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3 **Epidemiological and functional profile of patients diagnosed with multiple sclerosis in**
4 **Manaus, Amazonas**
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6 *Perfil epidemiológico e funcional de pacientes com diagnóstico de esclerose múltipla em*
7 *Manaus, Amazonas*
8

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24 **ABSTRACT**
25 Multiple sclerosis (MS) is an immune-mediated, inflammatory disease characterized by repeated
26 episodes of demyelization. **Objective:** The present study aimed to trace the epidemiological
27 and functional profile of patients with Multiple Sclerosis treated at a Reference Hospital in
28 Manaus-AM. **Method:** 80 charts were selected for screening and subsequent application of the
29 Functional Independence Measure (MIF) scale. **Results:** 32 patients were included in the study,
30 23 females (74%), whose mean age was 35 (± 12) years, with a relationship between females
31 and males of 2.5. The mean diagnostic time for men was 7.8 years and for women of 5.3 years.
32 The mean score on the Total MIF scale was 110.9 (± 17.5). **Conclusion:** Epidemiological
33 characteristics are in line with most similar studies, but lack further studies aimed at assessing
34 the functionality of individuals with MS.
35

36 **Keywords:** Multiple Sclerosis, Medical Records, Epidemiologic Studies
37

38 **RESUMO**
39 A esclerose múltipla (EM) é uma doença imuno-mediada, inflamatória, caracterizada por
40 repetidos episódios de desmielinização. **Objetivo:** Traçar o perfil epidemiológico e funcional
41 dos pacientes com Esclerose Múltipla atendidos em um Hospital de Referência de Manaus-AM.
42 **Método:** Foram selecionados 80 prontuários para triagem e posterior aplicação da escala de
43 Medida de Independência Funcional (MIF). **Resultado:** Foram incluídos no estudo 32
44 pacientes, 23 do sexo feminino (74%) cuja média de idade era de 35 (± 12) anos verificando
45 uma relação entre mulheres e homens de 2.5. O tempo de diagnóstico médio para os homens
46 foi de 7.8 anos e para as mulheres de 5,3 anos. A média do escore na escala de MIF Total foi

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47 de 110,9 (± 17,5). **Conclusão:** As características epidemiológicas estão em consonância com
48 a maioria dos estudos semelhantes, mas carecem de mais estudos voltados para a avaliação
49 da funcionalidade de indivíduos com EM.
50
51 **Palavras-chave:** Esclerose Múltipla, Registros Médicos, Estudos Epidemiológicos
52
53 **INTRODUCTION**
54
55 Multiple sclerosis (MS) is an autoimmune, inflammatory, demyelinating and chronic disease that
56 affects the central nervous system (CNS; It is more common in young adults and has an
57 unknown etiology. Given the differences in prevalence rates among populations, the most
58 accepted pathogenic hypothesis presumes that the development of MS is influenced by an
59 interaction among factors related to genetics, infectious agents, and environment.[1-4] The illness
60 is characterized by demyelination episodes that lead to multiform clinical manifestations, which
61 may be disabling, and functional deficits resulting from damage to parts of the neuraxis.[5,6]
62
63 The incidence and prevalence of MS vary considerably around the world, presenting a
64 significant relationship with ethnicity and geographical area.[7,8] More recent studies have
65 suggested that there are several regions in Brazil and Latin America where there are mixed-
66 race populations (European, African and Indian) that have developed over many generations.
67
68 As a consequence, these areas show peculiar population-shaping characteristics and important
69 ethnic differences, which lead to distinct regional prevalence's of MS. A recent review defined
70 five regional prevalence levels according to the number of affected people per 100,000
71 inhabitants: very low for 0 to 13; low for 13 to 38; intermediate for 38 to 70; high for 70 to 170;
72 and very high for 170 to 35.[09,10]
73
74 In Brazil, the highest prevalence's are reported in the South and Southeast regions, which
75 suggests the existence of a South – North gradient. Even with this difference, the country is
76 considered to have low prevalence of MS, with an average number of 15 affected people per
77 100,000 inhabitants.[11,12]
78
79 Because of diversity of symptoms and physiopathological processes, MS can vary in
80 itssymptomatic presentation and follow an unpredictable, complex and heterogeneous clinical
81 evolution.[13,14]
82
83 Based on the decision of experts from the National Multiple Sclerosis Society in 1999, and
84 according to clinical criteria characterized by progression or outbreak occurrence, the disease
85 can be classified into several forms: relapsing-remitting (RRMS), primary progressive (PPMS),
86 secondary progressive (SPMS) and progressive-relapsing (PRMS), as well as being categorized
87 as benign or malignant.[15] RRMS is the most common, and is characterized by clearly defined
88 exacerbations, with complete recovery or permanent consequences and residual deficits. The
89 other three types – PPMS, SPMS and PRMS – are marked by periods of progression of the
90 disease.[16-18]
91
92 It is known that, after an injury to the CNS, many symptoms may imply the development of long-
93 term consequences that can compromise the independent execution of functional activities;
94 however, patients with the same disease and similar impairments may show different
95 disabilities.[19] The number of outbreaks, the time of evolution of the disease, the type of
96 pyramidal impairments, and the presence of cerebellar or motor manifestations in the beginning
97 of the condition are the main factors related to functional incapacity. [20] Because of the variety of

