EARLY MORTALITY IN NEW PATIENTS ON TREATMENT FOR SMEAR POSITIVE PULMONARY TUBERCULOSIS IN YAOUNDE-CAMEROON

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SUMMARY :

Setting : Tuberculosis centre of Hôpital Jamot, Yaoundé, Cameroon.
Objective: - Identify simple clinical determinants associated with early death in hospitalized patients with new smear positive pulmonary tuberculosis (PTB).
Design: - A prospective cohort of 501 patients aged ≥ 15 years consecutively admitted from April 2009 to March 2010 was followed up in hospital during the 2-month intensive phase of treatment. On admission, patients were interviewed, their admission chest x-rays read and laboratory tests performed. Deaths occurring between admission and the end of the first 2 months of treatment were recorded as early deaths.
Results: - Of the 501patients with a mean age of 35.5 (range: 15-72) years, 59.1% were males and 160 (31.9%) were HIV positive. Twenty-one (4.2%, 95% CI: 2.4-5.9%) eventually died in hospital. Logistic regression analysis showed age ≥ 40 years (OR=3.64, 95% CI: 1.37- 9.67), HIV infection (OR=12.8, 95% CI: 2.74-59.46), anaemia (OR=3.64, 95% CI: 1.09-8.31) and hypoalbuminaemia (OR=3.18, 95% CI: 1.19-8.55) were independent predictors of early death.
Conclusion: Our results highlight the importance for the early detection and treatment of HIV infection in these patients. They also emphasize the need of measuring their serum albumin and haemoglobin levels in our environment as they are indicators of prognosis for which specific interventions could improve outcomes.

Keywords: Pulmonary tuberculosis, early death, determinants, Yaoundé, Cameroon.

RESUME:

Mortalité précoce chez les nouveaux patients sous traitement pour tuberculose pulmonaire a frottis positif a Yaoundé, Cameroun.

Cadre : Centre antituberculeux de l'Hôpital Jamot à Yaoundé, Cameroun.
Objectif : Identifier les déterminants cliniques simples associés au décès précoce parmi les malades hospitalisés pour une primo-atteinte de tuberculose pulmonaire à frottis positif.
Méthodes : Une cohorte prospective de 501 malades d'âge> 15ans consécutivement admis à l'hôpital d'avril 2009 à mars 2010 était suivi au cours de la phase intensive du traitement. A l'admission à l'hôpital, les patients étaient interviewés, leurs clichés radiographiques lus et les tests de laboratoire réalisés Le décès survenant entre l'admission et la fin de 2 premiers mois de traitement était considéré comme décès précoce.
Résultats : Parmi les 501 malades avec un âge moyen de 35,5 (extrêmes : 15-72) ans, 59,1% étaient de sexe masculin et 160 (31,9%) étaient séropositifs pour le VIH. Vingt-un (4,2% ; IC95% :2,4 – 5,9) décès ont été enregistrés lors de l'hospitalisation. Dans une analyse multivariée par régression logistique, l'âge> 40ans (OR=3,64, IC95% : 1,37 – 9,67), l'infection à VIH (OR= 12,8 ;IC 95% : 2,74 – 59, 46), l'anémie (OR=3,64 ; IC95% : 1,09 -8,31) et l'hypoalbuminémie (OR=3,18 ; IC95% : 1,19 – 8,55) étaient des facteurs indépendants associés au décès précoce.
Conclusion : Nos résultats soulignent l'importance de dépistage et de traitement précoces de l'infection à VIH chez ces malades. Ils soulignent également la nécessité de déterminer le taux sérique d'albumine et de l'hémoglobine de ces malades dans notre milieu car ils sont les indicateurs pronostiques sur lesquels les interventions spécifiques pourraient améliorer leur devenir.
Mots clés : Tuberculose pulmonaire, décès précoce, déterminants, Yaoundé, Cameroun.

