Annales Africaines de Médecine
Article original

Survie et prédicteurs de mortalité des patients tuberculeux pré ultrarésistant traité par Bpal comparé au régime long à Kinshasa

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Résumé

Contexte & objectif. Le bénéfice sur la survie des patients sous schéma thérapeutique Bpal introduit depuis 2022 en République démocratique du Congo, n'a pas encore été prouvé. Cette étude visait à décrire la survie globale et rechercher les prédicteurs de la mortalité des patients tuberculeux pré ultrarésistants traités par le régime Bpal comparés au régime individualisé à base de bédaquiline à Kinshasa. *Méthodes.* Il s'agissait d'une cohorte historique portant sur la mise en œuvre d'un schéma thérapeutique chez deux groupes de patients atteints de tuberculose pré-XDR au cours des trois premières années : le schéma Bpal (2022, 2023 et 2024) et un schéma thérapeutique individualisé au long cours à base de bédaquiline (2015, 2016 et 2017). *Résultats.* Cinquante-huit patients (27 dans le groupe Bpal et 31 dans le schéma au long cours de bédaquiline). La survie globale était meilleure dans le groupe de patients ayant suivi le schéma Bpal que dans le groupe traité par le schéma traditionnel (p = 0,001), et moins bonne chez les patients séropositifs pour le VIH (p < 0,0001). Dans le groupe entier, les principaux facteurs prédicteurs de mortalité étaient essentiellement des antécédents de tuberculose multirésistante (HR : 3,21 ; IC à 95 % : 1-10,2 ; p = 0,048) et une sérologie VIH positive (HR : 5,9 ; IC à 95 % : 1,6-21,8 ; p = 0,007). *Conclusion* **:** L'utilisation du schéma thérapeutique Bpal offre une bonne survie malgré la présence des prédicteurs communs de la mortalité.

Summary

Context and objective. The survival benefit of the BPaL treatment regimen, introduced in the Democratic Republic of the Congo (DRC) in 2022, has not yet been demonstrated. The present study aimed to describe the overall survival and identify predictors of mortality among patients with pre-extensively drug-resistant tuberculosis (pre-XDR-TB) treated with the BPaL regimen, compared with those receiving an individualized bedaquiline-based regimen in Kinshasa. *Methods*. This is a historical cohort study examining the implementation of a treatment regimen in two groups of pre-XDR tuberculosis patients during the first three years: the Bpal regimen (2022, 2023, and 2024) and a long-term, individualized bedaquiline-based regimen (2015, 2016, and 2017). *Results*. We included 58 patients (27 in Bpal regimen and 31 long term regimens of bedaquiline). Overall survival was better in the group of patients following the Bpal regimen than in the group treated with the traditional regimen (p = 0.001), and worse in HIV-positive patients (p < 0.0001). In the general population, the main predictors of mortality were primarily symptoms of multidrug-resistant tuberculosis (HR: 3.21; 95% CI: 1‑10.2; p = 0.048) and positive HIV serology (HR: 5.9; 95% CI: 1.6‑21.8; p = 0.007). *Conclusion***.** The use of the BPaL treatment regimen resulted in good survival despite the presence of common mortality predictors.

Keywords: BPaL Regimen, Kinshasa, Mortality Predictors, Pre-extensively drug-resistant tuberculosis, Survival

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Article original

Mots-clés : Kinshasa, prédicteurs de la Mortalité, Régime Bpal, Survie, Tuberculose pré-ultrarésistante

