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Mortality in successfully treated tuberculosis patients in southern Ethiopia: retrospective follow-up study

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SUMMARY

SETTING: The tuberculosis (TB) programme in the Sidama zone of southern Ethiopia.

OBJECTIVE: To measure excess mortality in successfully treated TB patients.

DESIGN: In a retrospective cohort study of TB patients treated from 1998 to 2006, mortality was used as an outcome measure, and was calculated per 100 person-years of observation (PYO) from the date of completion of treatment to date of interview if the patient was alive, or to date of death. Kaplan-Meier and Cox regression methods were used to determine the survival and hazard ratios. Indirect method of standardisation was used to calculate the standard mortality ratio (SMR).

RESULTS: A total of 725 TB patients were followed for 2602 person-years: 91.1% (659/723) were alive and 8.9% (64/723) had died. The mortality rate was 2.5% per annum. Sex, age and occupation were associated with high mortality. More deaths occurred in non-farmers (SMR = 9.95, 95%CI 7.17–12.73).

DISCUSSION: The mortality rate was higher in TB patients than in the general population. More deaths occurred in non-farmers, men and the elderly. Further studies are required to identify the causes of death in these patients.

KEY WORDS: tuberculosis; mortality; standard mortality ratio; Ethiopia

THE DECENTRALISATION of the World Health Organization (WHO) recommended DOTS strategy has increased the number of successfully treated tuberculosis (TB) patients. TB treatment ensures long-term success by reducing transmission, recurrence (relapse or re-infection) and death.[1–5] However, in some countries, mortality in TB patients has increased, mainly due to the human immunodeficiency virus (HIV) epidemic.[6,7] TB mortality, as defined by the WHO, includes the number of TB cases dying during treatment, irrespective of cause, and is obtained from routine reports. This excludes deaths that occur among TB patients after treatment completion under DOTS, defaulters and transfers out, and underestimates mortality in TB patients.[8] Mortality in successfully treated TB patients could be taken as an important measure of the efficacy of treatment. However, there is no routine monitoring of TB patients after treatment completion to understand what happens to them after successful treatment under the DOTS strategy.

Post-treatment studies conducted among TB patients reported high mortality (24%) after 22 months of follow-up.[9] Mortality was highest among HIV-infected (65%) and multidrug-resistant TB (MDR-TB) patients (69%; i.e., cases with strains resistant to at least isoniazid [H] and rifampicin [R]).[9–11] High recurrence rates may also increase TB incidence, reduce treatment success and increase post-treatment mortality or reduce post-treatment survival of successfully treated TB patients.[12,13]

To our knowledge, no follow-up study has been conducted in Ethiopia to determine mortality in TB patients after completion of treatment. The aim of the present study was to measure mortality in TB patients after treatment completion under the DOTS strategy.

MATERIALS AND METHODS

Study area and population

The present study was conducted in the Dale and Wonsho Districts of the Sidama zone of southern Ethiopia. This is a densely populated agrarian community with a population of 296 811. The farmers cultivate cash crops (coffee and 'khat') that non-farmers depend on for commercial activities. The DOTS strategy was introduced in the study area in 1996.[14] Six health facilities were providing DOTS by trained general health workers, using standard recording and reporting formats. District TB programme coordinators regularly checked the completeness and accuracy of TB case recording in the unit TB register. The 2007

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estimate of mortality among TB patients on treatment was 92 per 100 000 population per year.[3]

Study design

This retrospective cohort study was based on TB patients who were registered in the unit TB registers in the health facilities providing DOTS. TB cases who completed treatment under the DOTS programme from 1998 to 2006 were enrolled in the study.

