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ORIGINAL ARTICLE

Profile and treatment outcomes of elderly patients with tuberculosis in Delhi, India: implications for their management

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Background: Given India's high rate of TB, rising burden of non-communicable diseases (NCDs) and growing elderly population, elderly TB patients may be at higher risk of adverse outcomes including death, loss-to-follow-up (LTFU) and treatment failure. This may call for modifications in their management. This study thus aimed to compare the profile and treatment outcomes between elderly (≥60 years) and non-elderly (15–59 years) TB patients.

Methods: This was a retrospective cohort study using routinely-collected programme data from a chest clinic in Delhi, India. It included all elderly and selected non-elderly TB patients registered for treatment between 2005 and 2010. Data on patients' clinical and demographic characteristics and treatment outcomes were analysed.

Results: There were 812 elderly and 1624 non-elderly TB patients. Elderly patients were more likely to be male (63.2% vs 51.1%) and have smear-positive TB (56.0% vs 47.4%). Adverse outcomes were more frequent among elderly patients (adjusted OR 1.9 [95% CI: 1.5–2.4]), specifically deaths (adjusted OR 5.0 [95% CI: 3.1–8.1]) and lost-to-follow-up [Adjusted OR 1.4 (95% CI: 1.0–1.9)].

Conclusions: The profile and worse outcomes of elderly Indian TB patients may be indicative of co-existing NCDs. This needs further investigation and likely calls for a more comprehensive and intensive approach to their management.

Keywords: Elderly, Tuberculosis, India, Treatment outcomes

Introduction

India has the highest burden of TB in the world with 2.3 million cases reported in 2011.[1] Improvements in life expectancy in India mean that there is a growing elderly population (7.5% of the total population was aged 60 years or more in 2011).[2] As such, the number of elderly TB patients is likely to increase with time. Being elderly may have a negative effect on TB treatment success due to age-associated factors such as the presence of co-morbidities (for example, diabetes), immunosuppression and a greater likelihood of adverse drug reactions.[3–5] To date, very few published studies have reported on TB treatment outcomes in the elderly in resource poor settings like India. A better understanding of the profile of elderly TB patients and their treatment outcomes in India may help to identify ways to improve the care and management of these patients.

In a TB clinic in Delhi, India, this study aimed to compare elderly and non-elderly adult TB patients in relation to demographic and clinical characteristics; treatment outcomes; and adverse outcomes according to different demographic and clinical characteristics. In addition, we examined the factors associated with adverse outcomes among elderly patients.

Methods

Study design

This was a retrospective cohort study using routinely-collected programme data from a chest clinic in Delhi, India. It included all elderly and selected non-elderly TB patients registered for treatment between 2005 and 2010.

Study setting

The study was conducted at Guru Teg Bahadur (GTB) chest clinic in eastern Delhi, India. GTB is one of 24 chest clinics in Delhi that functions under the country's Revised National Tuberculosis

Control Programme (RNTCP). GTB serves a population of approximately 600 000 and registers around 2100 TB patients for treatment annually.

TB diagnosis, treatment and follow-up

TB patients were diagnosed, registered and treated according to the RNTCP guidelines.[6] Patients were diagnosed with sputum smear examination, clinical assessment and history of previous TB. TB treatment was per directly observed treatment short course (DOTS) strategy. New patients were treated three times a week with an intermittent six-month regimen, comprising a two-month intensive phase using rifampicin, isoniazid, pyrazinamide and ethambutol (RHZE) for patients with smear positive TB and rifampicin, isoniazid, and pyrazinamide (RHZ) for patients with smear negative or extrapulmonary TB (EPTB), followed by a four-month continuation phase (isoniazid and rifampicin). Previously treated patients received a three month intensive phase comprising RHZE plus streptomycin for two months, then RHZE for one month, followed by a continuation phase of rifampicin, isoniazid and ethambutol for five months. Patients whose sputum smears were positive for acid-fast bacilli at the end of the intensive phase of treatment received an additional month of intensive-phase treatment.

Bacteriological follow up was done with three sputum smear examinations: the first at the end of the intensive phase, the second at two months of the continuation phase and the last at the end of treatment.