Reçu le 1 septembre 2025

Accepté le 10 juin 2026

https://dx.doi.org/10.4314/aamed.v19i4.16

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Received September 1, 2025

Accepted June 10, 2026

https://dx.doi.org/10.4314/aamed.v19i4.16

Introduction

Tuberculosis (TB) is the leading cause of death from infectious agents worldwide, with 1.3 million deaths in 2023. Its treatment involves a combination of antibiotics belonging to different groups. Some forms of TB can exhibit resistance to common, known antibiotics; these are therefore called drug-resistant TB (DR-TB). This can include multidrug-resistant TB (MDR-TB), rifampicin-resistant TB (RR-TB), pre-extensively drug-resistant TB (pre-XDR-TB), or extensively drug-resistant TB (XDR-TB) (1). Drug-resistant Mycobacterium tuberculosis is one of the 24 pathogens included in the WHO's list of priority bacterial pathogens (2). Nearly 400,000 new cases of multidrug-resistant tuberculosis (MDR-TB) were reported worldwide in 2023, with 26% being extensively drug-resistant tuberculosis (XDR-TB) (1). Several individualized treatments have been implemented for XDR-TB, based on drug susceptibility testing (DST) and treatment history, with mixed results. The introduction of new antituberculosis drugs (bedaquiline, pretomanide) and the repurposing of other antibiotics with proven efficacy in the treatment of tuberculosis, such as fluoroquinolones, clofazimine, and linezolid, have led to the development of new treatment regimens. (3). A new short-course treatment regimen, Bpal, shows great promise for the treatment of XDR-TB patients worldwide. This regimen has been used in the Democratic Republic of Congo (DRC) since 2022 (3, 4). However, although there is a substantial body of literature on the Bpal regimen in several countries with satisfactory results, and despite its existing use in the DRC, less literature discusses this experience in our setting. Therefore, we deemed it appropriate to undertake this research to determine the overall survival and predictive factors of mortality in pre-XDR tuberculosis patients treated with the Bpal regimen compared to an individualized bedaquiline-based regimen in Kinshasa.

Methods

Setting, population, and type of study

A historical cohort study was conducted, including pre-XDR patients treated with the Bpal regimen and those receiving individualized treatment (long regimen) based on bedaquiline at the Damien Center of Excellence (CEDA) in Kinshasa, Democratic Republic of Congo. Patients were followed throughout their treatment. Patients treated with the Bpal regimen were followed from January 2022 after their inclusion in the protocol, and those in the long regimen from 2015 to 2017.

Data collection and parameters of interest

Patients included in this study were those with a pre-XDR TB diagnosis confirmed by laboratory analysis (culture), with no prior exposure to bedaquiline, pretomanide, or linezolid for more than one month, and no extrapulmonary

involvement or severe forms (meningitis, osteoarticular involvement, miliary tuberculosis). The data were recorded in specific patient files. The parameters of interest were primarily patient characteristics, clinical and laboratory examinations, monitoring of drug treatments, and adverse events, including laboratory abnormalities. Adverse events were recorded monthly and classified according to the National Agency for Research on AIDS and Emerging Infectious Diseases (ANRS) adult adverse event severity scale, which comprises four grades. Grade 1, mild abnormality (mild or temporary discomfort, with no limitation of normal daily activities; does not require medical intervention or corrective treatment); Grade 2, moderate abnormality (partial limitation of normal daily activities; medical intervention or corrective treatment is not necessarily required); Grade 3, severe abnormality (limitation of normal daily activities; requires medical intervention and corrective treatment, hospitalization possible) and Grade 4, life-threatening (may result in death).

Some definitions of the concepts

The long-term regimen is defined, according to the National Tuberculosis Control Program (PNLT), as a 20-month treatment divided into two phases: a 6-month intensive phase and a 14-month maintenance phase. The medications available under the National Tuberculosis Control Program (PNLT) were: kanamycin (Km), PAS, linezolid (Lzd), isoniazid (H), clofazimine (Cfz), pyrazinamide (Z), bedaquiline (Bdq), delamanid (Dlm), levofloxacin (Lfx), meropenem-clavulanic acid (Mpm-Clv), amikacin (Am), imipenem-clavulanic acid (Ipm-Clv), and cycloserine (Cs). The Bpal regimen consists of bedaquiline (B), pretomanid (Pa), and linezolid (L), administered exclusively orally for a duration of 6 months. Only patients with a positive smear or culture at 4 months continue treatment for up to 9 months, in accordance with WHO recommendations (4,11). The term "cure" refers to a patient who has completed their treatment according to the national protocol, with bacteriological confirmation (at least three consecutive negative control cultures, performed at least one month apart after the intensive phase) (4). The term side effect and adverse event means any unexpected or harmful medical occurrence that happens to a patient during medical treatment.

