberculosis treatment and clinical follow-up. Clinical evaluation on admission routinely includes a full medical history and RBG screening if the patient is not known to have DM. If RBG is  $\geq 6.1$  mmol/l, fasting blood glucose (FBG) is tested. If the FBG is  $>7$  mmol/l,<sup>8</sup> patients are diagnosed as having DM and referred to a physician for further assessment and diagnosis. Patients with TB and DM are treated according to national TB and DM guidelines.<sup>7,11</sup>

Patients with sputum smear-positive pulmonary TB (PTB) undergo a repeat sputum smear test 2 months after starting treatment. Those patients with a positive sputum smear result receive another month of intensive phase treatment (i.e., four anti-tuberculosis drugs), while those with a negative result move to the continuation phase (i.e., two anti-tuberculosis drugs).

### AFFILIATIONS

- 1 College of Medicine, Nursing and Health Sciences, Fiji National University, Suva, Fiji
- 2 National Tuberculosis Programme, Fiji Ministry of Health, Suva, Fiji
- 3 Public Health Division, Secretariat of the Pacific Community, Nouméa, New Caledonia
- 4 National Centre for Epidemiology and Population Health, Australian National University, Canberra, ACT, Australia

### CORRESPONDENCE

Padma Prasad  
College of Medicine  
Nursing and Health Sciences  
Fiji National University  
Suva, Fiji Islands  
Tel: (+679) 332 1499  
e-mail: Padma.prasad@fnu.ac.fj

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The 2-month smear result is therefore an important clinical indicator. After completion of a course of anti-tuberculosis treatment, treatment outcomes for all TB patients are recorded in the TB register according to standardised, internationally accepted definitions.<sup>7</sup>

### Study population

The study population consisted of 577 TB patients registered with the NTP during a 3-year period from 1 January 2010 to 31 December 2012. The study population comprised 94% of all TB cases notified during the study period.

### Data variables and data collection

Data were collected using a data collection form designed for the study. Data variables comprised TB register number, age, sex, ethnicity, type and category of TB, DM status, year of DM diagnosis and whether DM was already known or newly diagnosed after TB diagnosis. Outcome variables included sputum smear status at 2 months and treatment outcome following a full course of anti-tuberculosis treatment.

### Analysis and statistics

All data were double entered into EpiData version 3.1 (EpiData Association, Odense, Denmark) and validated prior to analysis. Data were analysed using EpiData Analysis version 2.2.2.178. We calculated frequencies to compare TB patients with and without DM and used the  $\chi^2$  test to determine the difference between proportions. The level of significance was set at 5%.

### Ethics approval

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

## RESULTS

Of 614 TB patients registered during the study period, medical case notes were available for 577 (94%). Information on DM status was available for 567 (98%), of whom 68 (12%) had a documented diagnosis of DM. The demographic and clinical characteristics of the patients are given in Table 1. TB patients with a diagnosis of DM were older (mean age 53.6 vs. 35.7 years,  $P < 0.001$ ), more likely to be of Fijians of Indian ethnicity (32.4% vs. 15.2%,  $P < 0.05$ ) and more likely to have pulmonary sputum smear-positive TB (75% vs. 51.7%,  $P < 0.001$ ) than TB patients without DM. Of the TB patients with a DM diagnosis, 11.8% were newly diagnosed due to the policy of screening TB patients for DM as part of routine clinical care. A further 38.2% of TB patients were already aware of their DM status; this information was not documented for almost half of the TB patients (50%).

Sputum smear-positive PTB was noted in 309 patients, of whom 254 (82%) had smear status available at 2 months (Table 2). The sputum smear conversion rate, from positive to negative, was similar in TB patients with and without DM (78.4% vs. 79.4%,  $P = 0.66$ ), and respectively 11.8% and 9.7% of patients re-

mained sputum smear-positive in the two groups. Information on sputum smear conversion at 3 or 5 months was not available.

Information on anti-tuberculosis treatment outcome was available for 462 patients (Table 3). There were no significant differences in treatment outcome when comparing successfully treated patients with those with an unsuccessful treatment outcome; 90.5% of TB patients with DM had a successful treatment outcome (the sum of cured and completed treatment) compared to 84% of TB patients without DM ( $P = 0.06$ ). In terms of mortality, 7.4% of TB patients with DM died compared to 3.3% of TB patients without DM; the difference was not statistically significant ( $P = 0.09$ ). We did, however, note a difference in the cure rate when comparing patients with and without DM. In TB patients with DM, 54.4% were cured, compared to 37% of TB patients without DM; this result was statistically significant ( $P < 0.01$ ). We also noted a significant difference in the proportion of TB patients with and without DM who were lost to follow-up (1 [1.5%] TB patient with DM vs. 48 [10.5%] TB patients without,  $P < 0.05$ ); however, overall numbers were small.