Patients were given scheduled appointments at the clinic for review and drug collection at fixed intervals. If a patient failed to return for a scheduled follow-up appointment, a health worker attempted to visit them at their home to encourage them to attend the clinic.

Population

The study included all elderly TB patients (≥60 years) and a selected number of non-elderly adult TB patients (15–59 years) registered for treatment under the RNTCP in GTB chest clinic between 2005 and 2010.

TB treatment outcomes

Treatment outcomes were defined in accord with the RNTCP definitions[6] as follows:

Cured: a patient who was initially sputum smear-positive, completed treatment and who had negative sputum smears on two occasions, one of which was at the end of treatment.

Completed treatment: a patient who was sputum smear-positive, completed treatment and had negative smears at the end of the intensive phase but not at the end of treatment, or a patient with sputum smear-negative TB or a patient with EPTB who received a full course of treatment and had not become smear-positive during or at the end of treatment.

Death: a patient who died while on treatment regardless of the cause.

Failure: a patient who was initially sputum smear positive, who either remained or became smear positive at or subsequent to the fifth month of treatment.

Lost to follow-up: any patient who, having started treatment, was not seen again for a minimum of two months after his/her last scheduled appointment during the course of treatment.

Transfer out: any patient who, after starting treatment, was sent to another unit to complete treatment but for whom the ultimate treatment result was not recorded in the register.

A favourable outcome was defined as including cured and treatment completed, while any other outcome was classified as unfavourable.

Data collection

Data were sourced from the GTB TB register and entered into a data file using EpiData Entry version 3.1 (Epidata Association, Odense, Denmark). The following variables were collected: TB registration number, age, gender, disease classification: pulmonary TB (PTB) and EPTB, type of patient (new, retreatment), HIV-serostatus, sputum positivity before starting treatment and at the end of the intensive phase, and treatment outcome.

Statistical analysis

Categorical comparisons between elderly and non-elderly patients were made using the χ^2 test. Relative differences in treatment outcomes between these two groups were compared using crude ORs and adjusted ORs. Adjusted ORs were determined through multivariate logistic regression. All variables that were significant at the level of p=0.2 in the univariate analysis were included in the multivariate model. Those with a Walds test p-value of <0.15 were kept in the model. Others were maintained in the model if removing them resulted in a change of greater than 15% in the OR of variables. A backward stepwise elimination approach was used until all remaining variables in the model were significant at p=0.05 or less. Data analysis was done using STATA 8.2 software (Stata Corporation, College Station, TX, USA).

Sample size

Epi-Info version 3.5.3 (CDC, Atlanta, GA,USA; http://wwwn.cdc.gov/epiinfo/) was used to calculate the required sample size. The calculation was based on non-elderly patients having a 13% risk of an adverse outcome (the national average in the entire population)[7] and the elderly having an 18% risk. Assuming a confidence level of 95%, 80% power, and a 1:2 ratio of elderly to non-elderly patients, we calculated that a sample of 634 elderly and 1268 non-elderly patients would be needed. Given that there were 116 patients in 2010, we determined that we would need data from the six previous years. All elderly patients registered between 2005 and 2010 were included in the study. For non-elderly TB patients, twice the number of elderly TB patients were selected for each year of the study, starting at the beginning of the register and taking consecutive patients for that year.

Ethical approval

Ethical approval was received from the UNION Ethics Review Board and from the Ethics Review Committee of the University of Medical Services (UCMS) and GTB Hospital, Delhi India.

Results

Characteristics of the study population

The study population included 812 elderly and 1624 non-elderly TB patients. Table 1 shows their demographic and clinical characteristics. Among elderly patients, there was a higher proportion of men (63.2% vs 51.1% among non-elderly, p<0.001), and a higher proportion with smear positive TB at baseline (56% vs 47.4%, p<0.001).

Treatment outcomes

Table 2 shows the treatment outcomes for elderly and non-elderly patients. Elderly patients had a lower frequency of favorable outcomes (73.2% vs 86.2%, p<0.001). Death and loss to follow-up were higher among the elderly (7.6% vs 1.5% (p<0.001) and 10% vs 6.5% (p=0.002) respectively. No difference was observed with regards to treatment failure.