Statistical analysis

The collected data were analyzed using Stata/IC version 15 software. Variables were presented as central tendencies and frequencies. Comparisons of proportions were performed using Pearson's chi-squared test and Fisher's exact test as appropriate. Predictors of mortality were identified by Cox regression with a 5% risk of error, and survival was predicted using Kaplan-Meier curves with log-rank calculation at the same confidence level.

Ethical considerations

The study protocol was approved by the Ethics Committee of the Kinshasa School of Public Health (ESP/CE/289/2019), and treatment was provided free of charge as part of the National Tuberculosis Control Program (PNLT). Data were collected by healthcare staff and analyzed anonymously.

Results

We selected 58 patients divided into two groups

General characteristics of patients

These results show a male predominance in both populations with a sex ratio M/F of 1.4 with a mean age of 32.2 ± 14.8 years in the general population (p=0.377) and seven out of ten patients were under 40 years old. A history of multidrug-resistant tuberculosis was found in 18 patients, or 31% of cases, and was more common in the population using the long regimen, or a proportion of 38.7% of cases (p=0.001). Six out of ten patients had a chest X-ray for lesion assessment; an attitude found in 81.5% of patients using the Bpal regimen (p=0.001). Four patients, or 6.9% of cases, had positive viral serology. Mortality was approximately 24% overall and exclusively found in the population using the long regimen (p <0.0001). Side effects were present in 48% of cases and were more common in patients taking the long regimen (p <0.0001). The median treatment duration was 9 months (Table 1).

Table 1. General characteristics of patients

	All patients	Bpal regimen	Long regimen	p -Value
	n = 58 (%)	n = 27 (%)	n = 31 (%)	

Gender				0.36
Male	34 (58.6)	17 (62.9)	17 (54.8)	
Female	24 (41.4)	10 (37.1)	14 (45.2)	
Age (Mean ± SD)	32.2 ± 14.8	33.3 ± 13.1	31.5 ± 9.8	0.377
<40 years old	43 (74.1)	19 (70.4)	24 (77.4)	
≥40 years old	15 (25.9)	8 (29.6)	7 (22.6)	
History of MDR-TB				**0.001**
Yes	18 (31,0)	6 (22.2)	12 (38,7)	
No	40 (69,0)	21 (76.8)	19 (61,3)	
Performing a chest x-ray				**0.001**
Yes	34 (58.6)	22 (81.5)	12 (38.7)	
No	24 (41.4)	5 (18.5)	19 (61.3)	
HIV serology				0.36
Positive	4 (6.9)	1 (3.7)	3 (9.7)	
Negative	54 (93.1)	26 (96.3)	28 (90.3)	
Therapeutic outcome				**<0.0001**
Death	14 (24.1)	0 (0.0)	14 (45.2)	
Alive	44 (75.9)	27 (100.0)	17 (54.8)	
Side effects				**<0.0001**
Present	28 (48.3)	2 (7.4)	26 (83.9)	
Absent	30 (51.7)	25 (92.6)	5 (16.1)	
Duration of treatment	9 (9-20)	9 (9-9)	20 (1.6-20.2)	**<0.0001**

SD=Standard deviation; MDR-TB=Multidrug-resistant Tuberculosis; HIV=Human immunodeficiency virus

Types of adverse events (AE)

Side effects (AE) were almost entirely reported in the population that had been put on the long regimen. Neuropathies occupied the first place with 15 cases (25,86%) followed by anemia, vomiting and skin rash found in 14 patients (24,13%). Hyperuricemia was present in 10 patients (17,24%). In the group that took the Bpal regimen, 2 cases of adverse effects were reported. The figure had showed type of side effects.