Treatment regimen, duration and outcome

Treatment for smear-positive patients consisted of 8 months of daily supervised streptomycin (S), R, H and pyrazinamide (Z) for 2 months, followed by 6 months of self-administered ethambutol (E) and H for adults (2SRHZ/6EH), and 4 months of RH for children (2SRHZ/4RH). Smear-negative and extrapulmonary TB (EPTB) cases received 2 months of RHZ followed by 6 months of EH (2RHZ/6EH). The treatment regimen was the same throughout the study period. Follow-up sputum examination was performed at the end of months 2, 5 and 7 of treatment. A smear-positive pulmonary TB (PTB) patient who had a negative sputum smear result in the last month of treatment and on at least one previous occasion (month 2 or 5) was reported as cured. Smear-positive PTB cases without month 7 smear results, smear-negative PTB and EPTB cases who finished the full course of treatment were declared 'treatment completed'. TB cases declared as cured or treatment completed were reported to be successfully treated under the DOTS strategy. The treatment success rate is the sum of the cured and treatment completion rate. A patient who died for any reason after treatment was recorded as 'death during treatment'.[9]

Data collection

A list of TB patients declared cured or treatment completed from 1998 to 2006 was obtained from the unit TB registers in the health institutions in the two districts. From September 2007 to February 2008, information was collected on unit register number, name, age, sex, address, TB classification, smear result, treatment outcome and the date of interview.

Health extension workers (HEWs, i.e., trained community health workers) were trained to conduct house-to-house visits and collect data. Information was collected on whether or not the TB patient was alive and had TB symptoms. The date of interview for those who were alive and the date of death for those who had died were noted.

Data analysis

Data entry and analysis were performed using SPSS 14 for Windows (Statistical Package for Social Sciences, Chicago, IL, USA). We described the patients by age, sex, TB classification, marital status and occupation. Mortality was used as an outcome measure. Person-years of observation (PYO) were calculated from the date of treatment completion to date of interview if the patient was alive, or to date of death. The study outcomes of participants were censored if they were reported to be alive at the time of interview.

Event-free survival and the log-rank test for statistical significance were determined using the Kaplan-Meier method. Cox regression method was used to determine the hazard ratio (HR) and 95% confidence intervals (95%CI). $P < 0.2$ was used as a cut-off point to include the variable in the multivariate Cox regression model. Mortality was calculated as the number of deaths/100 PYO. Excess mortality was calculated by subtracting age- and occupation-specific mortality in the reference population from mortality among successfully treated TB patients. $P < 0.05$ was considered statistically significant.

To ascertain whether more than the expected number of deaths had occurred among our cohort, we used the indirect method of standardisation to calculate the standard mortality ratio (SMR).[15] As such reference data for Sidama were not available, we used the data from the Demographic and Health Survey of the Butajira Rural Health Programme, an open cohort,[16] as the reference to calculate SMR. We believe that the two areas are comparable as they have similar socio-economic development and are located at the same altitude. In addition, about 50% of the population has access to health services and the DOTS strategy was implemented in the same year in the health centres of the two areas. The SMR was calculated as the ratio of the number of observed deaths over expected deaths, using age- and occupation-specific mortalities in the reference population.

Ethical clearance

The Ethical Review Committee of the Regional Health Bureau approved the study. Study participants were enrolled after providing informed consent. For patients who had died, informed consent was obtained from the heads of household or next of kin. Patients with a recent history of cough and other symptoms suggestive of TB were advised to visit health facilities for further examination.

RESULTS

A total of 799 TB patients were registered. Five (0.6%) did not have TB classification, 21 (2.6%) had moved to other districts and no information was available for 48 (6.01%) patients. Valid data were obtained for 725 (90.7%) cases, of whom data on current status (whether they were alive or dead) were not available for two patients (Figure 1). We found no baseline differences by age, sex, treatment outcome or TB classification between study participants and those for whom no information was obtained.

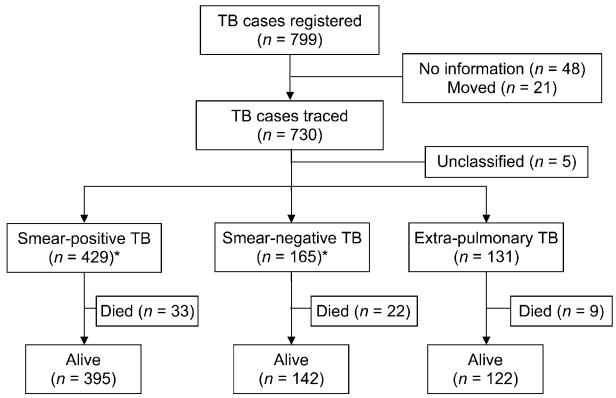

Figure 1 Flow chart of TB patient enrolment in the study. *Survival status unknown for one patient in each of these two groups. TB = tuberculosis.