Overall, elderly patients had just over two times greater risk of an adverse outcome after controlling for sex, TB type and TB category (adjusted OR 2.2, 95% CI: 1.7–2.7). Of the adverse outcomes, elderly patients had a significantly greater risk of death and loss to follow-up (adjusted OR 5.0, 95% CI: 3.1–8.1 and adjusted OR 1.4, 95% CI: 1.0–1.9, respectively) but there was no difference in terms of treatment failure (adjusted OR 1.0, 95% CI: 0.7–1.5).

Across all categories of the different characteristics, elderly patients had a higher risk of an adverse outcome than non-elderly patients. In particular, being elderly in the presence of having smear negative PTB, EPTB or being a new patient, was associated with a far greater relative risk of an adverse outcome (Table 3).

Among elderly patients, factors associated with a higher risk of an adverse outcome included being male (adjusted OR 1.6, 95% CI: 1.1–2.2) and having sputum smear positive TB (adjusted OR 2.2, 95% CI: 1.3–3.8; Table 4).

Table 1. Demographic and clinical characteristics of elderly and non-elderly TB patients, Delhi, India, 2005–2010

Variable	Elderly n (%)	Non-elderly n (%)	p value[a]
Total	812 (33.3)	1624 (66.7)	
Sex			
Male	513(63.2)	830 (51.1)	<0.001
Female	299 (36.8)	794 (48.9)	
TB type			
PTB smear positive	455 (56)	769 (47.4)	<0.001
PTB smear negative	190 (23.4)	284 (17.5)	0.001
EPTB	152 (18.7)	560 (34.5)	<0.001
PTB smear unknown	15 (1.8)	11 (0.7)	0.008
TB category			
New	564 (69.5)	1149 (70.8)	NS
Retreatment	248 (30.5)	475 (29.2)	
Sputum positivity at end of IP			
Total PTB	660	1064	
Yes	62 (9.4)	76 (7.1)	NS
No	481 (72.9)	907 (85.2)	<0.001
Not recorded	117 (17.7)	81 (7.6)	<0.001
HIV status			
Positive	1 (0.1)	4 (0.2)	NS
Negative	97 (11.9)	185 (11.4)	NS
Unknown	34 (4.2)	24 (1.5)	<0.001
Not recorded	680 (83.7)	1411 (86.9)	0.04

EPTB: extrapulmonary tuberculosis; IP: intensive phase; NS: not significant; PTB: pulmonary tuberculosis; TB: tuberculosis.
[a] p-value: calculated using x^2 test.

Discussion

This study is one of few that reports on the profile and treatment outcomes of elderly TB patients in the high TB burden setting of India. Compared with non-elderly patients, elderly patients were more likely to be male and have smear positive TB, and they had a higher frequency of adverse treatment outcomes, specifically death and loss to follow-up.

The main study strengths were that a large sample size was included; the data were routinely collected in a national programme and therefore likely reflect the reality on the ground; and the study adhered to the STROBE Guidelines[8] (guidelines for the reporting of observational studies). The main study limitations were that data sourced from the TB registers were not validated, however, regular programme supervision and monitoring was in place and, therefore, we believe that the data were relatively robust; there were no routinely collected data available at the time of the study on co-morbidities such as diabetes mellitus (DM) and, therefore, we could not assess or control for the

Table 2. Tuberculosis treatment outcome of elderly and non-elderly TB patients, Delhi, India 2005–2010

Variable	Elderly n (%)	Non-elderly n (%)	p value[a]
Total	812	1624	
Favorable[b]	594 (73.2)	1400 (86.2)	<0.001
Adverse	195 (24.0)	212 (13.1)	<0.001
Death	62 (7.6)	25 (1.5)	<0.001
Failure	42 (5.2)	73 (4.5)	NS
Loss to follow-up	81 (9.9)	105 (6.5)	0.002
Transferred out	10 (1.2)	9 (0.6)	NS
Not recorded	23 (2.8)	12 (0.7)	<0.001

NS: not significant.
[a] p-value: calculated using x^2 test.
[b] Cured and completed treatment.

