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Adherence sub-optimality rate to anti-tuberculosis drugs, among patients treated and cared at the Franceville Epidemiology and Endemic Disease Control Base, in South-Eastern Gabon

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ABSTRACT

Background: *In light of growing bacterial resistance and the side effects of medications, this study investigates the factors leading to poor treatment adherence among patients receiving care at the Franceville Epidemiology and Endemic Disease Control Base in southeastern Gabon.*

Material and Methods: *Prospective and observational, this study was conducted from February 13 to September 28, 2024, and collected the records and charts of patients aged 15 years and over, primo-infected with pulmonary tuberculosis. Subjected to the initial phase of standard first-line antituberculosis treatment for 2 months, patients underwent a 4-month continuation phase of antituberculosis treatment under direct observation (DOT). Overall treatment adherence was assessed and calculated at the end of each calendar month during the study, following WHO recommendations. Using a standard questionnaire, sociodemographic, clinical, and medical history characteristics were recorded. Correlations between different variables were performed using R software version 3.6.1, for statistical analysis of trends over time. Within a 95% confidence interval, results were considered significant at p ≤0, 05.*

Results: *This study involved a total of 178 individuals diagnosed with tuberculosis (TB). After six months of first-line anti-TB treatment (2EHRZ/4HR) and achieving a 100% response rate, the results revealed that overall adherence to anti-TB treatment was sub-optimal in 32 patients (18%, 95% CI: [0.13-0.24]), compared to 146 patients (82%, 95% CI: [0.76-0.88]) who demonstrated optimal adherence. Statistical analyses, including univariate and multivariate models, indicated that being male (adjusted Odds Ratio = 3.49; 95% CI [1.7; 7.03], p=0.000), living outside Franceville (adjusted Odds Ratio = 1.03; 95% CI [1.01; 1.04], p=0.000), and co-infection with HIV/TB (adjusted Odds Ratio = 3.24; 95% CI [1.47; 7.15], p=0.002) were significantly associated with sub-optimal treatment adherence, regardless of the specific regimen used (INH + RIF + PZA, INH + RIF + EMB, or INH + RIF + PZA + EMB). These findings highlight key factors influencingtreatment adherence among TB patients*

Conclusion: *The different therapeutic combinations evaluated in this study demonstrated varying levels of effectiveness against tuberculosis. Nevertheless, to achieve the eradication of this disease, significant improvements in the treatment of multidrug-resistant tuberculosis are essential.*

Keywords: *Assessment, Suboptimal outcomes, Treatment adherence, Tuberculosis, Anti-tuberculosis medications, Gabon*

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I- INTRODUCTION

Tuberculosis is an infectious disease caused by *Mycobacterium tuberculosis* (also known as Koch's bacillus or BAAR, for acid-fast bacillus) [1, 2]. Globally, it affects approximately 10.6 million people annually and is responsible for 1.3 million deaths [3, 4]. Tuberculosis can manifest as pulmonary tuberculosis (PT), the most common and contagious form, transmitted through airborne droplets from coughs or sneezes of infected individuals [5, 6], or as extra-pulmonary tuberculosis (EPT), which affects organs other than the lungs. EPT, though infectious, does not significantly contribute to transmission due to its low bacterial load [7,8].

Common forms of EPT include lymph node tuberculosis (>50% of cases), pleural tuberculosis (>20%), and, less frequently, osteoarticular, urogenital, and meningeal tuberculosis.

Tuberculosis remains a major global public health challenge, with prevalence rates varying across regions. It is particularly widespread in low-income areas such as Southeast Asia (46% of cases), Africa (23%), and the Western Pacific (18%), while lower rates are observed in the Eastern Mediterranean, the Americas, and Europe [9]. In Gabon, the incidence is estimated at 525 cases per 100,000 inhabitants [10]. In response, the World Health Organization (WHO) urged Gabon to establish a National Tuberculosis Control Program (NTBCP) in 2017, which

includes tuberculosis centers (CAT) and diagnostic and treatment centers (CDT) across the country [11]. However, the performance of these facilities remains inconsistent and insufficient to meet the set objectives. Challenges such as underdiagnosis, inappropriate treatment, and the emergence of drug-resistant strains continue to hinder efforts to control the disease [12].