Overall, 429 smear-positive PTB, 165 smear-negative PTB and 131 EPTB cases were studied. Of the 725 patients, 377 (52.1%) were men, 482 (70.6%) were married, 299 (45.3%) were illiterate and 269 (37.1%) were farmers; 91.1% (659/723) were alive (Table 1).

Of the 723 patients for whom this information was available, 64 (8.9%, 95%CI 6.8–10.9) had died. Of 428 patients with smear-positive PTB, 33 had died (7.7%, 95%CI 5.2–10.2), 22/164 patients (13.4%, 95%CI 8.2–18.6) with smear-negative PTB and 9/131 patients (6.9%, 95%CI 2.5–11.2) with EPTB cases (Table 1).

The average PYO was 3.59 and the total was 2602. Mortality per 100 PYO was 2.5% per annum (64/2602.1; 2.2/100 PYO [33/1504.8] for smear-positives, 3.6/100 PYO [22/606.9] for smear-negatives and 1.9/100 PYO [9/481.1] for EPTB cases; Tables 2 and 3). In smear-positive cases, there was no difference in mortality between new and retreatment cases (log-rank $P = 0.139$). No difference in mortality was observed by type of TB (log-rank $P = 0.098$).

In univariate analysis, age (HR = 1.05, 95%CI 1.04–1.06) and non-farming occupations (HR = 5.65, 95%CI 3.30–9.67) were associated with increased mortality. Non-farming occupations included

Table 1 Socio-demographic characteristics of successfully treated TB patients in southern Ethiopia, 1998–2006

Variables	Smear-positive TB (*n* = 429) *n* (%)	Smear-negative TB (*n* = 165) *n* (%)	EPTB (*n* = 131) *n* (%)	Total (*N* = 725) *n* (%)
Sex				
Male	221 (51.5)	93 (56.4)	63 (48.5)	377 (52.1)
Female	208 (48.5)	72 (43.6)	67 (51.5)	347 (47.9)
Unknown	0	0	1	1
Marital status				
Single	100 (24.2)	42 (28.4)	42 (34.4)	184 (26.9)
Married	303 (73.4)	105 (70.9)	74 (60.7)	482 (70.6)
Divorced/widowed	10 (2.4)	1 (0.7)	6 (4.9)	17 (2.5)
Unknown	16	17	9	42
Level of education, years				
Illiterate	181 (45.7)	68 (46.9)	50 (42.0)	299 (45.3)
1–4	62 (15.7)	25 (17.2)	25 (21.0)	112 (17.0)
5–8	130 (32.8)	41 (28.3)	37 (31.1)	208 (31.5)
⩾9	23 (5.8)	11 (7.6)	7 (5.9)	41 (6.2)
Unknown	33	20	12	55
Occupation				
Student	70 (16.3)	32 (19.4)	35 (26.7)	137 (18.9)
Farmer	171 (39.9)	61 (36.9)	37 (28.2)	269 (37.1)
Housewife	45 (10.5)	25 (15.2)	22 (16.8)	92 (12.7)
Merchant	21 (4.9)	10 (6.1)	8 (6.1)	39 (5.4)
Others	122 (28.4)	37 (22.4)	29 (22.1)	188 (25.9)
Current status				
Alive	395 (92.3)	142 (86.6)	122 (93.1)	659 (91.1)
Died	33 (7.7)	22 (13.4)	9 (6.9)	64 (8.9)
Unknown	1	1	0	2

TB = tuberculosis; EPTB = extra-pulmonary TB.

