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Tuberculosis and diabetes: association with sociodemographic characteristics and diagnosis and treatment of tuberculosis. Brazil, 2007-2011

Tuberculose e diabetes: associação com características sociodemográficas e de diagnóstico e tratamento. Brasil, 2007–2011

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ABSTRACT: ***Introduction:*** Tuberculosis and diabetes comorbidity remains a challenge for global public health. ***Objective:*** To analyze the sociodemographic profile and the diagnostic and treatment characteristics of tuberculosis cases with and without diabetes in Brazil. ***Methods:*** This is a cross-sectional study with data from the Notifiable Diseases Information System and the Hypertension and Diabetes Mellitus Primary Care Clinical Management System, from 2007 to 2011. We adopted a Poisson regression model with robust variance to estimate the prevalence ratios (PR) and their respective confidence intervals. ***Results:*** We found the studied comorbidity in 7.2% of cases. The hierarchical model showed a higher PR among women (PR=1.31; 95% confidence interval – 95%CI 1.27–1.35); a greater association in the age groups 40–59 years and ≥ 60 years (PR=11.70; 95%CI 10.21–13.39, and PR=17.49; 95%CI 15.26–20.05), and in those with positive sputum smear microscopy results – 1st sample (PR=1.40; 95%CI 1.35–1.47). Return after treatment discontinuation and treatment discontinuation were inversely associated with comorbidity (PR=0.66; 95%CI 0.57–0.76 and PR=0.79; 95%CI 0.72–0.87). ***Conclusion:*** The findings, such as the inverse relationship with tuberculosis treatment discontinuation in the group of people with comorbidity, reinforce the importance of integrated actions in health services to change the scenario of this challenging comorbidity.

Keywords: Tuberculosis. Diabetes mellitus. Comorbidity. Information management. Regression analysis.

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RESUMO: ***Introdução:*** A comorbidade tuberculose e diabetes ainda continua um desafio para a saúde pública mundial. ***Objetivo:*** Analisar o perfil sociodemográfico e as características do diagnóstico e tratamento dos casos de tuberculose com e sem diabetes no Brasil. ***Métodos:*** Estudo transversal, com dados do Sistema de Informação de Agravos de Notificação e do Sistema de Gestão Clínica de Hipertensão Arterial e Diabetes *Mellitus* da Atenção Básica, no período de 2007 a 2011. Modelo de regressão de Poisson com variância robusta foi utilizado para estimar a razão de prevalência (RP) e seus respectivos intervalos de confiança. ***Resultados:*** A comorbidade estudada foi encontrada em 7,2% dos casos. Modelo hierárquico mostrou maior RP entre indivíduos do sexo feminino (RP = 1,31; intervalo de confiança de 95% — IC95% 1,27 – 1,35); maior associação nas faixas etárias 40–59 anos e ≥ 60 anos (RP = 11,70; IC95% 10,21 – 13,39 e RP = 17,49; IC95% 15,26–20,05) e com resultado positivo da baciloscopia — primeira amostra (RP = 1,40; IC95% 1,35 – 1,47). Reingresso após abandono e abandono foram inversamente associados na comorbidade (RP = 0,66; IC95% 0,57 – 0,76 e RP = 0,79; IC95% 0,72 – 0,87). ***Conclusão:*** Os achados, como a relação inversa do abandono ao tratamento da tuberculose no grupo das pessoas com comorbidade, reforçam a importância de ações integradas nos serviços para mudar o cenário dessa desafiadora comorbidade.

Palavras-chave: Tuberculose. Diabetes *Mellitus*. Comorbidade. Gestão da Informação. Análise de Regressão.

INTRODUCTION

In the early 20th century, associations between diabetes mellitus (DM) and tuberculosis (TB) were found. This comorbidity requires attention and more complex care, since diabetes can interfere with the metabolism of antituberculosis drugs, and the risk of a person with diabetes developing tuberculosis can be 2.44 to 8.33 times higher when compared to a person without diabetes[1-4].

Doubts remain because TB induces temporary hyperglycemia, which is resolved by treating this disease[5,6], and uncontrolled diabetes is associated with numerous complications, such as vascular diseases, neuropathies, and increased susceptibility to infections[2].