Treatment for drug-susceptible tuberculosis typically involves a combination of drugs, including isoniazid (INH), rifampicin (RIF), ethambutol (EMB), and pyrazinamide (PZA), which can cure over 90% of patients within six months [13]. However, these medications can cause adverse reactions (AR), ranging from mild symptoms to severe complications such as hepatitis, renal failure, and hematological or cutaneous reactions. While minor reactions can often be managed symptomatically, severe cases may require temporary or permanent discontinuation of the offending drugs [14].

In 1998, Gabon adopted the WHO's Directly Observed Treatment Short Course (DOTS) strategy to improve treatment adherence and prevent drug resistance [15]. Despite this, the country's epidemiological situation remains concerning. Factors such as the high prevalence of TB/HIV co-infection, poor socio-economic conditions, treatment abandonment, weaknesses in the national TB program, limited community engagement, and insufficient training of healthcare workers contribute to this ongoing challenge [16].

Against this backdrop, this study aims to evaluate the sub-optimal adherence rate to first-line anti-tuberculosis drugs among patients treated at the Franceville Epidemiology and Endemic Disease Control Base in southeastern Gabon.

II- MATERIALS AND METHODS

1 Study location

Situated in southeastern Gabon, Franceville serves as the capital of the country's third most populous province, with a population of 110,568 inhabitants as of 2013 [17]. The city is traversed by the Ogooué and Mpassa rivers and spans approximately 40,000 km^2, covering about one-sixth of Gabon's total land area. Over 80% of its terrain is blanketed by dense forest, while the remaining landscape consists of savannahs and natural pastures. The region experiences an equatorial climate, characterized by two rainy seasons and two dry seasons annually. Average rainfall reaches 1,831 mm per year, fluctuating between 1,400 and 3,800 mm, with temperatures ranging from 21 to 28°C.

Figure1 : Map of the study area

2 Description of the host structure

This study was conducted at the medical analysis laboratory of the Franceville Epidemiology and Endemic Disease Control Base (FEEDCB).

Situated in the 3rd district of the town, this healthcare facility is equipped with a robust technical infrastructure capable of performing routine examinations and supporting the hospital-based monitoring of patients.

3 Study Design, Duration, and Population

This prospective observational study was carried out between February 13 and September 28, 2024. It included patients aged 15 years and older, who were newly diagnosed with pulmonary tuberculosis. Diagnosis was confirmed using both microscopic (acid-fast bacillus detection) and molecular (Xpert test) techniques. The study population consisted of patients receiving care at the medical analysis laboratory of the Franceville Epidemiology and Endemic Disease Control Base.

4. Inclusion and exclusion criteria

The study included only patients aged 15 and older with newly diagnosed pulmonary tuberculosis who had provided consent to participate. Patients with extra-pulmonary tuberculosis, drug-resistant tuberculosis, incomplete or unusable medical records, or those who declined to participate were excluded from the study.

5 Sampling

Systematic sampling was used to collect records from primary pulmonary tuberculosis-positive patients undergoing consultation at the Franceville Epidemiology and Endemic Disease Control Base, who had consented to participate in the study.

5.1. Data collection

After obtaining informed consent from the patients, a standardized questionnaire was administered to gather sociodemographic information, including sex, age, marital status, occupation, place of residence, and type of housing. Data on medical history (such as diabetes, HIV status, or other conditions) and lifestyle habits (like smoking and alcohol consumption) were also collected. Additionally, diagnostic results for tuberculosis using microscopic methods (acid-fast bacillus testing) and molecular techniques (Xpert), along with clinical data, were recorded.

6. Different anti-tuberculosis drugs prescribed to study patients

The standard TB treatment used in the present study generally lasts six months on the basis of triple or quadritherapy including Isoniazid (INH), Rifampicin (RIF), Pyrazinamide (PZA) and Ethambutol (EMB) for two months, followed by continuation therapy including isoniazid and Rifampicin administered daily according to weight, and the dosages of the antituberculosis drugs were as follows:

- In adults: for 2 months.
(INH: 5 mg / kg + RIF: 10 mg / kg + PZA: 25 mg / kg) per day.
(INH: 5 mg / kg + RIF: 10 mg / kg + EMB: 15 mg / kg) per day
(INH : 5 mg / kg + RIF : 10 mg / kg + PZA : 25 mg / kg + EMB : 15 mg / kg) per day.