Table 2 Factors predictive of mortality in successfully treated tuberculosis patients in southern Ethiopia, 1998–2006

Variables	Death: Yes *n*	Death: No *n*	PYO	Mortality /100 PYO	Crude HR (95%CI)	*P* value	Adjusted HR (95%CI)	*P* value
Age, years	64	657	2586.1	2.5	1.1 (1.0–1.1)	<0.01	1.0 (1.0–1.1)	<0.01
Sex								
Female	24	321	1270.8	1.9	1.0			
Male	40	337	1320.5	3.0	1.6 (0.9–2.7)	0.1	2.2 (1.3–3.9)	0.01
Level of education								
Illiterate	15	284	1118.5	1.3	1.0			
Literate	11	350	1289.9	0.9	0.6 (0.3–1.4)	0.3		
Marital status								
Never married	5	179	632.3	0.8	1.0			
Married	23	476	1861.3	1.2	1.6 (0.6–4.1)	0.4		
Occupation								
Farmers	19	479	1838.4	1.0	1.0			
Non farmers	45	180	757.2	5.9	5.7 (3.3–9.7)	<0.01	6.3 (3.6–11.1)	<0.01
TB classification								
Smear-positive PTB	33	394	1504.8	2.2	1.0			
Smear-negative PTB	22	142	606.9	3.6	1.7 (0.9–2.9)	0.1	1.1 (0.6–1.9)	0.8
EPTB	9	122	481.1	1.9	0.9 (0.4–1.8)	0.7	1.1 (0.5–2.2)	0.9

PYO = person-year of observation; HR = hazard ratio; CI = confidence interval; TB = tuberculosis; PTB = pulmonary TB; EPTB = extra-pulmonary TB.

Table 3 Mortality in successfully treated tuberculosis patients in southern Ethiopia, 1998–2006

Variables	Deaths *n*	Total *n*	PYO	Observed deaths/ year in study population	Deaths/year in referent population*	Expected deaths/ year in study population	SMR (95%CI)
Age category, years							
0–9	0	17	3.1	0.0	14.3	0.2	0.00 (0.00–0.00)
10–19	4	117	3.5	1.2	1.8	0.2	5.63 (0.38–10.87)
20–29	12	263	3.7	3.3	2.7	0.7	4.56 (2.04–7.09)
30–39	10	158	3.7	2.7	4.9	9.8	3.48 (1.36–5.60)
40–49	13	88	3.4	3.8	6.6	0.6	6.50 (3.15–9.84)
50–59	11	46	3.9	2.9	12.6	0.6	4.95 (2.02–7.87)
60–69	12	24	2.9	4.2	23.8	0.6	7.35 (3.76–10.94)
70–79	1	5	4.9	0.2	35.5	0.3	1.16 (–1.40–3.72)
80–89	0	1	2.9	0.0	45.4	0.1	0.00 (0.00–0.00)
Total	63†	719	3.6	17.5	5.4	3.9	4.50 (3.42–5.57)
Occupation							
Farmer	19	497	3.7	5.1	5.3	2.6	1.97 (1.10–2.84)
Non farmer	44	222	3.4	12.8	5.8	1.3	9.95 (7.17–12.73)

*Mortality in the general Butajira population in southern Ethiopia, 2000–2004.
†One participant was aged 90 years.
PYO = person-year of observation; SMR = standardised mortality ratio; CI = confidence interval.

merchants, former soldiers and government and private sector employees. In Cox regression analysis, age ($P < 0.01$), sex ($P < 0.01$) and occupation ($P < 0.01$) were associated with increased mortality (Figure 2, Table 2).

Overall excess mortality was 13.6/100 PYO, 2.5/100 PYO for farmers and 11.5/100 PYO for non-farmers. Our results suggest that more deaths occurred than expected after treatment of TB patients. The SMR for all patients was 4.5 (95%CI 3.42–5.57). The SMR was higher in non-farmers (9.95, 95%CI 7.17–12.73) than in farmers (1.97, 95%CI 1.10–2.84).

DISCUSSION

One of the targets of the Millennium Development Goals is to reduce TB mortality.[17] However, reliable data on TB mortality are not available.[8,18] This could be improved by measuring mortality in successfully treated cases. We report higher mortality in successfully treated TB cases than the general population.