In Brazil, a study comparing the information gathered by the Health Supplement of the National Household Sample Survey (*Pesquisa Nacional por Amostra de Domicílios* – PNAD), in 1998, and data estimated by the Global Burden of Disease Project in Brazil on the prevalence of five chronic diseases — cirrhosis, depression, diabetes, chronic renal failure, and tuberculosis — pointed to high incidence rates of these diseases in the country[7].

In 2015, estimates by the International Diabetes Federation (IDF) indicated that 415 million adults aged 20–79 years had diabetes worldwide. If we add the 193 million undiagnosed individuals, the disease could reach 642 million people by 2040. In areas of high prevalence of diabetes, the impact of this disease on tuberculosis may be as significant as that of the human immunodeficiency virus (HIV)[8,9].

According to data from the survey *Vigilância de Fatores de Risco e Proteção para Doenças Crônicas por Inquérito Telefônico* (Vigitel), conducted in 2016, among the 53,210 interviews

performed in the 27 state capitals of Brazil, the frequency of adults who reported previous medical diagnosis of diabetes ranged from 5.3% in Boa Vista to 10.4% in Rio de Janeiro. All these cities showed a frequency of 8.9%, with 7.8% among men and 9.9% among women. The diagnosis of the disease became more common with advancing age, in both genders, particularly after the age of 45 years. More than a quarter of individuals aged 65 years or older declared being diagnosed with diabetes. In both genders, the frequency of diabetes was particularly high in subjects with up to eight years of schooling[10].

Regarding tuberculosis, estimates indicate that 10 million people developed the disease globally, of whom 5.8 million were men, 3.2 million were women, and 1 million were children, in 2017[11].

According to estimates by the World Health Organization (WHO), Brazil presented an incidence coefficient of 44 cases per 100,000 inhabitants, ranking 30th among the 30 countries with the highest burden of tuberculosis in the world, in 2017. In 2015, the percentage of tuberculosis detection in the country was 87%, according to WHO[11].

In this context, this study aimed to identify, describe, and analyze the association between the sociodemographic profile and the diagnostic, follow-up, and treatment characteristics of tuberculosis cases with and without diabetes from 2007 to 2011, after a probabilistic linkage of databases from tuberculosis and diabetes information systems from the public health system (*Sistema Único de Saúde* – SUS). The information generated will expand the knowledge about the magnitude of the issue and may contribute to discussions on the subject, supporting decision-making within the three management domains to improve or implement new public policies for preventing and controlling these diseases.

METHODS

STUDY TYPE

We carried out an analytical cross-sectional epidemiological study.

DATA SOURCES

The study data were collected from the national database of the Notifiable Diseases Information System – Tuberculosis (*Sistema de Informação de Agravos de Notificação da tuberculose* – Sinan-tuberculosis) and the Hypertension and Diabetes Mellitus Primary Care Clinical Management System (*Sistema de Gestão Clínica de Hipertensão Arterial e Diabetes Mellitus da Atenção Básica* – Hiperdia).

Sinan is the official compulsory notification system in Brazil, and tuberculosis is one of the diseases that require notification[12]. Until 2013, Hiperdia was the official system used for

diabetes notification, generating information about the performance and clinical results during follow-up. This system aimed at registering and monitoring individuals with hypertension and/or DM treated in SUS outpatient clinics, enabling information production for the regular and systematic acquisition, dispensing, and distribution of drugs for all registered patients[13].

STUDY POPULATION

The study comprised data from individuals with tuberculosis and without diabetes reported to the national Sinan-tuberculosis databases and from individuals with tuberculosis and diabetes reported to the national Sinan and associated databases, after the probabilistic linkage of these Sinan databases with diabetes cases recorded in Hiperdia.

DATABASE LINKAGE

We standardized the common fields in the database linkage by using:

(i) comparison of the person's name, mother's name, and date of birth; application of algorithms for approximate character string comparison;
(ii) blocking, with the databases divided into mutually exclusive blocks, comparisons restricted to records of the same block, and optimization of the comparison between records;
(iii) score calculation;
(iv) definition of thresholds to classify pairs of records and identify them as true or non-pairs.