- In children: a single type of combination therapy was prescribed for 2 months.
(INH: 2 mg / kg + RIF: 4 mg / kg + PZA: 10 mg / kg) per day.

During the continuation phase, which lasted 4 months, all patients used dual therapy including isoniazid and Rifampicin.

7. Methods for assessing overall adherence to anti-tuberculosis treatment

Following WHO recommendations, overall adherence to anti-tuberculosis treatment over six months was calculated and assessed at the end of each calendar month, in the form of a short interview (± 5 minutes) with patients taking their treatment under direct observation (DOT), every day in the laboratory of the Epidemiology and Endemic Disease Control Base in Franceville, according to the following formula:

Adherence rate = (NDP - (NMD + NID) / NDP x 100

- Number of days prescribed (NDP): days in the month when anti-tuberculosis treatment was prescribed.

- Number of missed days (NMD): days of the month during which the patient did not take any prescribed anti-tuberculosis medication.

- Number of incomplete days (NID): days of the month during which the patient took some but not all of the prescribed anti-tuberculosis drugs.

8. Evaluation of adverse effects

Using direct patient observation, adverse events were assessed according to the symptoms observed. In the event of serious adverse reactions, symptomatic treatment was prescribed, or the anti-tuberculosis treatment was discontinued.

9. Ethical considerations

For this study, authorizations were obtained from the Regional Health Directorate of the Southeast in Franceville, and from the Head of the Franceville Epidemiology and Endemic Disease Control Base, in view of the partnerships with the USTM Faculty of Sciences. An internship agreement was signed by the Dean of the Faculty of Science to conduct the study in the said structure. Informed written consent was obtained from each participant, who was informed beforehand of the right to terminate participation in the present study at any time. Confidentiality of information was maintained by means of codes and storage in a lockable cabinet.

10. Statistical analysis of data

The collected data were entered into a Microsoft Excel 2021 spreadsheet, cleaned, and subsequently analyzed using R software version 3.6.1. To identify potential statistical associations between sub-optimal adherence to tuberculosis treatment and independent variables, Pearson's chi-square test and odds ratios were employed, with binary logistic regression applied. Within a 95% confidence interval, p-values were calculated and deemed significant when they were less than or equal to 0.05.

III- RESULTS

1 Overall sub-optimality of adherence to antituberculosis drugs in study patients (N= 178)

A total of 178 pulmonary tuberculosis patients were included in this study. The average age was 27.05 ± 14.38 years, with a male-to-female sex ratio of 2.63, indicating a higher number of men (129) compared to women (49). While the ideal adherence rate for anti-tuberculosis treatment is 100%, this study found that after six months of first-line treatment (2EHRZ/4HR: Ethambutol 275mg, Isoniazid 75mg, Rifampicin 150mg, Pyrazinamide 400mg), the overall adherence rate was sub-optimal. Specifically, 32 patients (18%; 95% CI: [0.13–0.24]) showed sub-optimal adherence, while 146 patients (82%; 95% CI: [0.76–0.88]) demonstrated optimal adherence.

2 Overall sub-optimality of adherence to anti-tuberculosis drugs, according to socio-demographic and clinical characteristics of study patients (N= 178)

A univariate, then multivariate logistic regression analysis of overall sub-optimal adherence to anti-tuberculosis treatment as a function of study patients' sociodemographic characteristics revealed that being male (adjusted Odds Ratio = 3.49; 95% CI [1.7; 7.03], p=0.000), residing outside Franceville (adjusted Odds Ratio = 1.03; 95% CI [1.01; 1.04] p= 0. 000), were significantly associated with sub-optimal adherence to anti-tuberculosis treatment, among patients in the study Table 1.

Table 1:Univariate and multivariate analysis of overall sub-optimality of adherence to anti-tuberculosis drugs, according to socio-demographic characteristics of study patients, (n=178).