Table 3. A comparison of adverse outcomes between elderly and non-elderly TB patients according to different demographic and clinical factors, Delhi, India, 2005–2010

Variable	Elderly		Non-elderly		OR (95% CI)	Adjusted OR[b] (95% CI)	p value[c]
	n	Adverse outcome[a] n (%)	n	Adverse outcome[a] n (%)			
Total[d]	789	195 (24.7)	1612	212 (13.2)	2.2 (1.7–2.7)	1.9 (1.5–2.4)	<0.001
Sex							
Male	496	141 (28.4)	818	134 (16.4)	2.0 (1.5–2.7)	1.9 (1.4–2.5)	<0.001
Female	293	54 (18.4)	794	78 (9.8)	2.0 (1.4–3.0)	1.9 (1.3–2.9)	0.001
TB type							
PTB smear positive	442	131 (29.6)	760	162 (21.3)	1.6 (1.2–2.0)	1.5 (1.2–2.0)	0.002
PTB smear negative	185	40 (21.6)	281	21 (7.5)	3.4 (1.9–6.0)	3.0 (1.7–5.4)	<0.001
EPTB	149	21 (14.1)	560	27 (4.8)	3.2 (1.8–6.0)	3.4 (1.9–6.3)	<0.001
PTB smear unknown	13	3 (23.1)	11	2 (18.2)	1.4 (0.2–10.9)	1.5 (0.2–13.0)	NS
TB category							
New	548	123 (22.4)	1140	114 (10.90)	2.6 (2.0–3.5)	2.3 (1.7–3.0)	<0.001
Retreatment	241	72 (29.9)	472	98 (20.8)	1.6 (1.1–2.3)	1.5 (1.0–2.1)	0.04

EPTB: extrapulmonary tuberculosis; NS: not significant; PTB: pulmonary tuberculosis; TB: tuberculosis.
HIV status not included in the table due to HIV status being unknown/unrecorded for 2149 (89.5%) patients.
[a] Includes deaths, loss to follow-ups, treatment failures and transfers-out.
[b] Adjusted odds ratios only presented for variables included in the multivariate model.
[c] p-value: calculated using x^2 test.
[d] 35 records excluded due to missing outcome data.

Table 4. Adverse outcomes among elderly patients according to different demographic and clinical characteristics, Delhi, India, 2005–2010

Variable[a]	n[b]	Adverse outcomes[c] n (%)	OR (95% CI)	Adjusted OR[d] (95% CI)	p value[e]
Total	789	195 (24.7)			
Age (years)					
60–64	451	104 (23.1)	1		
65–74	285	75 (26.3)	1.2 (0.8–1.7)		
75+	53	16 (30.2)	1.4 (0.8–2.7)		
Sex					
Male	496	141 (28.4)	1.8 (1.2–2.5)	1.6 (1.1–2.2)	0.02
Female	293	54 (18.4)	1		
TB Classification					
PTB smear positive	442	131 (29.6)	2.6 (1.6–4.3)	2.2 (1.3–3.8)	0.002
PTB smear negative	185	40 (21.6)	1.7 (0.9–3.0)	1.5 (0.8–2.6)	NS
EPTB	149	21 (14.1)	1		
Unknown	13	3 (23.1)	1.8 (0.5–7.2)	1.8 (0.4–7.0)	NS
TB type					
New	548	123 (22.4)	1		
Retreatment	241	72 (29.9)	1.5 (1.0–2.1)		

EPTB: extrapulmonary tuberculosis; NS: not significant; PTB: pulmonary tuberculosis; TB: tuberculosis.
[a] HIV status not included in the table due to HIV status being unknown/unrecorded for 691 (87.5%) patients.
[b] 23 patients excluded due to missing outcome data.
[c] Includes deaths, loss to follow-ups, treatment failures and transfers-out.
[d] Adjusted odds ratios only presented for variables included in the multivariate model.
[e] p-value: calculated using x^2 test.

effect of this; and HIV status was not recorded for the vast majority of patients and could not be controlled for in our analysis. Despite these limitations, our findings raise a number of points for discussion which may have implications for the future management of elderly TB patients in India.