For the probabilistic linkage and verification of possible cases of comorbidity that were not notified to Sinan-tuberculosis, the database of Sinan-tuberculosis considered the cases reported from January 1, 2001 to December 31, 2012, and the database of Hiperdia, from January 1, 2007 to December 31, 2011. The periods are different to try to gather a higher number of cases for this comorbidity. The final database included cases of tuberculosis without tuberculosis and diabetes comorbidity, notified to Sinan from January 1, 2007 to June 30, 2011 and cases with tuberculosis and diabetes comorbidity — those reported to Sinan-tuberculosis informing the association with diabetes and the ones retrieved after the linkage of these databases. We excluded cases of tuberculosis registered in Sinan after June 2011, as cases diagnosed after this date would finish the six-month recommended treatment[14] only in 2012 (outside the study period and without information from the diabetes records in Hiperdia).

We adopted probabilistic procedures to generate a combined database with TB and DM cases, using the Reclink software, version 3.0, with common fields to identify, with established

probabilities, whether the paired records belonged to the same individual. This final formatted database considered paired cases, present in both bases, and those that were only in Sinan-tuberculosis (not paired with the records from Hiperdia). In the database with TB cases only, TB cases reported without associated diabetes were classified as without comorbidity, i.e., those whose variable *associated diseases and illnesses — diabetes* had code 2 (No) on the Sinan form. Cases with code 9 (ignored) or blank for the same variable were excluded. The other part of the database, with the paired cases for comorbidity, included: cases of tuberculosis reported to Sinan with code 1 (Yes) for the variable *associated diseases and illnesses — diabetes*; cases of diabetes registered in Hiperdia before the tuberculosis case reported to Sinan; and cases of diabetes and tuberculosis registered and notified in the same year in both systems — Hiperdia and Sinan.

VARIABLES OF INTEREST

This study considered the presence and absence of TB and DM comorbidity as dependent variables. The two groups were compared having as independent variables the following sociodemographic characteristics: gender, age group, ethnicity, years of schooling, and regular alcohol consumption; as well as diagnostic and treatment characteristics of tuberculosis, such as: HIV serology, smear microscopy with the first sputum sample, sputum culture, smear microscopy after the sixth month of treatment, chest X-ray, supervised treatment, type of case for treatment, and condition at the end of treatment.

DATA PROCESSING AND ANALYSIS

Before processing and analyzing the data in the final database, we cleaned and adjusted the variables we would use, excluding blank fields and those filled with the ignored code (9) in the sociodemographic characteristics (gender, ethnicity, regular alcohol consumption) and diagnostic and treatment characteristics of tuberculosis (HIV serology, smear microscopy with the first sputum sample, sputum culture, smear microscopy after the sixth month of treatment, chest X-ray, and supervised treatment). In addition, the variables were adjusted and categorized into strata according to date of birth, ethnicity, and years of schooling. Moreover, for the diagnostic and treatment characteristics of tuberculosis, we chose to consider only the tests performed, with a positive or negative result, or the X-ray tests carried out, with normal or suspicious results, with the exclusion of some fields.

After organizing the database, we conducted a bivariate analysis to estimate the differences between the proportions of the variables in the groups with and without comorbidity. Data were processed in the software Microsoft Excel® and the Statistical Package for the Social Sciences (SPSS), version 20, with the application of Pearson's χ^2 test, considering a 5% statistical significance level.

After the bivariate analysis, we used the Poisson regression model with robust variance in the analytical stage, following the hierarchical model shown in Chart 1, and adopting the prevalence ratio (PR) as an association measure. We used the Akaike information criterion to select the models. Each hierarchical level employed the backward method to select the independent variables. Associated variables with $p \leq 0.05$ remained in the model to control confounding factors. We calculated 95% confidence intervals (95%CI) and assessed the quality of the model adjustment by using standardized residuals to investigate whether the model assumptions, such as homoscedasticity and normally distributed errors, were violated. The analyses were performed with the assistance of the STATA 12 software (StataCorp, 2011).

ETHICAL ASPECTS

The Ministry of Health provided the nominal databases of Sinan and Hiperdia, through the National Program for Tuberculosis Control and the SUS Technology Department (Datasus), upon signature of a Responsibility Form by the researcher. The Research Ethics Committee of the School of Health Sciences at Universidade de Brasília approved the research project, under report number 552,561, on March 11, 2014.