INTRODUCTION

Tuberculosis (TB) kills about 2 million people a year with 99% of all deaths in developing countries (1) especially those of sub-Saharan Africa. In these latter countries, case fatality rates in TB patients have enormously risen in the last few decades and have been highly associated with HIV infection(2). A substantial proportion of these deaths appear to occur early in the course of treatment (3-6). Preventing the occurrence of these deaths in resource poor countries such as Cameroon is a major challenge for clinicians as presently factors associated with them are not well characterized (6).

The aim of this study was to identify simple clinical, radiological and laboratory findings associated with early death in hospitalized patients undergoing the intensive phase of treatment for new smear-positive pulmonary tuberculosis (PTB) in Yaoundé, Cameroon.

MATERIALS AND METHODS:

Study setting:

The study was undertaken at the tuberculosis centre of Hôpital Jamot, the main referral and TB treatment facility for Yaoundé and surrounding areas. In this centre, a diagnosis of smear-positive PTB is made on the basis of a suggestive clinical history and the presence of acid-fast bacilli (AFB) on at least two of the three sputum samples submitted on two consecutive days by the patients for microscopic examination. Cultures are hardly ever done because of costs.

All new patients with sputum smear-positive PTB are hospitalized during the intensive phase of treatment which lasts for 2 months. The total duration of treatment is 6 months. It consists of a two month intensive phase of daily rifampicin (R), isoniazid (H), pyrazinamide (Z) and ethambutol (E) followed by a four month continuation phase of daily rifampicin and isoniazid on out-patient basis (2RHEZ/4RH). Treatment in the intensive phase is administered under direct supervision of the health personnel while compliance to treatment during the continuation phase is assessed by monthly return for drug collection.

METHODS:

A prospective cohort of all patients aged ≥ 15 years consecutively admitted in the tuberculosis centre from April 2009 to March 2010 with smear positive and previously untreated PTB was enrolled and followed up for two months in hospital. After obtaining informed consent on inclusion, information was got from each patient on age, sex, marital status, history of BCG vaccination, associated history of diabetes mellitus, alcohol and tobacco consumption as well as the duration of symptoms before the diagnosis of the disease. Admission chest x-rays were reviewed and interpreted for all patients .Each radiograph was divided into six zones by eye and the presence or absence of parenchymal disease was recorded for each zone. The chest radiographic extent of lesions was defined as minimal if only one to two lung zones were involved, moderate if involvement of 3 to 4 zones and as extensive lung involvement if more than four zones were affected (13). The presence or absence of cavities on the chest x-ray films was also noted. When a diagnosis of tuberculosis was obtained from another site in addition to the pulmonary form, the patient was classified as having both pulmonary and extra pulmonary tuberculosis.

Blood samples were collected from each patient on admission for HIV serology after counselling and for the measurement of serum albumin, and haemoglobin levels as well as leukocyte count. HIV antibodies were detected using two rapid tests: Determine HIV1/2 (Abbot Laboratories, Tokyo, Japan) and ImmunoComb II HIV 1 and 2 Bispot (Orgenics, Courbevoie, France). When the two tests were positive, the patient was considered positive for HIV. In case of discordant results, a confirmation test was carried out by the Western blot technique (New Lav blot, Sanofi Diagnostics, Pasteur). A serum albumin level less than 30g/litre defined hypoalbuminaemia while a haemoglobin level less than or equal to 9 g/dl defined anaemia. The sputum smear with the highest bacillary load of the three examined for diagnosis for each patient and measured by the semi-quantitative method in use in tuberculosis control programmes (i.e 1+,2+,3+)(7) was extracted from the medical file and recorded.

Each patient was then placed on the standard antituberculosis treatment regimen for new smear-positive PTB cases (2RHEZ/4RH) and followed up for two months in hospital. All HIV positive patients who had no contra-indication were also offered cotrimoxazole preventive treatment as well as anti-retroviral therapy if they were already eligible for this latter treatment according to the directives of the Cameroon National AIDS Committee (8). All deaths occurring between registration for treatment and the first two months of antituberculosis treatment were recorded and regarded as early in-hospital deaths. Autopsies

were not performed and the exact cause of death was usually unknown.

Ethical issues:

The study was approved by the National Ethics Committee of Cameroon. All participants were informed that data emerging from the study would be kept confidentially, anonymity would be ensured and they would be free to withdraw from the study at any time without prejudice.

