INT J TUBERC LUNG DIS 23(9):1029–1034

http://dx.doi.org/10.5588/ijtld.18.0617

To be or not to be hospitalised with tuberculosis in Portugal

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SUMMARY

SETTING: In Portugal, as in other countries, tuberculosis (TB) is considered a disease that should be managed on an ambulatory basis. However, hospitalisation remains important to manage some at-risk groups and complications.

OBJECTIVE: To identify the possible risk factors associated with hospitalisations in TB patients in Portugal.

DESIGN: Data extraction through two national databases (one for registration of TB cases and the other with hospitalisation information in public health facilities) between 2007 and 2013. Univariate and multivariate analysis of demographic and clinical variables was performed.

RESULTS: We identified 4421 hospitalisations. Chronic diseases, cancer, substance abuse, a higher social/economic risk, extra-pulmonary TB, lung cavitary disease and previous uncompleted treatment were more frequent among hospitalised patients. Human immunodeficiency virus coinfection, cancer, alcohol abuse, extra-pulmonary TB and uncompleted previous TB treatment were the most important predictors of hospitalisation with TB. The hospitalisation rate among TB patients in Portugal was lower when compared with other countries with lower and higher incidences.

CONCLUSION: Immune dysfunctions and progression of chronic diseases are associated with more severe forms of TB and frequent adverse effects which can be sufficiently severe to necessitate hospital admission. Despite having an intermediate TB incidence, the hospitalisation rate in Portugal is not higher than that of other countries.

KEY WORDS: hospitalisation; risk factors; TB

TUBERCULOSIS (TB) reports and incidence rates in Portugal have declined steadily since 2005, reaching 21.8 and 20.0 cases per 100 000 inhabitants respectively in 2014.[1] This trend has followed the trend seen over all of Europe, where TB has decreased at an average rate of 5.0% per year since 2001, making Europe the continent with the lowest TB burden.[2,3]

Historically, Portugal has witnessed a change in the management of TB. The first sanatoria were founded in 1853, and dispensaries created at the beginning of the 1900s. A network of out-patient centres for TB diagnosis and treatment, *Centros de Diagnóstico Pneumológico* (CDP), were developed in the 1990s. Currently, as in other countries, TB is managed in the out-patient setting.

Hospitalisation, however, remains important. Recently, the World Health Organization (WHO) Regional Office for Europe developed two documents suggesting key criteria for in-patient care. These include severe forms and disease-associated complications, serious adverse reactions to anti-tuberculosis drugs, incapacity of assuring out-patient management and/or non-adherence to treatment.[4,5] Furthermore, these guidelines promote several policies and work practices to help reduce hospitalisation and to minimise the risk of TB transmission while addressing different levels of intervention (administrative, environmental, human resources, financial).

A recent study focusing on the burden of TB hospitalisations in Portugal showed a decrease in the hospitalisation rate of 58.8%—42.7/100 000 in 2000 to 17.6/100 000 in 2015—with 47 997 admissions during this period in public hospitals in continental Portugal. This reduction was more notable after 2007, when hospitalisations decreased more rapidly than the notification and incidence rates, suggesting a change in the admission criteria.[6]

However, Portugal continues to be a country considered to have an intermediate incidence of TB, close to that of Eastern European countries.[2,3]

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Article submitted 5 September 2018. Final version accepted 28 January 2019.