RESULTS

The final database included 24,443 people with TB and diabetes comorbidity – from the Sinan-tuberculosis database and the linked database – and 314,382 individuals with TB and no diabetes – from the Sinan-tuberculosis database.

The bivariate analysis assessed 338,825 records of people with TB, from 2007 to 2011. Out of this total, 7.2% had TB and diabetes, and 92.8% had only TB. Among the cases with comorbidity, 6.8% (224,661) were male and 8.1% (108,144), female; the predominant age group was 60 years and older (17.6%); white people were the most frequent (7.5%), unlike the group with people with TB alone, which showed prevalence of other ethnicities (94.2%); and the proportion of individuals with up to four years of schooling was the highest in this

Chart 1. Hierarchical levels of the adjusted analysis: robust Poisson model.

Hierarchical levels	Variables
Level 1	Gender, age, ethnicity
Level 2	Level 1 (significant) + HIV, sputum smear microscopy – first sample, chest X-ray
Level 3	Level 2 (significant) + type of case
Level 4	Level 3 (significant) + outcome

HIV: human immunodeficiency virus.

group. In the group without comorbidity, those with more than eight years of study were more prevalent (95.3%). All analyses were statistically significant, with $p<0.001$. Alcohol consumption was the only non-statistically significant variable, with $p=0.735$ and similar proportions in each group (Table 1).

Regarding the diagnostic tests, follow-up, and treatment of TB, the comorbidity group showed positive HIV serology in 2.9% of patients and negative in 7.2%; 6.4% of cases presented negative smear microscopy of the first sputum sample, while 8.1% had a positive result; the proportion of suspicious chest X-ray was 7.6% and results were normal in 5.1% of these individuals. Regarding the type of case, 7.4% were new cases; 7.2% were relapses; and 4.0% were cases of return after treatment discontinuation. The outcome analysis included cure, treatment discontinuation, and death from TB, with proportions of 7.4, 4.1, and 10.2%, respectively. All variables were statistically significant, except supervised treatment, with $p=0.682$ (Table 2).

Table 1. Distribution of tuberculosis cases with and without diabetes, according to sociodemographic characteristics. Brazil, 2007–2011.

Characteristics* (n)		Tuberculosis and diabetes mellitus comorbidity		p (**)
		Yes	No	
		n (%)	n (%)	
Gender (338,805)	Male	15,230 (6.8)	209,431 (93.2)	<0.001
	Female	9,211 (8.1)	104,933 (91.9)	
Age group (334,281)	0–19	331 (1.1)	29,245 (98.9)	<0.001
	20–39	3,303 (2.2)	146,358 (97.8)	
	40–59	12,763 (11.5)	98,681 (88.5)	
	60+	7,671 (17.6)	35,929 (82.4)	
Ethnicity (294,473)	White	8,698 (7.5)	106,966 (92.5)	<0.001
	Black/ multiracial	12,424 (7.2)	159,717 (92.8)	
	Other	388 (5.8)	6,280 (94.2)	
Years of schooling (210,177)	≤ 4 years	1,852 (11.0)	14,917 (89.0)	<0.001
	5–8 years	13,418 (7.2)	172,301 (92.8)	
	> 8 years	362 (4.7)	7,327 (95.3)	
Alcohol consumption (333,346)	Yes	3,277 (6.5)	46,784 (93.5)	0.735
	No	18,659 (6.6)	264,626 (93.4)	

*Valid values; **Pearson's χ^2 test.

Table 3 presents the adjusted analysis through the Poisson hierarchical model with robust variance of the association between TB and diabetes comorbidity and the independent variables. The prevalence of comorbidity was higher in females (PR=1.31; 95%CI 1.27–1.35) when compared to males. The hierarchical model also showed that individuals in the 40–59 and ≥60 years age groups had the highest association with comorbidity (PR=11.70; 95%CI 10.21–13.39 and PR=17.49; 95%CI 15.26–20.05, respectively). The same occurred with those with positive smear microscopy – first sputum sample (PR=1.40; 95%CI 1.35–1.47). Moreover, individuals with suspicious chest X-ray also had a greater association with comorbidity (PR=1.22; 95%CI 1.09–1.37)

Table 2. Distribution of tuberculosis cases with and without diabetes, according to diagnostic and treatment characteristics. Brazil, 2007–2011.