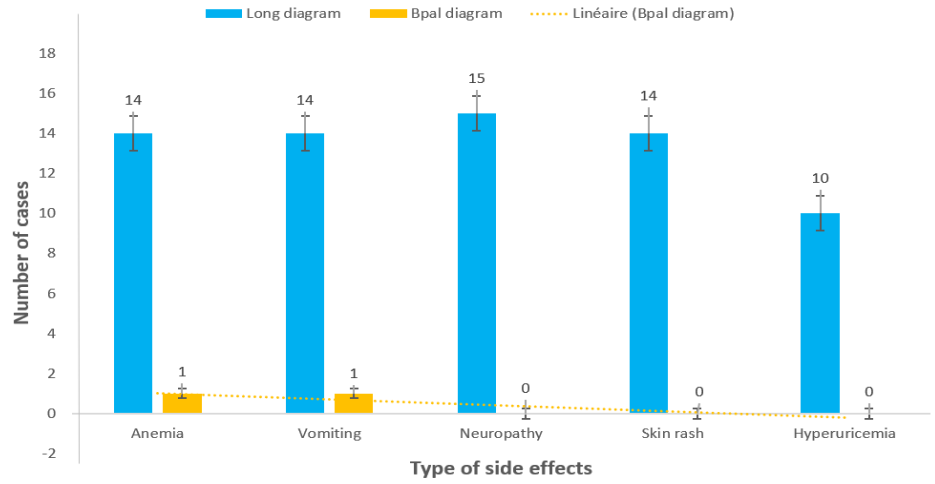
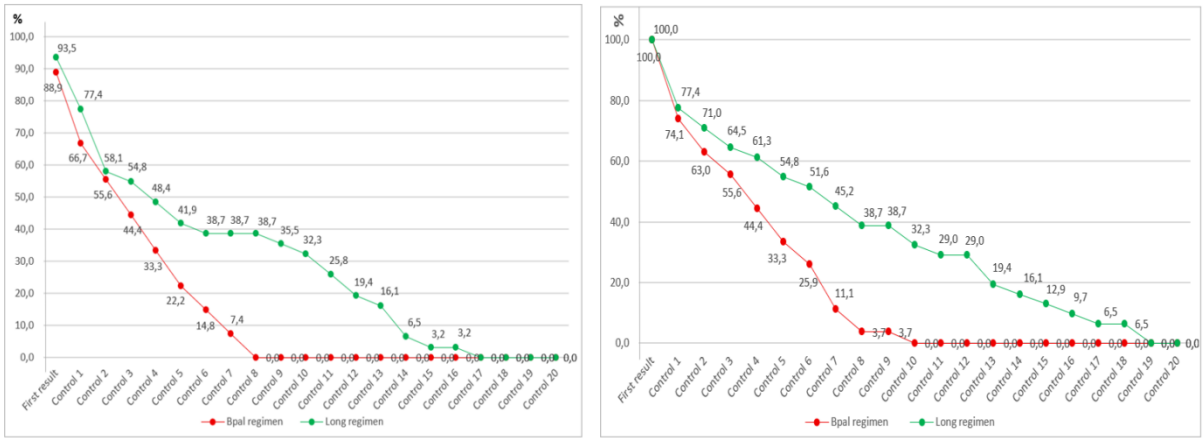


Figure 1. Type of side effects

Evolution of the results of patients smears and sputum

Sputum smear and culture results evolved similarly in both groups of patients. Results gradually became negative in both populations and for both examinations**.** The figure 2 has showed the evolution and chronology of bacteriological follow up during the treatment.



(a) (b)

Figure 2: Evolution of sputum smear (a) and culture (b)in patients receiving the long regimen and the Bpal regimen

Predictors of mortality and adverse events

Regarding the predictors of mortality, in the general population, history of MDR-TB (HR: 3.21; 95% CI: 1-10.2; p=0.048) and positive HIV serology (HR: 5.9; 95% CI: 1.6-21.8; p=0.007) emerged as the main predictors. In the population of patients who received the long regimen, age over 40 years (HR: 2.8; 95% CI: 0.94-8.7; p=0.062) and positive HIV serology (HR: 5.8; 95% CI: 1.4-23.2; p=0.013) emerged as the main predictors. In the group of patients who received the Bpal regimen, there were no deaths.