## DISCUSSION

According to our study findings, 11.8% of TB patients had DM, a slightly higher rate than in the general population, which has an estimated DM prevalence of 10.9%.<sup>3</sup> However, both of these figures are lower than the results of the STEPs survey, which reported a population DM prevalence of 16% among adults.<sup>2</sup> Other studies in the Pacific and elsewhere have shown a higher prevalence of DM among TB patients than in the general population.<sup>12-14</sup> In an unpublished study from Kiribati, where the prevalence of both diseases is relatively high, the prevalence of DM in TB patients was twice that of the general population (37% vs. 19%,  $P \leq 0.001$ ).

Other studies from outside the Pacific Islands region have also reported a higher prevalence of DM among TB patients than in the general population. In Tanzania, the prevalence of DM among TB patients was 16.7% compared to 9.4% in a group of matched controls.<sup>12</sup> In a similar study in China, where all TB patients were tested for DM, 6.7% of TB patients had DM compared to 4.3% in the community ( $P < 0.05$ ),<sup>15</sup> while in Indonesia 13.2% of TB patients had DM compared to 3.2% in the community (odds ratio [OR] 4.7, 95% confidence interval [CI] 2.7-8.1).<sup>14</sup> In our study, the prevalence of DM among TB patients was only marginally higher than in the general community; this may be a valid finding or it may be due to incomplete screening of TB patients for DM, which was formally introduced as a policy by the Fiji NTP in 2011.<sup>7</sup> This may also be due to the fact that the TB patient population in our study included children, who have a lower prevalence of DM than adults.

We noted a higher proportion of sputum smear-positive PTB in patients with concomitant DM. Other studies do not report this consistently; some have noted that sputum smear-positive PTB is more com-

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Conflict of interest: none declared.

**TABLE 1** Demographic and clinical characteristics of TB patients with and without DM, Fiji, 2010–2012

Characteristic	TB patients with DM (n = 68) n (%)	TB patients without DM (n = 499) n (%)	P value
Age group, years			<0.001
<40	11 (16.2)	309 (61.9)	
40–49	10 (14.7)	74 (14.8)	
50–59	16 (23.5)	57 (11.4)	
60–69	22 (32.4)	39 (7.8)	
70–79	9 (13.2)	16 (3.2)	
≥80	0 (0)	3 (0.6)	
Not recorded	0 (0)	1 (0.2)	
Mean age (±SD)	53.6 (±15.1)	35.7 (±17.9)	
Sex			0.9421
Female	32 (47.1)	210 (42.1)	
Male	36 (52.9)	288 (57.7)	
Not recorded	0 (0)	1 (0.2)	
Ethnicity			<0.05
<i>i-Taukei</i>	41 (60.3)	387 (77.6)	
Fijian of Indian descent	22 (32.4)	76 (15.2)	
Others	4 (5.9)	34 (6.8)	
Not recorded	1 (1.5)	2 (0.4)	
Type of TB			<0.05
Pulmonary	61 (89.7)	371 (74.3)	
Extra-pulmonary	6 (8.8)	125 (25.1)	
Not recorded	1 (1.5)	3 (0.6)	
Smear status at diagnosis			<0.001
Positive	51 (75.0)	258 (51.7)	
Negative	14 (20.6)	237 (47.5)	
Not recorded	3 (4.4)	4 (0.8)	
Category of TB			<0.05
New	64 (94.1)	469 (94.0)	
Previously treated	2 (2.9)	29 (5.8)	
Other	0 (0)	1 (0.2)	
Not recorded	2 (2.9)	0 (0)	
DM status			—
Newly diagnosed	8 (11.8)	—	
Previously diagnosed	26 (38.2)	—	
Not recorded	34 (50.0)	—	
Total	68	499	

TB = tuberculosis; DM = diabetes mellitus; SD = standard deviation.

mon in TB patients with DM,<sup>16,17</sup> while others report no difference in type of TB at diagnosis.<sup>18,19</sup> Studies that have assessed radiological differences between TB patients with and without DM have noted that cavities are more common in TB patients with DM; this may also influence sputum smear status.<sup>20,21</sup> While data may be conflicting, there is some evidence to suggest that DM influences the clinical presentation of TB. This has implications for infection control and ongoing transmission of TB in the community, as sputum smear-positive TB patients are infectious and can transmit TB to others.