Characteristics* (n)		Tuberculosis and diabetes mellitus comorbidity		p (**)
		Yes	No	
		n (%)	n (%)	
HIV (198,941)	Positive	1,086 (2.9)	36,180 (97.1)	<0.001
	Negative	11,605 (7.2)	150,070 (92.8)	
Sputum smear microscopy – 1st sample (269,718)	Negative	5,587 (6.4)	81,733 (93.6)	<0.001
	Positive	14,737 (8.1)	167,661 (91.9)	
Sputum culture (64,424)	Positive	2,634 (6.6)	36,987 (93.4)	0.055
	Negative	1,554 (6.3)	23,249 (93.7)	
Sputum smear microscopy – 6th month (92,716)	Positive	214 (9.7)	2,000 (90.3)	0.002
	Negative	7,126 (7.9)	83,376 (92.1)	
Chest X-ray (286,243)	Normal	940 (5.1)	17,557 (94.9)	<0.001
	Suspicious	20,340 (7.6)	247,406 (92.4)	
Supervised treatment (278,452)	Yes	9,512 (7.4)	118,531 (92.6)	0.682
	No	11,235 (7.5)	139,174 (92.5)	
Type of case (322,861)	New case	20,896 (7.4)	261,698 (92.6)	<0.001
	Relapse	1,513 (7.2)	19,545 (92.8)	
	Return after treatment discontinuation	775 (4.0)	18,434 (96.0)	
Outcome (279,694)	Cure	17,059 (7.4)	214,292 (92.6)	<0.001
	Treatment discontinuation	1,536 (4.1)	35,839 (95.9)	
	Death from tuberculosis	1,114 (10.2)	9,854 (89.8)	

*Valid values; **Pearson's χ^2 test; HIV: human immunodeficiency virus.

when compared to individuals with normal results. In turn, individuals who tested positive for HIV were less associated with comorbidity (PR=0.53; 95%CI 0.49–0.58). The cases of return after treatment discontinuation and treatment discontinuation were also inversely associated in people with comorbidity (PR=0.66; 95%CI 0.57–0.76 and PR=0.79; 95%CI 0.72–0.87, respectively).

Table 3. Hierarchical multivariate analysis of the association between tuberculosis and diabetes comorbidity and sociodemographic, diagnostic, and treatment characteristics in Brazil, 2007 to 2011.

Levels	Characteristics* (n)		Adjusted analysis: robust Poisson model.		
			PR	p	95%CI
Level 1	Gender (338,805)	Male	1.00	<0.001	1.27–1.35
		Female	1.31		
	Age group (334,281)	0–19	1.00		
		20–39	2.15	<0.001	1.86–2.47
		40–59	11.70	<0.001	10.21–13.39
		60+	17.49	<0.001	15.26–20.05
	Ethnicity (294,473)	White	1.00		
		Black/ multiracial	1.04	0.030	1.00–1.07
		Other	0.84	0.005	0.75–0.95
Level 2	HIV (198,941)	Negative	1.00		
		Positive	0.53	<0.001	0.49–0.58
	Sputum smear microscopy – 1st sample (269,718)	Negative	1.00		
		Positive	1.40	<0.001	1.35–1.47
	Chest X-ray (286,243)	Normal	1.00		
		Suspicious	1.22	0.001	1.09–1.37
Level 3	Type of case (322,861)	New case	1.00		
		Relapse	0.87	<0.001	0.80–0.94
		Return after treatment discontinuation	0.66	<0.001	0.57–0.76
Level 4	Outcome (279,694)	Cure	1.00		
		Treatment discontinuation	0.79	<0.001	0.72–0.87
		Death from tuberculosis	0.95	0.426	0.84–1.08

*Valid values; HIV: human immunodeficiency virus; 95%CI: 95% confidence interval.

DISCUSSION

Diabetes is one of the main factors that hinder the reduction in the incidence of TB worldwide. As the prevalence of diabetes is increasing globally, particularly in low- and middle-income countries where TB is a public health problem, this growth creates additional obstacles for TB prevention and control[15,16].