Analysis of predictors of the occurrence of side effects in the general population showed that history of MDR-TB (HR: 2.34; 95% CI: 0.9-5.7; p=0.062) and positive HIV serology (HR: 5.5; 95% CI: 1.17-25.8; p=0.03) emerged as the main predictors. In the population of patients who received the long regimen, the main predictors were age over 40 years (HR: 3.3; 95% CI: 1.2-8.9; p=0.017) and positive HIV serology (HR: 7.9; 95% CI: 1.4-45.2; p=0.02). In the population of patients who received the Bpal regimen, history of MDR-TB (p=0.376) and male gender (p=0.708) came out with a high Hazard ratio without significant difference. The Table 2 summarize all predictor of mortality ans adverse event.

Table 2. Predictors of mortality and side effects

	Predictors of mortality		Predictors of side effects	
	p	**HR (95% CI)**	**p**	**HR (95% CI)**
General population				
Male gender	0.93	1.04 (0.36-3.02)	0.67	1.29 (0.6-2.76)
Age ≥40 years	0.294	1.79 (0.6-5.37)	0.184	1.93 (0.73-5.09)
History of MDR-TB	0.048	3.21 (1-10.26)	0.062	2.34 (0.9-5.7)
HIV positive serology	0.007	5.9 (1.6-21.8)	0.03	5.5 (1.17-25.8)
Long regimen				
Male gender	0.77	1.17 (0.4-3.37)	0.678	0.84 (0.4-1.86)
Age ≥40 years	0.062	2.8 (0.94-8.7)	0.017	3.3 (1.2-8.9)
History of MDR-TB	0.765	1.19 (0.37-3.8)	0.376	1.5 (0.5-3.8)
HIV positive serology	0.013	5.8 (1.4-23.2)	0.02	7.9 (1.4-45.2)
Bpal regimen				
Male gender	1	1	0.708	1.7 (0.1-27)
Age ≥40 years	1	1	1	1
History of MDR-TB	1	1	0.376	3.5 (0.2-55)
HIV positive serology	1	1	1	1

MDR-TB=Multidrug-resistant Tuberculosis; HIV=Human immunodeficiency virus

Overall patient survival

Overall survival was better in the group of patients who took the Bpal regimen compared to the long regimen (p=0.001). Both sexes had similar survival without significant difference (p=0.086) while subjects aged at least 40 years had poor survival compared to those under 40 years (p=0.034). Subjects with positive HIV serology experienced poor survival compared to subjects with negative serology (Figure 3).