We observed no significant differences in sputum smear conversion at 2 months among sputum smear-positive TB patients with and without DM, nor were there differences in rates of treatment success between the two groups. Generally speaking, a delayed sputum smear conversion rate may be influenced by the initial bacterial load in the patient, and this clinical indicator was not assessed in our study. In a more thorough prospective assessment of TB and DM, data should be collected on sputum smear

grade at diagnosis in order to be certain about sputum smear conversion at 2 months and the relationship between DM status and delayed sputum smear conversion.

**TABLE 2** Smear status of sputum smear-positive pulmonary TB patients with and without DM at 2 months, Fiji, 2010–2012

Sputum smear status at 2 months	TB patients with DM n (%)	TB patients without DM n (%)	P value
Smear-positive	6 (11.8)	23 (9.9)	0.66*
Smear-negative	40 (78.4)	185 (79.4)	—
Smear status not recorded	5 (9.8)	25 (10.7)	—
Total	51 (100)	233 (100)	

\* Comparing smear-positive with smear-negative (i.e., does not include those with unknown smear result at month 2).

TB = tuberculosis; DM = diabetes mellitus.

**TABLE 3** Treatment outcomes for TB patients with and without DM, Fiji, 2010–2012

Treatment outcome	TB patients with DM n (%)	TB patients without DM n (%)	P value
Treatment success	57 (90.5)	335 (84.0)	0.06
Cured	37 (54.4)	170 (37.0)	<0.01*
Completed	20 (29.4)	165 (35.9)	0.29†
Unsuccessful outcome	6 (9.5)	64 (16.0)	—
Treatment failure	0 (0)	1 (0.2)	—
Loss to follow-up	1 (1.5)	48 (10.5)	<0.05‡
Died	5 (7.4)	15 (3.3)	0.09§
Not recorded	5 (7.4)	60 (13.1)	—
Sub-total¶	63	399	
Total	68	459	

\*Comparing cured to all other treatment outcomes.

†Comparing treatment completed to all other treatment outcomes.

‡Comparing loss to follow-up to all other treatment outcomes.

§Comparing died to all other treatment outcomes.

¶Those with results recorded.

TB = tuberculosis; DM = diabetes mellitus.

In this study, TB treatment outcomes, including death, were not different in TB patients with and without DM. However, we noted that an outcome of 'cured' was more frequent among patients with DM. A systematic review has reported that TB patients with DM have a two-fold increased risk of anti-tuberculosis treatment failure and death (relative risk [RR] 1.69, 95%CI 1.36–2.12) and a four-fold increased risk of relapse (RR 3.89, 95%CI 2.43–6.23).<sup>6</sup> Higher treatment failure rates have also been observed in TB patients with DM in China (17% vs. 2%,  $P < 0.01$ ),<sup>22</sup> Maryland, USA (OR 6.9, 95%CI 1.1–38.0,  $P = 0.039$ )<sup>23</sup> and in southern Mexico (adjusted OR 2.93, 95%CI 1.18–7.23).<sup>24</sup> We are not sure why the cure rate was higher in TB patients with DM in our study, as these patients were also more likely to have sputum smear-positive TB. One possible reason may be that TB patients with concomitant DM are more closely linked to the health system due to their chronic disease, and are therefore more likely to be followed up and undergo sputum microscopy at the end of anti-tuberculosis treatment, thereby increasing their chance of an outcome of cure. It is also not clear why TB patients with DM were less likely to be lost to follow-up, but this may be for reasons similar to the above. The relatively small numbers and few deaths may have affected our findings regarding treatment outcome; an analysis of TB data over several years could therefore be useful.

Our study has some limitations. The Fiji NTP did not prescribe routine screening of TB patients for DM before 2011; the prevalence of DM among TB patients may therefore have been underestimated. A recent assessment of DM screening practices in Fiji noted that, in 2011, 62% of TB patients had their DM status recorded in the patient notes; the study concluded that improvements in screening practices were required.<sup>8</sup> It is also estimated that approximately 50% of DM in the Pacific Islands region is undiagnosed; we may therefore expect the proportion of TB patients with DM to be higher than observed in our study.<sup>3</sup> Studies conducted in India have reported that many TB patients had had undiagnosed DM.<sup>16,25</sup> In a recent prospective study in Kiribati, where all TB patients aged  $\geq 18$  years were tested for DM at the time of TB diagnosis, 55% were newly diagnosed with DM and had not known their DM status before attending the TB clinic.