Variables	Total number of patients on treatment (%)	Overall adherence under optimal	Univariate analysis		Multivariate analysis	
			Crude OR CI 95%	p-value	Adjusted OR CI 95%	p-value
Gender						
Female	49 (27,53)	4 (8,16)	Reference	-	-	-
Male	129 (72,47)	28 (21,71)	3,10 [0,99;12,89]	0,048*	3,49 [1,7 ; 7,03]	**≤0,001***
Age groups (years)						
15 -30	45 (25.28)	12 (26.66)	Reference	-	-	-
31 - 40	13 (16.66)	6 (46.16)	4.04 [1.06 ;14.97]	0.02*	1.036 [0.44 ; 2.5]	0.94
≥ 41	120 (58.06)	14 (11.66)	0.43 [0.18 ; 0.98]	0.031*	1.27 [0.54 ; 2,97]	2.97
Education level						
Without	2 (1.12)	2 (100)	Reference	-	-	-
Primary	81(42.51)	20 (24.69)	2.8 [1.21 ; 6.75]	0.02*	-	-
Secondary	90 (50.56)	9 (10)	0.40 [0.15 ; 0.97]	0.33*	-	-
Higher	5(5.81)	1(20)	1.3 [0.03 ;13.60]	1	-	-

Professional status						
Working	163 (91.58)	22 (13.50)	Reference	-	-	-
Inactive	15 (8.42)	10 (66.66)	12.52 [3.51 ;51.40]	≤ 0.001	-	-
Residence						
Franceville	152 (85.39)	28 (18.42)	**Reference**	-	-	-
Other	26 (14.61)	4 (15.38)	0.81 [0.18 ; 2.65]	1	1.03 [1.01 ; 1.04]	**0.000***
Smoking						
Yes	54 (30.34)	21(38.88)	6.45 [2.66 ;16.4]	≤ 0.001	-	-
No	124 (69.66)	11 (8.87)	Reference	-	-	-
Alcoholism						
Yes	72	23	5.01 [2.05 ; 13.3]	**0,000**	-	-
No	106	9	Reference	-	-	-

*OR= Odds Ratio; CI= Confidence Interval; * = Significant Test.*

3. Overall sub-optimality of adherence to anti-tuberculosis drugs, according to clinical characteristics of study patients (N= 178)

A combined univariate and multivariate logistic regression analysis of sub-optimal adherence to anti-tuberculosis treatment, based on the clinical characteristics of the study participants, revealed that HIV/tuberculosis co-infection (adjusted Odds Ratio = 3.24; 95% CI [1.47; 7.15], p=0.002) was significantly associated with suboptimal adherence to anti-tuberculosis treatment among the patients. See Table 2 for details

Table 2: Univariate and multivariate analysis of overall suboptimal adherence to anti-tuberculosis drugs, according to clinical characteristics of study patients, (n=178).

Variables	Total number of patients on treatment N (%)	Overall adherence under optimal	Univariate analysis		Multivariate analysis	
			Crude OR CI 95%	p-value	Adjusted OR CI 95%	p-value
History of tuberculosis						
Yes	20 (11,24)	17 (85)	51.62 [12.95 ; 304]	**≤ 0.001**	1.25 [0,67;2,3]	0.5
No	158 (88.76)	15 (3.16)	Reference	-	-	-
HIV positive						
Yes	63 (35.39)	26 (9.52)	12.54 [4.6 ; 40.2]	≤ 0.001	3.24 [1.47 ; 7.15]	**0.002***
No	115 (64.61)	6 (5.22)	Reference	-	-	-
Diabetes mellitus						
Yes	39 (30.34)	20 (38.88)	10.91 [4.31;29]	≤ 0,001	0.6 **[**0.3;1.35**]**	0.23
No	139 (69.66)	12 (5.22)	Reference	-	-	-
Arterial hypertension (AH)						
Yes	62	13	3.47 [1.48 ; 8.4]	0.002	0.96 [0.44;2,1]	0.96
No	116	19	Reference	-	-	-

*OR= Odds Ratio; CI= Confidence Interval; * = Significant Test*

4. Overall sub-optimality of adherence to anti-tuberculosis drugs, according to treatment regimens prescribed to study patients (N= 178)

Table 3 shows that, after univariate and multivariate logistic regression analysis of the overall sub-optimality of adherence to anti-tuberculosis drugs, according to the treatment regimens prescribed to study patients, regardless of the regimen used, INH + RIF + PZA (adjusted Odds Ratio = 3.49; 95% CI [1.7; 7.03], p=0.000), INH + RIF + EMB (Adjusted Odds Ratio = 1.03; 95% CI [1.01; 1.04] p= 0. 000), INH + RIF + PZA + EMB (Adjusted Odds Ratio = 1.03; 95% CI [1.01; 1.04] p= 0.000) were all significantly associated with overall sub-optimal TB drug adherence among study patients.