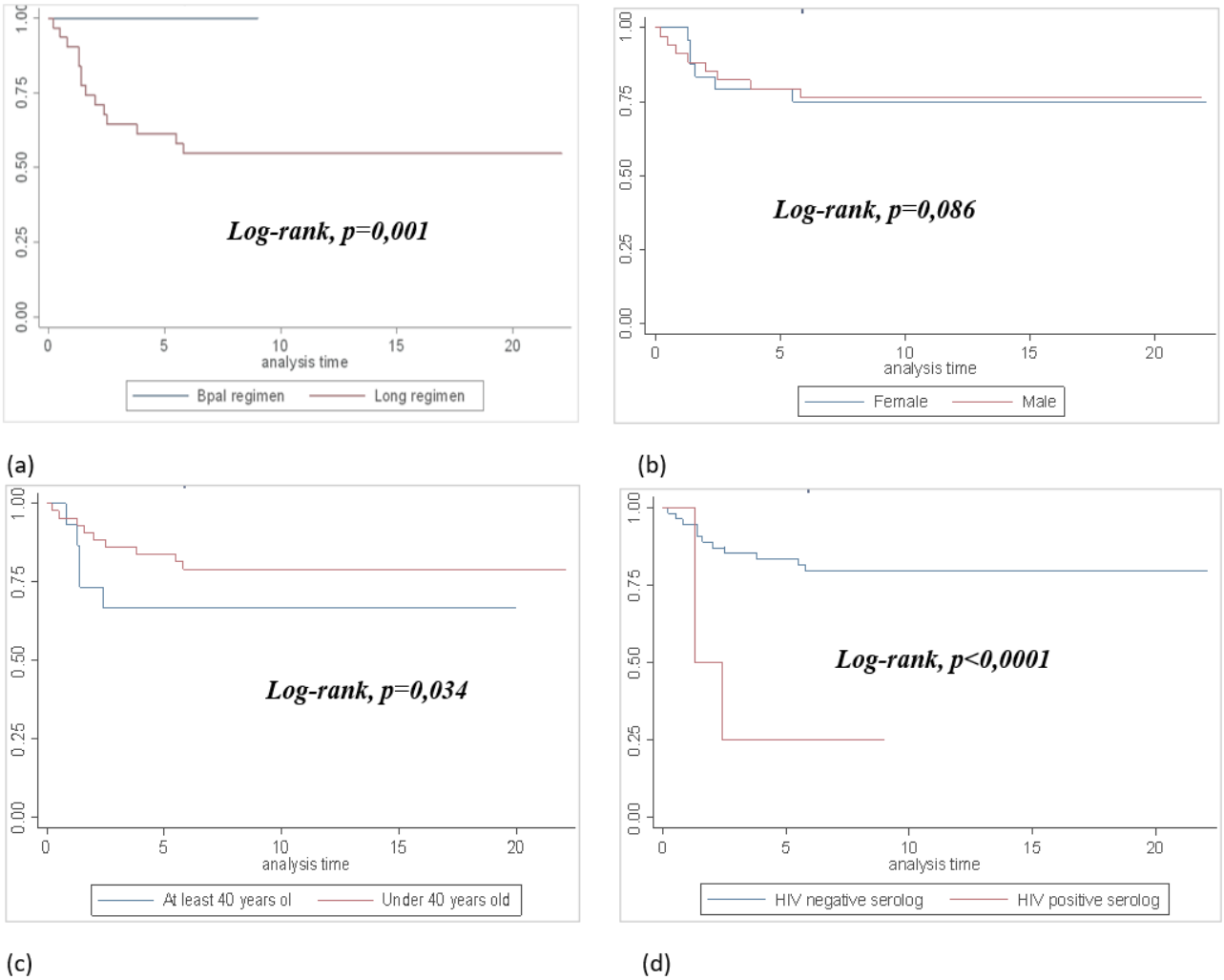


Figure 3. Overall survival of patients according to the treatment regimen used (a), gender (b), age (c) and HIV serostatus (d)

Discussion

This study aimed to determine the overall survival and predictive factors of mortality of pre-existing drug-resistant tuberculosis patients treated with the BPaL regimen compared to the long-individualized bedaquiline-based regimen in Kinshasa. In this study, we observed a male predominance in both populations, at 58.6%, and a mean age of 32.2 ± 14.8 years in both groups. This male predominance and the young age of the patients are consistent with the epidemiology of tuberculosis worldwide (1).

A history of multidrug-resistant tuberculosis was found in 18 patients, representing 31% of cases in both groups, and was more frequent in the population following the long treatment regimen, accounting for 38.7% of cases (p = 0.001). 6.9% of cases presented with HIV coinfection. These results are similar to those observed in the series by M.B. Souleymane et al., who also noted a male predominance; the mean age was 35 years and HIV coinfection was found in 5.8% of cases (5).

Adverse effects were present in 48% of cases in both groups and were more frequent in patients treated with the long individualized treatment regimen, with a statistically significant difference (p < 0.0001).The high rate of adverse effects in the group of patients treated with the long therapeutic regimen could be justified by the number of drugs used; BpaL requires only three drugs, compared to the individualized long therapeutic regimen based on bedaquiline, which required a minimum of eight drugs. (9,12).

Among the adverse effects observed: Neuropathy was the most common, occurring in 15 cases (25.86%), followed by anemia, vomiting, and skin rashes in 14 patients (24.13%). Hyperuricemia was present in 10 patients (17.24%).