Table Patient characteristics

Patients characteristics	Hospitalised patients ($n = 4421$) n (%)	All TB patients ($n = 15\,233$) n (%)	Univariate analysis		Multivariate analysis	
			OR (95% CI)	P value	OR (95% CI)	P value
HIV	858 (19.4)	1751 (11.5)	3.580 (2.381–5.382)	<0.001	3.439 (2.284–5.178)	<0.001
Alcohol dependence	803 (18.2)	1939 (12.7)	1.643 (1.138–2.273)	0.008	1.605 (1.109–2.234)	0.012
Drug dependence						
Intravenous drugs	411 (9.3)	897 (5.9)	0.735 (0.420–1.288)	0.282	0.773 (0.437–1.365)	0.374
Other drugs	440 (10.0)	1057 (6.9)	0.811 (0.481–1.367)	0.431	0.868 (0.511–1.474)	0.600
Diabetes mellitus	325 (7.4)	886 (5.8)	1.027 (0.533–1.979)	0.935	1.040 (0.539–2.005)	0.908
Liver disease	236 (5.3)	550 (3.6)	1.266 (0.698–2.295)	0.438	1.258 (0.684–2.312)	0.461
Cancer	193 (4.4)	612 (4.0)	1.910 (1.003–3.640)	0.049	1.926 (1.012–3.667)	0.046
Chronic kidney disease (under dialysis)	71 (1.6)	186 (1.2)	0.905 (0.227–3.608)	0.887	0.898 (0.226–3.575)	0.879
Chronic obstructive pulmonary disease	131 (3.0)	352 (2.3)	1.471 (0.774–2.795)	0.238	1.482 (0.780–2.814)	0.230
Silicosis	33 (0.8)	176 (1.2)	0.176 (0.023–1.351)	0.095	0.176 (0.023–1.352)	0.095
Sarcoidosis/other interstitial lung diseases	17 (0.4)	57 (0.4)	3.492 (0.527–23.144)	0.195	3.499 (0.527–23.236)	0.195
Unemployment	759 (17.2)	2099 (13.8)	1.143 (0.792–1.649)	0.475	1.127 (0.779–1.630)	0.527
Homeless/community housing	217 (4.9)	551 (3.6)	0.999 (0.528–1.890)	0.997	0.916 (0.476–1.760)	0.791
TB						
Pulmonary	2804 (63.4)	9902 (65.0)	0.823 (0.546–1.240)	0.351	0.806 (0.533–1.218)	0.305
Pulmonary + extra-pulmonary	503 (11.4)	1076 (7.1)				
Extra-pulmonary	1109 (25.1)	4213 (27.7)	1.891 (1.071–3.339)	0.028	1.805 (1.014–3.211)	0.045
Previous TB treatment						
Uncompleted	161 (3.6)	445 (2.9)	1.476 (1.096–1.988)	0.010	1.495 (1.108–2.018)	0.009
Male sex	3094 (70.0)	9904 (65.0)	0.855 (0.613–1.192)	0.356	0.859 (0.616–1.198)	0.371
Age, years, mean ± SD	47.5 ± 18.8	46.7 ± 18.9	0.988 (0.985–1.010)	0.742	0.988 (0.985–1.010)	0.709
Cavitary disease on chest radiography	1768 (40.0)	5570 (36.6)	0.907 (0.660–1.247)	0.548	0.910 (0.661–1.252)	0.561
Incarceration*	32 (0.7)	303 (1.9)	—	—	—	—

* Excluded from univariate and multivariate analysis.
TB = tuberculosis; OR = odds ratio; CI = confidence interval; HIV = human immunodeficiency virus; SD = standard deviation.

Chronic diseases and high-risk groups (alcohol/illicit drug users, incarceration, immigrants) are known risk factors.[3,7] Human immunodeficiency virus (HIV) stands out: by 2014, 13.3% of TB patients were HIV-positive.[1] It is, therefore, important to understand who these patients are and which factors lead to hospitalisation.

STUDY POPULATION AND METHODS

Data source and population

This was an observational and retrospective study. Data were obtained from two nationwide databases coordinated by the Central Administration of the Health System. The Portuguese national surveillance system for Tuberculosis—*Sistema de Vigilância da Tuberculose em Portugal* (SVIG-TB)—comprises information on subjects who started TB treatment in Portugal (new cases and re-treatments) up to its completion. The Portuguese public hospitalisations database–*Base de Dados Nacional de Grupos de Diagnósticos Homogéneos*, Diagnosis Related Group database (DRG)—contains information on the diagnoses and procedures recorded in public health facilities according to the International Classification of Diseases, 9th Revision Clinical Modification (ICD-9).[7] Demographic and clinical variables were extracted and are shown in the Table.