Statistical analysis:

In order to determine factors associated with early mortality, variables of patients who died during the two months of follow-up in hospital were compared to those of patients who survived. Chi square or Fisher's exact test was used to compare proportions and differences in means by the Student's t-test. A difference was considered significant if $p \leq 0.5$. Logistic regression analysis was performed using variables found to be significantly associated with early mortality in the univariate analysis to identify factors independently and significantly associated with it.

RESULTS: -

A total of 516 new patients with smear-positive PTB were admitted in the tuberculosis centre during the enrolment period. Ten (1.9%) of these were excluded because they were transferred out to other health facilities. Five others were excluded because they either absconded (3) or died (2) before baseline biological measurements could be carried out.

Of the remaining 501 patients, 296 (59.1%) were male while 205 (40.9%) were female. Their mean age was 35.5 years (range: 15-72 years). Four hundred and sixty-eight (93.4%) of them had pulmonary tuberculosis only while 33(6.6%) had both pulmonary and extra-pulmonary forms of the disease. Of the 501 patients studied, 160 (31.9%) were HIV seropositive. The mean duration of symptoms for these patients at diagnosis was 3.3 months (range: 1-26 months).

Twenty-one of the 501 patients included in the study eventually died in hospital during the intensive phase of treatment giving an early mortality rate of 4.2% (95% confidence interval [CI]: 2.4-5.9%). Eighteen (85.7%) of these deaths occurred in the first month of hospitalization.

Table 1 compares the socio-demographic and clinical characteristics of patients who died to those who survived the two month intensive phase of treatment. Age $\geq$ 40 years (p=0.02) and concomitant presentation of pulmonary and extra-pulmonary tuberculosis (p=0.038) were significantly associated with early death. Table 2 presents a comparison of various baseline chest radiographic and laboratory findings of patients who died to those who survived the initial two month intensive phase of treatment. An HIV positive status (p=0.0000), anaemia (p=0.00002) and hypoalbuminaemia (p=0.0001) were significantly associated with early death on this univariate analysis.

On the multivariate level (table 3) including only those variables that were significantly associated with early death on univariate analysis (tables 1 and 2), age $\geq$ 40 years (OR=3.64; 95% CI: 1.37-9.67, p=0.0095), HIV positive status (OR=12.8; 95% CI: 2.74-59.46; p=0.0012), anaemia (OR=3.01; 95%CI:1.09-8.31; p=0.0335) and hypoalbuminaemia (OR=3.18; 95% CI: 1.19-8.55, p=0.0126) were significantly and independently associated with early death.

DISCUSSION

Death rates in TB patients particularly in the high human immunodeficiency virus prevalence populations of sub-Saharan African countries including Cameroon have substantially risen in the last few decades threatening the credibility of TB control programmes in the eyes of the patients, health care providers and the community (2). A substantial proportion of these deaths occurs early in the course of treatment (3-6). For example in Hlabissa, South Africa, the probability of death from TB was greatest during the first two weeks of the start of treatment in both HIV positive and negative patients (4). In Thylolo district in Malawi, Zachariah et al (6) reported an early mortality rate of 8% among their patients during the first 4 weeks of treatment. In our cohort of patients, the mortality rate during the first 4 weeks of treatment was 3.8%. This figure rose to 4.2% by the end of the two month intensive phase of antituberculosis therapy.

Factors associated with early mortality are at present not well characterized (6). Several potential reasons for early death of patients with TB have however been advanced by different authors. These include late presentation of patients with severe and extensive disease, life threatening HIV- related complications such as severe anaemia and bacteraemia (9,10), advanced age (6,13), malnutrition (6,11), hypoalbuminaemia (14,15), anaemia (16) and HIV infection (2,4,5). There also seems to be some evidence that early deaths may be due to delays in starting antituberculosis treatment (2). In this

study, factors associated with early mortality were age ≥ 40 years, HIV infection, anaemia and hypoalbuminaemia.