The main demographic and clinical differences between elderly and non-elderly TB patients were the higher proportion of men and the higher prevalence of sputum smear positive cases among the elderly. One plausible reason for this difference may be a higher prevalence of co-existing DM. While we cannot substantiate this with actual data, in a previous study conducted in India,[9] not only were over two fifths of TB patients found to have DM, but also being aged 50 years or above, male and having sputum smear positive TB, were found to be risk factors for DM.

The lower proportion of women among elderly patients, while possibly reflecting the epidemiological pattern of TB in India (i.e., elderly women having a lower prevalence of TB), may also be related to this group being less able to access health care services. Previous studies have shown that women suffer greater stigma in relation to TB than men[10–14] and this, in conjunction with age-related issues around poorer health[15,16] and mobility, may make accessing health facilities even more problematic for elderly women. We can, however, only speculate on this; further investigation would thus be needed.

Adverse treatment outcomes, specifically death and loss to follow-up, were more prevalent among elderly than non-elderly Indian patients, which supports the findings reported from other studies in Africa and Asia.[17–21] Since conducting our study, we have become aware of a very similar study,[22] conducted in a state in Southern India. Our study findings corroborate the findings of this study, adding to the evidence base on TB treatment outcomes in the elderly and lending weight to the generalisability of our findings since our setting was Delhi in northern India. The higher mortality observed among elderly TB patients may be due to age-related factors such as co-existing morbidities like DM (which has been shown to increase the case fatality rate during TB treatment),[23] a higher likelihood of adverse drug reactions and poorer adherence to treatment. The higher loss to follow-up among elderly TB patients may be due to factors such as unascertained deaths; adverse drug reactions leading to poor treatment adherence;[24] and difficulties accessing health facilities due to limited mobility and poor-health. Further investigation would be needed to determine which of these factors is contributing to the loss to follow-up before appropriate measure to mitigate this could be devised.

Finally, while being male and having sputum smear positive TB were associated with a higher risk of adverse outcome amongst elderly patients, these are known risk factors among all TB patients,[3,25] and not specific for the elderly.

The findings of our study have a number of practice and policy implications. First, if, as we suspect, DM is a problem among elderly patients, active screening and treatment of DM among this group of patients would seem important given its known association with TB. At the time of this study, DM was not routinely screened for in TB patients in India. This is now part of the RNTCP guidelines but yet to be implemented and as such, programmes need to be well supported and given the capacity to roll out the appropriate measures.

Second, in addition to DM, elderly TB patients should also be screened for other age-related non-communicable diseases such as hypertension and cardiovascular disease. These diagnoses should be included in the routine monitoring and recording system for TB patients. Management of TB patients with such co-morbidities would require close collaboration with the National Programme for Prevention and Control of Cancer, Diabetes Mellitus, Cardiovascular Diseases and Stroke (NPCDCS).[26]

Third, while being male and having sputum smear positive TB are known risk factors for poorer outcomes among all TB patients, given that elderly TB patients already face a greater risk of death and loss to follow-up, these specific groups should be given special attention including community outreach support, comprehensive screening and management of co-existing morbidities, and social assessment and support.

In conclusion, this study showed that elderly TB patients in India have worse treatment outcomes than the non-elderly, particularly greater mortality. A more comprehensive and intensive approach to their management is needed, including screening and integrated treatment for non-communicable diseases.

Authors' contributions: PS, SS and EDA conceived the study idea and designed the protocol. MM helped in designing the data collection tool. PS and LS did data collection and entry. PS and TSK did the statistical analysis and drafted the manusctript. KAT, NRK and RT critically revised the manuscript. KAT also did the overall supervision of the entire project. All authors read and approved the final manuscript. PS and KAT are guarantors of the paper.

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Competing interests: None declared

Ethical approval: This study has met the Medecins Sans Frontieres' Ethics Review Board-approved criteria for analysis of routinely-collected program data, Geneva, Switzerland and has also been approved by the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France and from the Ethics Review Committee of UCMS and GTB hospital, Delhi India.

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