The present study included all cases registered between 1 January 2008 and 31 December 2013 in the SVIG-TB as well as patients discharged from Portuguese public health system hospitals within the DRG database between 3 April 2007 and 29 December 2013 with active TB as the primary or secondary diagnosis (ICD-9-CM 010-018) and hospitalised for >24 h. The DRG time-window was wider than that of the SVIG-TB to include hospitalisations before the diagnosis of TB (and possibly related with it), as well as admissions after diagnoses due to possible disease- or treatment-related complications.

Using SVIG-TB as the reference, deterministic matching between the two databases was made using the patient's municipality of residence, date of birth, sex and date of discharge from hospital. Hence, we ensured that all patients hospitalised with TB were included and the same hospital admission was not repeated. Patients without known residency or birthdate and whose treatment outcome was missing were not included. The incarcerated population was excluded: in Portugal, these patients are hospitalised in a specialised facility and clinical chart review is not possible (which can lead to biased results). Notification is mandatory so, theoretically, all patients diagnosed with TB in Portugal are included.

Statistical analysis

Univariate and multivariate analyses of demographic and clinical variables were carried out. Values were expressed with 95% confidence intervals (CIs). In the univariate analysis, categorical data were compared using the χ^2 test or Fisher's exact test. Odds ratios (ORs) with 95%CIs were calculated. For the multi-

variate analysis, logistic regression analysis was used in a nominal logistic model. $P < 0.05$ was considered statistically significant. χ^2 tests and logistic regression were performed using SPSS v24 (IBM, Armonk, NY, USA).

Ethical approval

Our study protocol followed the ethical standards set in the Helsinki Declaration, and was approved by the Ethics Committee of Centro Hospitalar de São João/Faculdade de Medicina da Universidade do Porto, Porto, Portugal (154/18).

RESULTS

Between January 2008 and December 2013, 15,233 patients with a confirmed TB diagnosis were reported and 4,421 hospitalisations occurred in public hospitals in continental Portugal. This corresponded to 29.0% of all patients with TB.

Patient characteristics (hospitalised and all cases diagnosed) are shown in the Table. Age and sex were similar in both groups. Chronic diseases (diabetes mellitus (DM), liver disease, chronic obstructive pulmonary disease), cancer, substance abuse (alcohol and other drugs), concomitant pulmonary and extra-pulmonary presentations, cavitary disease and previous uncompleted TB treatment were more frequent among hospitalised patients. This population also had a higher social/economic risk (unemployment, homelessness, community housing). Univariate analysis revealed that cancer, HIV infection, alcohol abuse, extra-pulmonary TB and uncompleted previous TB treatment were predictors of hospital admission (Table).

In the multivariate analysis, HIV coinfection (OR 3.439, 95%CI 2.284–5.178; $P < 0.001$), cancer (OR 1.926, 95%CI 1.012–3.667; $P = 0.046$), alcohol dependence (OR 1.605, 95%CI 1.109–2.324; $P = 0.012$), extra-pulmonary disease (OR 1.805, 95%CI 1.014–3.211; $P = 0.045$) and uncompleted previous treatment (OR 1.495, 95%CI 1.108–2.018; $P = 0.009$) were predictors of hospitalisation (Table).

DISCUSSION

HIV infection, alcohol dependence, cancer, extra-pulmonary disease and uncompleted previous treatment were identified as the most important predictors of hospitalisation with TB. Patients were predominantly male and aged <50 years, and showed demographic similarities with the annual national report.[1,6]

The number of new HIV diagnoses has declined in Portugal in the last decade. This reduction has also been seen in patients suffering from acquired immunodeficiency syndrome (AIDS) and in the mortality directly associated with HIV infection. However, Portugal continues to have one of the highest HIV infection rates in the European Union, with TB as the most important coinfection.[1] HIV screening is mandatory in newly diagnosed cases: in 2015, 88.6% of patients who completed TB treatment had known HIV infection.[1] The fact that HIV was a predictor of hospitalisation may reflect the continued surveillance of HIV patients in the infectious diseases out-patient setting, where TB signs and symptoms and treatment complications are searched for thoroughly, thereby increasing the chances of a correct diagnosis.