Old age has been well documented in several studies as a risk factor for death among TB patients (6,13). Our results are in agreement with this observation as age ≥ 40 years was an independent predictor of early death in our cohort of new patients .The exact reasons why old age should be a risk factor for early death during treatment are not known. It is however believed that the increased early mortality among older TB patients may be accounted for by comorbidity and lower immunity (17).

This study also revealed that HIV infection was an independent predictor of death in our patients during the intensive phase of antituberculosis therapy. Our results are in line with those of several authors (4,5), who have reported on the direct influence of a positive HIV status on early mortality among TB patients undergoing treatment. For example, in Zomba, Malawi, about half of all deaths reported in HIV positive TB patients during 12 months of follow-up occurred in the first month of treatment (5). Similarly, in Hlabissa, South Africa, the probability of death for both HIV positive and HIV negative patients was greatest during the first two weeks following the start of treatment (4). It is known that TB accelerates the course of HIV-infection and contributes to the mortality of HIV infected individuals by a one to twofold increase (18,19). In our study the majority of HIV seropositive PTB patients who died presented advanced immunodeficiency expressed by a CD4 cell count lower than 200 cells/mm^3 (result not shown). The severity of immunodeficiency among TB-HIV co-infected patients has been described as a predictor of decreased survival (20-22) and was likely the main determinant of early death in our HIV-infected PTB patients despite their use of antiretroviral therapy.

In this study, anaemia on admission in the tuberculosis centre was an independent predictor of early death in our new PTB patients. Sachs et al (16) observed in a similar study in Johannesburg, South Africa, that lower admission haemoglobin levels were significantly associated with TB-patients who died in hospital. Anaemia is a common haematological abnormality in patients with TB. Like all chronic infections, TB can cause anaemia (23). Various pathogenic pathways have been suggested in TB-associated anaemia but most studies have shown suppression of erythropoiesis by inflammatory mediators (24-26) as a cause of anaemia. However the observation that patients with TB-associated anaemia display an absence of bone marrow iron (27) and the same red blood cell distribution width as that observed in iron-deficiency anaemia (24) suggests that iron deficiency is a possible cause of anaemia in patients with TB. The situation is made worse in HIV positive TB patients as it is known that in HIV positive persons, anaemia is also a prognostic marker of future disease progression or death independent of CD4 and viral load (28).

Hypoalbuminaemia was also an independent predictor of early death in our new PTB patients. Our results are in agreement with the findings reported by other authors. Mehta et al (14) reported that serum albumin and haemoglobin concentrations are strong predictors of survival in adults with pulmonary tuberculosis in the United States of America. In Brazil, Matos et al (15) reported a strong positive association between serum albumin levels at admission to hospital and in-hospital death due to tuberculosis as well as a greater risk of death in patients with serum albumin levels ≤ 2.7 g/dl at the time of admission. Malnutrition is a frequent finding in tuberculosis patients (11). It has been observed that moderate to severe malnutrition as assessed by body mass index is a risk factor for early death in patients with tuberculosis. (6). Hypoalbuminaemia in addition to being a complicating factor in a wide range of infectious diseases is also an important marker of severe malnutrition (29).

Our study has some limitations. First only patients with pulmonary tuberculosis admitted consecutively into the tuberculosis centre of Hôpital Jamot in Yaoundé over the study period were included. Consequently there is bound to be some bias with regard to our study population being representative of Yaoundé and its environs as a whole. Nevertheless, the tuberculosis centre of Hôpital Jamot is the sole referral and tuberculosis treatment facility for Yaoundé and has cared for pulmonary tuberculosis patients for several decades. The patient series in this study can therefore be taken as an adequate reflection of PTB patients in the area. Second, since we examined only hospitalized patients, our findings may not be equally relevant to pulmonary tuberculosis patients who are diagnosed and managed completely as out-patients. Third, we could not ascertain the cause of death among our patients and therefore we cannot attribute their deaths with certainty to TB and/or to another additional

disease including complications of HIV infection. Like others, we were therefore forced to use all-cause mortality as a surrogate marker of mortality attributable to tuberculosis (30). Fourth, due to costs, mycobacterial cultures and drug susceptibility tests were not done. Our study was therefore limited to patients whose TB was bacteriologically confirmed only by smear examination of sputum for acid-fast bacilli. The presence of multi-drug resistant tuberculosis (MDR-TB) could increase mortality particularly among HIV seropositive PTB patients as high case fatality rates amongst hospitalized HIV seropositive patients with MDR-TB has been described elsewhere (31,32). This notwithstanding, in 1998 the prevalence of initial MDR-TB reported from the tuberculosis centre of Hôpital Jamot in Yaoundé was 0.8% and there was no significant difference between HIV positive and negative PTB patients (46).