Conradie et al, 2020: observed that linezolid administered at a dose of 1200 mg was associated

with peripheral neuropathy in 81% of cases and with myelosuppression or anemia in 48% of cases, often leading to a reduction in the dose of linezolid or to a discontinuation of treatment (6,14).

Connie et al, 2022: noted that linezolid administered at a dose of 600mg was associated with peripheral neuropathy in 5.9% of cases and myelosuppression or anemia in 4.4% of cases (15).

In the present study, bacteriological follow-up noted 25% of cases of late conversion of the smear at 4 months, with treatment extended for 9 months, and a good result with the BPaL treatment. However, it is important to perform a culture at the same time to discuss the best management option (10-11).

Mortality in both groups was approximately 24% of cases and was observed exclusively in the group of patients using the individualized long treatment regimen ($p < 0.0001$).The high number of deaths in the group of patients treated with the long individualized bequiline-based therapy regimen was due to the delay in initiating treatment: in 2015, bedaquiline was not widely available (8), a problem that was not observed in 2022 with BPaL, as all drugs were available.In this series, overall survival was better in the group of patients receiving the BPaL treatment than in the group receiving individualized long-term therapy, with a statistically significant difference ($p = 0.001$). In 2015, bedaquiline was not available to all patients; some waited a long time before starting treatment with poor results.Regarding Bpal treatment in 2022, all indicated medications were available to all patients.

Subjects with positive HIV serology had lower survival rates than subjects with negative serology ($p < 0.0001$). This could be explained by the negative influence of HIV infection in patients with tuberculosis, increasing the risk of death.

In the present series, a history of MDR-TB (HR: 3.21; 95% CI: 1–10.2; $p = 0.048$) and positive HIV serology (HR: 5.9; 95% CI: 1.6–21.8; $p = 0.007$) were found to be the main predictors in both groups. Alemu A. et al., 2021, also identified a history of MDR-TB and HIV infection among the predictors of mortality in drug-resistant tuberculosis patients (12).

Woldeyohannes D et al, 2021 identified positive HIV serology and radiographic lung damage as predictors of mortality in drug-resistant tuberculosis patients (13).

Limitations

The main weakness of the study lies in the fact that it excluded severe forms of tuberculosis, extrapulmonary locations (miliary, meningitis, osteoarticular), patients with extensive lung lesions, and patients under 15 years of age due to a lack of available data. Another weakness is the nature of the study; it is a retrospective study based on data from registries and patient follow-up records, which is subject to potential biases related to missing or incomplete data.but also the fact of comparing two groups of patients belonging to two distinct periods separated by several years (2015-2017 versus 2022-2024) can give rise to time bias.

On the other hand, its strength is that it is a first study that compared the first three years of the implementation of a long therapeutic regimen based on bedaquiline with those of a short therapeutic regimen, entirely oral (Bpal Scheme) used in the management of pre-extensively resistant tuberculosis in Kinshasa, DR Congo.

Conclusion

A history of HIV and multidrug-resistant tuberculosis at the time of diagnosis are factors that should be considered during the initial management of the patient.

The use of the BPaL regimen offers many advantages in terms of sucees rate, mortality and even patient tolerance compared to the long regimen.

Further studies will be needed with updated cohorts.

Contribution of authors

All author participates in all step of this study: protocol conception, data collection, data analysis, reviews manuscript et validation of final manuscript. Munzengi ND; Lukaso LL; Kabengele OB; Tshilanda BM; Fina M, Mbulula L; Kashongwe MZ, Kashongwe MI

Declaration of conflict of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

At the Damian Foundation which hospitalizes in his specialized TBPR center (CEDA) and supports all patients with chemoresistance and has offered all medical and nutritive supports.

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Cite this article as: Muzengi DN, Kashongwe IM, Balekela MT, Lukaso LL, Kabengele BO, Mawete F, *et al*. Survival and mortality predictors of pre-extensively drug-resistant tuberculosis patients treated with Bpal compared to long à Kinshasa. *Ann Afr Med* 2026; **19** (4): e7424-e7433 https://dx.doi.org/10.4314/aamed.v19i4.16.