However, the scenario in latent TB infection (LTBI) is different. In 2014, only 14.7% of the newly diagnosed HIV patients in Europe were provided with preventive treatment.[9] In Portugal, among groups in which screening and preventive therapy are strongly recommended, HIV has the lowest number of treated patients.[1] In addition, these patients usually have several other risk factors (DM, alcohol, malnutrition, homelessness, drug abuse, hepatitis C infection, smoking) that can contribute to disease severity and in-patient care.[10,11]

There is substantial evidence for a causal relationship between alcohol dependence and TB. Alcohol consumption is associated with impaired immunity and subsequent higher TB susceptibility/TBLI reactivation, an increased risk of hepatotoxicity and other adverse effects related to TB or antiretroviral therapy, as well as social marginalisation (which is, per se, a known risk factor).[12,13]

The immunosuppressive effects of chemotherapy (especially platinum-based regimens and concurrent radiation therapy), solid cancers (lung, breast, stomach and colon) and hematologic malignancies increase the risk of TB and TBLI.[14–18] Contrary to DM or chronic kidney disease (in which this risk is expected to be permanent), in cancer it is more likely to be temporary (e.g., during chemotherapy): a recent meta-analysis showed a decline in TB risk during follow-up after chemotherapy completion.[19] The cumulative risk for TB can be reduced because survival expectancy is diminished in several cancer types. The available data did not allow us to fully evaluate the impact of cancer (because treatment was chosen based on stage and the expected prognosis) nor to ascertain if TB resulted from recent transmission or was secondary to reactivation.

Certain forms of extra-pulmonary TB can be sufficiently severe to necessitate hospitalisation (e.g., TB disseminated to the central nervous system) and diagnosis can be elusive in the absence of pulmonary manifestations. A higher incidence is seen in immunocompromised patients.[20,21] In our study, important risk factors such as HIV infection and alcohol dependence represented 19.4% and 18.2% of the in-patient population respectively.

Previous TB treatment (whether in the context of failure, loss to follow-up or disease relapse) is a risk

factor for drug-resistant TB,[22] and multidrug regimens (e.g., second-line, multidrug resistant (MDR) TB treatments) are associated with higher toxicity/side effects: both situations can demand in-patient care. In a recent study,[23] male sex, HIV infection and age > 40 years were independent risk factors for retreatment and treatment success was lower in patients who had received prior TB treatment.

With the discovery of anti-tuberculosis drugs in the 1940s, pharmacotherapy became the mainstay of treatment and helped reduce TB burden (incidence would increase again in the 1980s, with the AIDS epidemic, and in the 1990s with MDR-TB). Furthermore, the WHO[4,5] proposed patient-centred management based on out-patient care. This approach would reduce hospitalisations and its costs, allowing investment in detection and treatment and promoting a shift of TB resources from hospitals to out-patient services.

Even though this may appear to be an obvious strategy, does it mean hospitalisation among TB patients has become the exception, especially in higher-income countries? Also, how is Portugal, an intermediate TB incidence country,[24] doing when compared with other low TB incidence countries?

A study published in 2010[25] considered the hospitalisations in New York City, NY, USA, between April and June 2003 and in 2008. More than 70% of TB patients diagnosed during this period were hospitalised (72% in 2003 vs. 74% in 2008). Those suffering homelessness, alcohol/drug abuse, HIV infection, or with smear-positive sputum or cavitary disease, were more likely to be hospitalised. Interestingly, in the same study, ~40% of admissions were considered as possibly avoidable; the airborne-spreading risk and need for appropriate isolation, treatment adherence concerns, being foreign-born and having cavitary TB and HIV were associated with inappropriate hospitalisation. Another study conducted in the US in 1995 in 10 public health programs[26] revealed that ~50% of participants had been hospitalised at least once due to TB—83% were initial hospitalisations and 17% occurred during treatment. Ethnicity, age > 65 years, positive sputum smear, HIV infection and homelessness were related with the former, whereas MDR-TB, alcohol dependence and homelessness were significant risk factors for the latter. More than 80% hospitalisations occurred at the time of diagnosis, so patients could have presented later in the disease course and be more severely ill, but also may not have had access to early medical care. As in our study, substance abuse and homeless populations were more prone to hospitalisation (higher number of episodes and increased duration of stay), thereby reinforcing the need for addressing these problems aggressively.