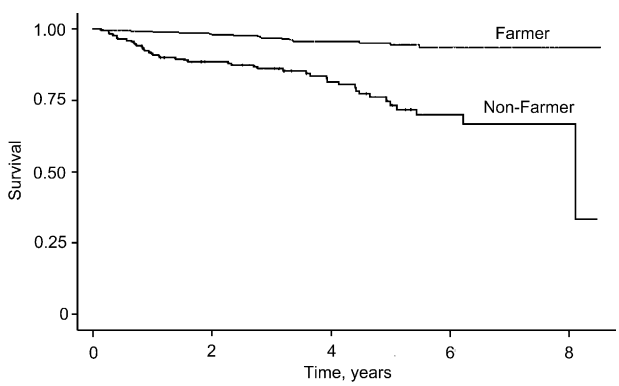

Figure 2 Kaplan-Meier survival curve showing post-treatment mortality in tuberculosis patients by occupation in southern Ethiopia.

In our study, overall mortality was 2.5/100 PYO (2.5% per annum), which is lower than in other reports from Africa (ranging from 3.1/100 PYO in the Democratic Republic of Congo [DRC] to 23.7/100 PYO in Malawi). This could be explained by the lower TB-HIV co-infection rate in our setting (17.5%) compared to other reports from Africa (ranging from 21% in the DRC to 77% in Malawi).[11] The mortality in our setting was also lower than reports from India (5.7/100 PYO in rural Velliyur and 6.8/100 PYO in Chennai City) and Vietnam (6.6/100 PYO).[19,20] The lower prevalence of MDR-TB among new and previously treated cases could explain this difference (respectively 1.6% and 12% in Ethiopia, 2.7% and 17% in India and 2.7% and 19% in Vietnam).[17] Although MDR-TB seems to be the least likely explanation in our setting, it should be cautiously interpreted in the presence of a reported resistance rate of 7.6% to at least one anti-tuberculosis drug.[21]

Some population groups are at higher risk of death due to occupational exposure or lifestyle. In our study, the risk of excess mortality was six times higher in non-farmers (including merchants, former soldiers and government or private sector employees) than farmers. This could be explained by the high mobility among these groups, and the high prevalence and increased risk of HIV infection, as these groups were most affected by HIV and were sources of HIV infection and transmission from urban to rural areas.[22] HIV infection in successfully treated non-farmer TB patients could thus be one of the plausible explanations for the high mortality in our setting. In addition, the risk of excess mortality was twice as high in males as in females, with the risk increasing with increasing age. This could be because more male TB patients were reported,[17,23] which could also result in more deaths. The higher risk of HIV infection in males than in females could explain the higher mortality in

rural communities.[22] Moreover, the traditional risk-taking role of males, given their role in society, puts them at higher risk for excess mortality.[24] As expected, mortality was higher in the elderly, possibly due to age-related diminution of immunity, and the increased magnitude of chronic illnesses such as diabetes and other comorbidities with age.[25–27] Case-fatality rates among TB patients during treatment at 6 months and at 12 and 20 months after treatment were reported to be increasing, and more deaths occurred in the elderly and in males.[8] The relative lower mortality in our setting could be because of the lower prevalence of HIV infection, and the lower burden of TB and other comorbidities.

Mortality rates in our setting were similar among smear-positive, smear-negative and EPTB cases, possibly due to similar rates of HIV infection in TB patients.[19] This is in contrast to many studies that have reported higher mortality in smear-negative and EPTB cases. In such settings, the mortality was higher in TB patients mainly due to HIV infection.[11]

Generally, mortality was higher in TB patients after successful treatment. We report excess mortality in our study participants over the general population and an SMR of 4.5, similar to the SMR of 4.2 reported in rural settings of India.[26] In our setting, mortality was higher in non-farmers than in farmers for similar reasons: HIV infection and related opportunistic infections, chronic illnesses such as diabetes and other comorbidities such as malaria, malignancies and others. Mortality was lower in our study participants than the reported SMR of 6.1 in urban settings in India.