Table 3: Univariate and multivariate analyses of overall sub-optimality of adherence to anti-tuberculosis drugs, according to treatment regimens prescribed to study patients (N= 178).

Variables	Total number of patients on treatment N (%)	Overall adherence under optimal	Univariate analysis		Analyse multivariée	
			Crude OR CI 95%	p-value	Adjusted OR CI 95%	p-value
INH + RIF						
Yes	178	32	Reference	-	-	-
No	0	0	-	-	-	-
INH + RIF + PZA						
Yes	59	26	14.56 [5.3 ;46.97]	≤ 0.001	2.7 [1.04 ; 7.3]	**0.04***
No	119	6	Reference	-	-	-
INH + RIF + EMB						
Yes	65	31	53.47 [8.5 ;2204]	≤ 0.001	5.5 [1.6 ; 18.6]	**0.006***
No	113	1	Reference	-	-	-
INH + RIF + PZA + EMB						
Yes	54	22	7.72 [3.14 ;20.3]	≤ 0.001	2.2 [1.02 ;4.9]	**0.045***
No	124	10	Reference	-	-	-

*OR= Odds Ratio; CI= Confidence Interval; * = Significant Test, INH = Isoniazid, RIF = Rifampicin, PZA = Pyrazinamide, EMB = Ethambutol*

IV- DISCUSSION

This large-scale prospective observational study, which assessed sub-optimal adherence to first-line anti-tuberculosis drugs among patients treated at the Franceville Epidemiology and Endemic Disease Control Base in southeastern Gabon, revealed a sub-optimal adherence rate of 18% (32 patients; 95% CI: [0.13–0.24]). This finding aligns closely with results from a study conducted in Somalia [18, 19] and is similar to the 17% reported in Norway [20]. However, it is higher than the rates observed in the USA (11.5%) [21], Ethiopia (11.5%) [22, 23], and China (12.5%) [24]. In contrast, it is notably lower than rates reported in earlier studies in Ethiopia (26%) [25], Zambia (22%) [26], and Europe (31%) [4]. The variability in adherence rates across studies can be attributed to differences in socio-demographic, clinical, psychological, and behavioral characteristics of participants, as well as treatment-related factors (e.g., treatment regimen, direct observation therapy (DOT), drug availability), community-related factors (e.g., stigma, social support), study duration, definitions of adherence, methods of adherence assessment, and accessibility to healthcare services [27].

In contrast to a study conducted in Northwest Ethiopia, which found that men with tuberculosis were 2.4 times more likely to achieve positive treatment outcomes compared to women [22], our study revealed that being male was a significant risk factor for suboptimal adherence to anti-tuberculosis treatment, with men 3.49 times more likely to exhibit suboptimal adherence. This finding aligns with studies from Eastern Ethiopia, where female TB patients were 1.89 times more likely to complete treatment successfully than males [28], and from Indonesia [25]. This discrepancy can be attributed to several factors. Firstly, sociocultural and behavioral influences play a role, as gender norms often discourage men from seeking medical care or expressing health concerns, potentially delaying diagnosis and treatment [26]. Additionally, higher rates of alcohol and drug use among men, as well as occupations like construction or agriculture that increase TB exposure, can complicate treatment adherence. Secondly, psychological factors, such as men's tendency to prioritize health less than women and their difficulty in expressing emotions like fear or anxiety, may further reduce their motivation to adhere to treatment [27]. Lastly, treatment-related factors, including side effects like libido issues or impotence, can be particularly challenging for men, leading to treatment discontinuation [28]. Similarly, rural residence was significantly associated with suboptimal adherence, increasing the risk by 1.03 times. This aligns with findings from other studies [29,30] and can be explained by several barriers faced by rural patients. Geographical distance from healthcare facilities, travel costs, and limited clinic hours make regular visits difficult, especially for the elderly or those with work commitments [31]. Additionally, frequent drug shortages, lower socioeconomic status, and limited education levels in rural areas can hinder understanding of treatment importance and access to care. Traditional practices, social stigma, and higher exposure to other infections further complicate adherence, while poor living conditions, such as overcrowding, can exacerbate TB transmission and reduce treatment effectiveness [32].