In Canada, a low-incidence TB country, a study between 1996 and 2007[27] revealed that 51% of patients were hospitalised during the period of diagnosis and/or treatment initiation, and 9% during treatment. Predictors of hospitalisation in both periods were similar to the ones found in our study (comorbidities such as renal and liver diseases, DM and cancer). In another low-incidence country, Spain (5.2/100 000[24]), a study focusing on the costs of TB hospitalisation between 1999 and 2006[28] revealed that 80.4% of patients with pulmonary TB were admitted to a health facility whereas, in another one study conducted between 1999 and 2009, the percentage estimated was ~68%. In a recent analysis, hospital admissions were considerable: 59%.[29] These studies focused on costs and demographic characterisation.

Overall, in published series focusing on North America and western European countries, percentages vary between 51% and 79%.[25–31] In countries with a high TB burden, such as Tajikistan (85/100 000[24]), hospitalisation varies from 27% to 73%, depending on the availability of specialised centres[32] (where patients are more likely to be referred to). In Russia, hospitalisation rates in 2006 were between 60% and 88%[33], and failure of the WHO Directly Observed Treatment (DOT) strategy and socio-economic factors seem to justify these percentages.

The literature suggests that at-risk social groups, HIV infection and substance abuse are common denominators for TB hospitalisation. Nonetheless, deeper characterisation is needed, particularly in high-burden countries, where hospitalisation rates are scarcely known. Considering this global information, our study revealed an lower hospitalisation rate (17.6/100 000[6]), even when compared with countries with a low incidence. Higher rates may have been due to a lack of experience from health care providers in managing TB, being more reluctant to discharge patients for fear of transmission, or an incapacity of out-patient follow-up or therapy surveillance.

In Portugal, out-patient care in specialised centres (CDP) allows patients with confirmed or presumptive diagnosis to be observed more readily, and an enormous effort to bring DOT to high-risk populations has been taken.

Most of the direct costs of treating TB result from hospitalisation. In Armenia, a country with a high incidence of TB and MDR-TB, health services used to be based on a 'vertical' system with extensive hospitalisation (80% of cases) and a high risk of nosocomial-TB transmission. In 2013, the government decided to reinvest in an out-patient-oriented programme to reduce TB-related costs to ensure quality patient care, and a reduction of 30% in bed occupancy was expected to occur in a 2-year period.[34] These policies (already adopted in Portugal) are considered crucial in the WHO perspective for TB elimination.

Risk factors such as HIV infection, DM and

alcohol abuse are more readily modifiable and should be managed with specific health measures. Comorbidities might be responsible for some hospitalisations rather than TB itself, which would result in overestimation of the TB-related hospitalisation rate.

TB remains an important public health problem even in low-incidence countries. The WHO TB Elimination Framework recently presented a 'tailored' response to this challenge.[35] These include the development of a national strategy that promotes TB notification and continued monitoring; easy access to health care; identification and support of at-risk groups; effective screening and treatment for active TB and LTBI and optimization of prevention and care of drug-resistant TB.

Strengths of our study included the theoretically national-scale capture of all confirmed TB cases, which allowed clinical and social characterisation of TB hospitalisations.

Retrospective data gathering was a limitation of our study because recording of some information may not have been complete (immunosuppression status in HIV patients and how many were under antiretroviral therapy, cancer type, previous investigation for TBLI); over- or under-coding, data quality and linkage errors between databases due to missing or wrongly recorded information should also have been considered. Also, in our analysis it was not possible to distinguish between relapse and reinfection. Incarcerated patients were not considered but, in 2014, they represented only 2.5% of the all cases in Portugal.