Regardless of the region where the studies were conducted, people with diabetes show an increased risk of developing TB. A study in India suggested that 14.8% of TB cases may be attributable to diabetes[17]. In 1991, an investigation conducted in the United States revealed that the risk of TB associated with DM among middle-aged Hispanics was 25.2%[4]. Among the TB cases reported to Sinan in 2009, Reis-Santos et al. found a prevalence of diabetes of 5.4%, below the findings of this study (7.2%) for the period[18]. In another study in Texas, on the border with Mexico, people with diabetes were almost twice as likely to have TB as those who did not have diabetes[19].

Contrary to other findings that showed no difference in frequencies between genders when comparing groups with and without comorbidity or pointed to a higher proportion of males among those with comorbidity[20-22], this study showed a predominance of females, probably due to the greater percentage of women notifying the diagnosis of diabetes to Basic Health Units of SUS and seeking health services more frequently than men. Vigitel 2014 presented similar results regarding the percentage of women who reported diabetes[10,23,24].

In India, Indonesia, Malaysia, Saudi Arabia, Taiwan, and Mexico, studies have shown the predominance of comorbidity with advancing age. This study revealed a similar result, possibly because of the association between type 2 DM and older age[21,22,25-30].

After analyzing the schooling among people with comorbidity, this study identified that individuals with up to four years of schooling were more prevalent. In the group without comorbidity, the proportion of people with more than eight years of study was higher. Still in the group with comorbidity, white people were more prevalent, similarly to findings from the study by Reis-Santos[18].

Concerning radiological examinations, some studies found no differences in X-ray patterns suspicious for pulmonary tuberculosis among people with and without diabetes[31,32], unlike the results from other investigations that showed atypical radiographic characteristics in individuals with comorbidity[8,33-35]. In this study, individuals with suspicious chest X-ray results had a greater association with comorbidity when compared to individuals who presented normal results.

Probably due to the larger number of tests performed in individuals with comorbidity, the present study revealed that this group had a higher incidence of positive smear microscopy of the first sputum sample, corroborating other findings[18,26,31,36-38]. In addition, DM may negatively affect the outcome of TB treatment[22,33,39,40].

With respect to TB relapse in people with diabetes, the findings have varied. Some studies have reported increased relapse in individuals with diabetes[39,40], while others claimed that there was no difference[21,41,42]. This study identified that the group with TB and diabetes had a lower prevalence of relapse.

Similar to the findings from the study by Reis-Santos[18] in 2009, this investigation revealed that individuals with comorbidity were less likely to return after discontinuing TB treatment, possibly because the probability of treatment discontinuation is lower in this group, which could be associated with the fact that people with diabetes have a closer relationship with Basic Health Units. In the 2000s, the Reorganization Plan for Hypertension and Diabetes Mellitus Care, from the Ministry of Health, proposed training the professionals from the primary care system, with guaranteed diagnosis and actions to expand the adherence to treatment and follow-up in health units among people with diabetes[43,44].

Considering that filling the field *disease associated with tuberculosis* is not mandatory in the Sinan form, the large percentage of blank records can be cited as a limitation of this study, resulting in an increase in underreporting of TB and diabetes comorbidity, as well as the inadequate treatment of the population. We emphasize that registering this field is extremely important, as diabetes and TB comorbidity has been growing, and clinical practices and the monitoring of cases are becoming more necessary every day. Other limitations include the non-completeness of variables used for the association, the use of secondary data, and, consequently, the possibility of underreporting of diabetes cases notified to Sinan-tuberculosis in the studied period – which may have been mitigated after the database linkage –, as well as the high number of smear microscopy of the first sputum sample, sputum culture, and chest X-ray not performed or not recorded. In addition, some TB cases had no outcome data, and some diabetes cases might not have been notified to Hiperdia. Thus, we cannot guarantee that the population with both diseases is represented in the database compiled.

Also, database linkage, as an applied method, does not replace primary data collection and may limit the analysis.

CONCLUSION

Although much has been done, investing in studies and adopting actions to prevent TB and diabetes comorbidity are still necessary, including health promotion activities, active search for cases, treatment and prevention, better monitoring of sick people, and, consequently, greater success in the therapy administered.

This study provided an epidemiological profile of reported cases of TB, as well as TB and diabetes comorbidity, describing the association between the main indicators of interest and reinforcing the importance of integrated care actions in health services to avoid future cases and change the scenario of this challenging comorbidity.

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