Consistent with studies highlighting the negative impact of HIV on TB control [33], our results showed that HIV-coinfected patients were 3.24 times more likely to have suboptimal adherence to anti-tuberculosis treatment. This is due to the complex interplay of disease-related, socioeconomic, and psychological factors. HIV/TB co-infection increases the therapeutic burden, with multiple medications and severe side effects like nausea and fatigue reducing quality of life and motivation [34]. Opportunistic infections further complicate treatment. Socioeconomic challenges, such as financial constraints and dual stigma, exacerbate the situation, while psychological issues like depression and anxiety diminish patients' ability to adhere to treatment [35].

Finally, regardless of the anti-tuberculosis treatment regimen, all patients in this study showed significant associations with suboptimal adherence [18]. This aligns with previous research indicating that systemic steroids, often used to manage complications or side effects of TB treatment, can contribute to poor adherence [36]. Steroids may cause weight gain and body shape changes, affecting self-esteem and motivation, while

masking symptoms like fever or joint pain, leading patients to underestimate treatment challenges [37]. Additionally, steroids can induce sleep disturbances, irritability, and anxiety, further reducing quality of life and adherence [38, 39].

Study limitations

Although this is the first study to provide information on adherence to anti-tuberculosis drugs among patients in Franceville, there are nevertheless a number of limitations that should be highlighted, so that they can be taken into account in future studies. In the design of the study, a number of factors were identified upstream (life context of TB patients and socio-demographic characteristics likely to influence the sub-optimal adherence observed in the present study. Firstly, the time available to us for this study meant that we were unable to determine the outcome of the patients in the study, after anti-tuberculosis treatment. Secondly, since first-line anti-tuberculosis drugs are administered in combination, it was difficult to assess the adverse effects of each component. As a result, it was not possible to determine the precise contribution of the different types of anti-tuberculosis drugs to the adverse effects observed in patients. The same applies to the precise time at which these effects appeared in each patient. Finally, it would have been appropriate to assess the incidence and severity of adverse drug reactions according to WHO toxicity grades. Given the inherent limitations of the DOT method, the results obtained in the present study cannot be generalized to all TB patients in Haut Ogooué province, or in Gabon as a whole.

CONCLUSION

This prospective observational study assessed adherence to first-line anti-tuberculosis treatment among 178 patients with primary pulmonary tuberculosis, followed for six months. Despite a 100% response rate at the end of treatment, we observed suboptimal adherence in 18% of patients. This study highlighted that male sex, residence outside of Franceville, and co-infection with HIV/tuberculosis were significantly associated with poorer treatment adherence, regardless of the prescribed therapeutic combination. These results, consistent with the literature, underscore the complexity of factors influencing treatment adherence in tuberculosis patients and the need to implement personalized strategies to improve adherence to anti-tuberculosis treatment.

PERSPECTIVES

The findings of this study highlight several promising directions for future research on adherence to anti-tuberculosis treatments and for enhancing patient care. Potential areas for exploration include: conducting a more in-depth analysis of the factors linked to non-adherence to anti-tuberculosis medications, designing and implementing interventions aimed at improving patient adherence to these treatments, assessing the effectiveness of innovative tuberculosis management strategies, such as shorter treatment regimens or new therapeutic molecules, and fostering collaboration with other researchers by sharing the data from this study to enable comparative analyses and meta-analyses.

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Authors' Contributions

TNM and HKM conceived the study idea. TNM, KKNT, and HKM contributed to the study design and implementation. TNM, CB, LCOE, and KKNT ensured data accuracy. TNM, BA, and ME drafted the manuscript. CB, TNM, and LCOE performed the statistical analysis and interpreted the results. All authors reviewed and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Artificial Intelligence

This manuscript was not created using artificial intelligence tools such as ChatGPT or others.

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