CONCLUSIONS

HIV infection, alcohol abuse, cancer, extra-pulmonary TB, and uncompleted previous TB treatment were predictors of hospitalisation in our population. Our study reflects the reality of a country with intermediate TB incidence, and revealed a reduced hospitalisation rate when compared with other countries with lower and higher incidence rates. This result may have been the result of effective outpatient management of these patients.

Conflicts of interest: none declared.

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RÉSUMÉ

CONTEXTE : Au Portugal, comme dans d'autres pays, la tuberculose (TB) est prise en charge en ambulatoire. L'hospitalisation reste cependant indispensable pour certains groupes à risque et en cas de complications.

OBJECTIF : Identifier les facteurs de risque éventuels associés à l'hospitalisation des patients avec la TB au Portugal.

SCHÉMA : Les données extraites de deux bases de données nationales (l'une pour l'enregistrement des cas de TB et l'autre relative aux informations relatives à l'hospitalisation des structures de santé publiques) entre 2007 et 2013. Une analyse univariable et multivariable des variables démographiques et cliniques a été réalisée.

RÉSULTATS : Des 4421 patients hospitalisés, la majorité avaient plus souvent une maladie chronique, un cancer, une toxicomanie, une précarité sociale/économique, une TB extra pulmonaire, une forme pulmonaire caverneuse et des antécédents de traitement antérieur inachevé. Les facteurs de prédiction les plus importants d'hospitalisation pour TB ont été la co-infection à virus de l'immunodéficience humaine, le cancer, l'alcoolisme, la TB extra pulmonaire et les antécédents de traitement inachevé. Le taux d'hospitalisation parmi les patients TB au Portugal a été inférieur à celui d'autres pays qu'ils aient une incidence plus faible ou plus élevée.

CONCLUSION : Une altération de l'immunité et la progression de maladies chroniques sont associées à des formes plus graves de TB et à des effets secondaires fréquents qui peuvent être suffisamment critiques pour justifier l'hospitalisation. Bien que le Portugal ait une incidence de TB intermédiaire, son taux d'hospitalisation n'est pas plus élevé que celui d'autres pays.

RESUMEN

MARCO DE REFERENCIA: En Portugal como en otros países, se considera la tuberculosis (TB) como una enfermedad de tratamiento ambulatorio. Sin embargo, son frecuentes los casos de hospitalización a fin de tratar algunos grupos vulnerables de la población y las complicaciones.

OBJETIVO: Definir los posibles factores de riesgo asociados con la hospitalización de los pacientes con TB en Portugal.

MÉTODO: Se extrajeron datos del 2007 al 2013 de dos bases nacionales de datos (el registro de casos de TB y la información sobre hospitalizaciones en los establecimientos de salud del sector público). Se realizaron análisis univariantes y multivariantes de las variables demográficas y clínicas.

RESULTADOS: Se registraron 4421 hospitalizaciones. Las características más frecuentes fueron enfermedades crónicas, cáncer, consumo de sustancias, vulnerabilidad social o económica, TB extrapulmonar, enfermedad pulmonar con cavernas y un antecedente de tratamiento incompleto. Los factores pronósticos más importantes de hospitalización por TB fueron la coinfección por el virus de la inmunodeficiencia humana, el cáncer, el abuso del alcohol, la TB extrapulmonar y un tratamiento antituberculoso previo incompleto. La tasa de hospitalización de los pacientes con TB en Portugal fue inferior a la tasa de otros países con incidencias más bajas y más altas.

CONCLUSIÓN: Las inmunodeficiencias y la progresión de las enfermedades crónicas se asocian con formas más graves de TB y con reacciones adversas frecuentes al tratamiento, que pueden necesitar una hospitalización. Pese a una incidencia de TB intermedia, la tasa de hospitalización Portugal no es más alta, comparada con la de otros países.