We did not collect information on sputum smear status at diagnosis and other potentially confounding factors such as smok-

ing and comorbidities, cause and time of death of those who died during anti-tuberculosis treatment, and other clinical information such as chest X-ray results. A comprehensive, prospective multi-country study may provide useful information on the presentation of TB patients with and without DM and the clinical course of anti-tuberculosis treatment in the two groups. Finally, a number of variables were not recorded in our data set and this may have affected our findings. The issue of incomplete recording of health data is a common one,<sup>26,27</sup> and highlights the importance of accurate and complete recording and reporting by health programme staff involved in DM and TB programmes.

## CONCLUSION

DM is a common condition among TB patients in Fiji: 12% of all TB patients had concomitant DM. TB patients with DM are more likely to present with sputum smear-positive PTB than those without. Health care workers caring for people with DM should be aware that TB is a common respiratory infection in this population. When comparing TB patients with and without DM, we noted no differences in sputum smear conversion at 2 months or treatment success, indicating that, at present, the presence of DM does not adversely affect TB outcomes. However, a larger prospective study could provide more definitive results; there is therefore scope for prospective studies on the association between TB and DM in the Pacific to improve health care for persons suffering from both diseases.

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**Contexte :** Trois centres de traitement de la tuberculose (TB) dans le cadre du Programme national de Lutte contre la TB aux Fidji.

**Objectif :** Déterminer la prévalence du diabète (DM) parmi les patients tuberculeux entre 2010 et 2012 et d'évaluer la conversion des frottis de crachats et les résultats du traitement de la TB en comparant les patients avec et sans DM.

**Schéma :** Etude rétrospective descriptive basée sur les données recueillies en routine à partir des registres de la TB et des dossiers des patients hospitalisés.

**Résultats :** De 577 patients tuberculeux identifiés, des informations relatives au DM étaient disponibles pour 567 d'entre eux (98%) ; parmi ceux-ci, 68 (12%) étaient diabétiques. Le résultat du frottis à 2 mois était disponible pour 254 (82%) patients atteints de TB

pulmonaire à frottis positif. Le taux de conversion du frottis (de positif à négatif) était identique chez tous les patients tuberculeux avec ou sans DM (78% contre 80% ;  $P = 0,66$ ). Le résultat du traitement anti-tuberculeux était disponible pour 462 patients ; il n'y avait pas non plus de différence significative en termes de succès du traitement (91% chez les patients avec DM contre 84% chez les patients sans DM ;  $P = 0,06$ ).

**Conclusion :** Le DM est fréquent chez les patients tuberculeux aux Fidji. Le taux de conversion du frottis ne s'est cependant pas avéré différent chez les patients avec et sans DM, et il n'y a pas non plus eu de différence significative en termes de succès du traitement entre les deux groupes.

**Marco de referencia:** Tres centros de tratamiento de la tuberculosis (TB) del Programa Nacional contra la Tuberculosis de Fiji.

**Objetivo:** Determinar la prevalencia de diabetes (DM) en los pacientes con diagnóstico de TB entre el 2010 y el 2012 y comparar la tasa de conversión de la baciloscopia del esputo y los desenlaces terapéuticos entre los pacientes con y sin diagnóstico concomitante de DM.

**Método:** Se llevó a cabo un estudio descriptivo retrospectivo a partir de los datos recogidos sistemáticamente en el registro de TB y en las historias clínicas de los pacientes hospitalizados.

**Resultados:** Se encontraron 577 pacientes con diagnóstico de TB, de los cuales 567 contaban con información sobre la DM (98%) y en 68 casos se registró DM concomitante (12%). Se contó con resultados de la baciloscopia a los 2 meses de 254 pacientes con TB pulmonar y

baciloscopia inicial positiva (82%). La tasa de conversión del esputo fue equivalente entre los pacientes con TB y DM o TB exclusivamente (78% contra 80%;  $P = 0,66$ ). Se obtuvieron datos sobre el desenlace del tratamiento antituberculoso de 462 pacientes; no se observó una diferencia significativa cuando se compararon los desenlaces favorables y desfavorables (éxito terapéutico de 91% en los pacientes con DM concomitante comparado con 84% en los pacientes sin DM;  $P = 0,06$ ).

**Conclusión:** La DM es una enfermedad frecuente en los pacientes con diagnóstico de TB en Fiji. Las tasas de conversión de la baciloscopia del esputo fueron equivalentes en los pacientes con DM concomitante o sin ella y no se observó una diferencia en la tasa de éxito terapéutico entre ambos grupos.