In conclusion, age ≥ 40 years, HIV co-infection, anaemia and hypoalbuminaemia are independent predictors of early death of new patients hospitalized and treated for smear-positive PTB in Yaounde, Cameroon. The identification of potentially reversible factors such as anaemia and hypoalbuminaemia suggests specific interventions that may lead to improvements in patient outcomes. Most importantly, patients with TB should be assessed for HIV infection as early recognition of HIV among these patients could help reduce its negative impact on TB patients' survival since it offers the opportunity for more appropriate therapy of both diseases.

ACKNOWLEDGEMENTS

We are grateful to Mr F. Bekang for helping in the analysis of our data. We also thank Mr L. Betchem for his secretarial assistance.

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Table 1: - Comparison of baseline socio-demographic and clinical characteristics of patients who died to those who survived during the intensive phase of treatment for new smear-positive pulmonary tuberculosis in Yaoundé, Cameroon.

Characteristic	Dead n = 21	Alive n = 478	p- value
Age (years): < 40	9	330	**0.02**
≥ 40	12	148	
Sex: Male	13	281	**0.95**
Female	8	197	
Marital status			
-Bachelor/Widow-widower	9	251	**0.51**
-Married/concubine	12	227	
BCG vaccination: Yes	12	296	**0.76**
No	9	175	
Diabetes: Yes	1	11	**0.38**
No	20	466	
Alcohol use: Yes	3	141	**0.20**
No	18	337	
Tobacco use: Yes	3	98	**0.37**
No	18	380	
Delay before diagnosis:			
< 3 months	8	231	**0.49**
≥ 3 months	13	247	
Types of tuberculosis:			
Pulmonary	**17**	**450**	**0.038**
Pulmonary + extra pulmonary	**4**	**28**	

Table 2: - Comparison of baseline chest radiographic and laboratory findings of patients who died to those who survived during the intensive phase of treatment for new smear-positive pulmonary tuberculosis in Yaoundé, Cameroon.

Aspect	Dead n = 21	Alive n = 478	p-value
Chest x-ray lesions involving:			
< 4 zones	11	246	**0.88**
≥ 4 zones	10	232	
Chest x-ray showing cavities			
Yes	6	237	**0.096**
No	15	241	
HIV sero-status			
Positive	19	141	**0.00000**
Negative	2	335	
Sputum AFB Smear			
< 3+	11	190	**0.35**
3+	10	288	
WBC count (per mm^3)			
≤ 5000	2	91	**0.22**
> 5000	19	387	
Haemoglobin level			
< 9g / dl	14	111	**0.00002**
≥ 9 g /dl	7	367	
Serum albumin level			
≤ 30 g/l	**13**	**102**	**0.0001**
> 30 g/l	**8**	**376**	

Table 3: - Logistic regression analysis for factors independently associated with early death during the intensive phase of treatment of patients with new smear-positive pulmonary tuberculosis in Yaoundé, Cameroon.

Factor	β- coefficient	p-value	Odds ratio	95% CI
Age ≥ 40 years	1.29	0.0095	3.64	**1.37-9.67**
Pulmonary + extra pulmonary tuberculosis	-0.12	0.8455	0.88	**0.24-3.21**
HIV positive status	2.55	0.0012	12.8	**2.74-59.46**
Haemoglobin level < 9g/dl	1.10	0.0335	3.01	**1.09-8.31**
Serum albumin level ≤ 30 g/l	**2.29**	**0.0216**	**3.18**	**1.19-8.55**