Gaps in the performance of the TB programme, such as inadequate patient follow-up, and the patients' general condition could lead to increases in mortality during treatment and put them at higher risk of excess mortality after completion of treatment. Inadequate treatment supervision, mainly during the continuation phase, when treatment is taken unsupervised, could also reduce treatment adherence and increase the recurrence rate of TB (recurrence rates as high as 1/100 PYO have been reported in the study area[28]), which could contribute to increased mortality. This could be worse where the importance of treatment adherence is not well addressed during health education sessions.[29]

We report mortality in successfully treated TB cases through home-based follow-up under programme conditions in Ethiopia. No baseline difference was found between the study participants and those who were not included in the study, which increases the representativeness of our study and its generalisability to the study area. However, using the general population may have underestimated the mortality in TB patients, while failure to ascertain the causes of death could also have included other causes of death, thus overestimating mortality. TB cases who die unregistered or undiagnosed by the DOTS programme are beyond the scope of this study.

In conclusion, post-treatment mortality was higher in TB patients than in the general population. There is a need for selective post-treatment follow-up of high-risk groups that could be identified at the start of treatment. Post-treatment mortality could be used as additional evidence of case fatality (obtained through routine reports) to better understand mortality in TB patients. Further studies are needed to ascertain the causes of death in TB patients.

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OK as set?

RÉSUMÉ

CONTEXTE : Le Programme de tuberculose (TB) dans la zone Sidama du Sud de l'Ethiopie.
OBJECTIF : Mesurer l'excès de mortalité chez les patients TB traités avec succès.
SCHÉMA : Dans une étude rétrospective de cohorte sur les patients TB traités entre 1998 et 2006, la mortalité a constitué la mesure de résultats, calculé par 100 années-personne d'observation (PYO) à partir de la date d'achèvement du traitement jusqu'à la date de l'entretien, si le patient était en vie, ou jusqu'à la date du décès. On a utilisé les méthodes de Kaplan-Meier et de régression de Cox pour déterminer la survie et le ratio de risque. On a utilisé la méthode indirecte de standardisation pour le calcul d'un ratio standard de mortalité (SMR).
RÉSULTATS : Un total de 725 patients TB ont été suivis pendant 2602 années-personne. Etaient en vie 91,1% (659/723) alors que 8,9% étaient décédés (64/723). La mortalité a été de 2,5% par an. Sont en association avec une mortalité élevée le sexe, l'âge et la profession. Le nombre de décès est plus élevé chez les non-fermiers (SMR = 9,95 ; IC95% 7,17–12,73).
DISCUSSION : La mortalité est élevée chez les patients TB par comparaison avec la population générale. Les décès sont plus fréquents chez les non-fermiers, chez les hommes et chez les sujets âgés. Des études complémentaires s'imposent pour identifier les causes de décès chez ces patients.

RESUMEN

MARCO DE REFERENCIA: El programa contra la tuberculosis (TB) en la región de Sidama, al sur de Etiopía.
OBJETIVO: Medir el exceso de mortalidad en los pacientes que recibieron un tratamiento exitoso contra la TB.
MÉTODO: Se llevó a cabo un estudio retrospectivo de cohortes de los pacientes tuberculosos tratados entre 1998 y 2006. El criterio de valoración fue la mortalidad que se calculó en años-persona de observación (PYO) por 100, a partir de los datos de compleción del tratamiento hasta la fecha de la entrevista cuando el paciente estaba vivo o hasta la fecha de la defunción. Con el fin de determinar la supervivencia y el cociente de riesgos instantáneos se aplicaron el método de Kaplan-Meier y el modelo de regresión de Cox. La razón estandarizada de la mortalidad (SMR) se calculó usando un método indirecto de normalización.
RESULTADOS: Se practicó el seguimiento de 725 pacientes tuberculosos por 2602 PYO. El 91,1% de los pacientes (659/723) estaba vivo y el 8,9% (64/723) había fallecido. La mortalidad anual fue 2,5%. Los factores asociados con una alta mortalidad fueron el sexo, la edad y la ocupación. Ocurrieron más defunciones en las personas que no eran agricultores (SMR = 9,95; IC95% 7,17–12,73).
CONCLUSIÓN: Se observó una alta mortalidad en los pacientes tuberculosos, comparados con la población general. La mortalidad fue mayor en los pacientes que no eran agricultores, en los hombres y en los ancianos. Se precisan nuevos estudios con el fin de determinar las causas de defunción en estos pacientes.