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98   symptoms in MS, several assessment scales have been created to evaluate those who are
99   affected. Kurtzke's Expanded Disability Status Scale (EDSS) is the one that is best known and
100 most used in clinical trials on MS, although the literature indicates that there are some limitations
101 to this tool that require it to be complemented by the addition of functional scales.[21,22]
102
103 Rehabilitation programs currently use the Functional Independence Measure (FIM) as a source
104 of information in order to determine limitations, plan the best therapeutic approaches, and follow
105 patients' evolution.[23,24] The FIM is one of the most common scales used to determine functional
106 level in neurological patients. It has been applied to different diseases of the nervous system
107 and in many age groups, and has been shown to be valid, sensitive and reliable.
108
109 **OBJECTIVE**
110
111 The aim of the present study was to describe the epidemiological and functional profile of
112 patients diagnosed with MS who were admitted to the Demyelinating Diseases Service of
113 Getúlio Vargas University Hospital, in Manaus, Amazonas.[14]
114
115 **METHODS**
116
117 This was a retrospective, cross-sectional and descriptive prospective study carried out with
118 patients previously diagnosed with MS, utilizing data collected at the Demyelinating Diseases
119 Service at Getúlio Vargas University Hospital, in Manaus, Amazonas.
120
121 The participants were informed of the objectives and procedures of the study, and signed free
122 and informed consent forms. This study was approved by the Research Ethics Committee of
123 Federal University of Amazonas, under approval certificate CAE 61619716.8.0000.5020, and
124 approval report 1.815.182.
125
126 Data collection occurred in two stages, without restrictions as for age, site or extent of the lesion,
127 origin and gender, and with participants who met the following inclusion criteria: having a definite
128 diagnosis of MS, being within reach to be found and contacted, and being able to answer the
129 FIM questionnaire.
130
131 The first stage consisted of analyzing reports on patients admitted and diagnosed with MS
132 between January 2010 and December 2015, with no restrictions regarding age, origin, gender,
133 location or extension of the injury. In the second stage, this information was entered into forms
134 with patients' personal and clinical data.
135
136 Patients were then identified, located, and contacted by phone in order to apply a functional
137 assessment. The tool used to evaluate the disability of patients with restrictions was the
138 Functional Independence Measure. The patients had to be able to answer simple questions or
139 be accompanied by an acquaintance during the application of the questionnaire.
140
141 Eighty medical records from patients identified during the first stage were analyzed; 48 were
142 discarded, 20 because they did not have a definitive MS diagnosis and 28 because it was not
143 possible to locate them to apply the FIM. Consequently, the sample for the study consisted of
144 32 patients who met the inclusion criteria.
145
146 The functional profile analysis was carried out by the FIM, which is a self-administered
147 instrument to evaluate performance of motor and cognitive/social skills, and the assistance
148 needed to carry out activities. The FIM includes 18 categories, each of which receives a score

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149 related to level of dependence: a score of 1 indicates total dependence and a score of 7 indicates
150 total independence. The total score ranges from 18 to 126, and the lower the score, the more
151 dependent the patient. The categories are grouped into six dimensions: 1) self-care (feeding,
152 personal hygiene, bathing, dress upper half, dress lower half, use of the toilet); 2) sphincter
153 control (control of urination and defecation); 3) transfers (bed, chair, wheelchair, toilet, bathroom,
154 shower); 4) locomotion (gaits, wheelchair, stairs); 5) communication (understanding,
155 expression); and 6) social cognition (social interaction, problem solving, memory).[24]
156
157 In the present study, only the total FIM score and the mobility (minimum of 3 and maximum of
158 21) and locomotion (minimum of 2 and maximum of 14) domains were assessed. An individual
159 with no deficiencies reaches a score of 126, and a person showing total dependence gets a
160 score of 18.[25,26]
161
162 The data was expressed as average ± standard deviation. Initially, the Shapiro-Wilk normality
163 test was used. The Student's unpaired t-test was applied to analyze the difference between the
164 normal means. The difference between several means was assessed through analysis of
165 variance (ANOVA) and a post hoc Bonferroni test. The significance level was set at $p<0.05$.
166
167 **RESULTS**
168
169 Among the 32 patients included in the study, 29 were from Manaus and 3 lived in the countryside
170 of the state of Amazonas. Twenty-three (74%) were females, with an average age of 35 ± 12
171 years, and 9 (26%) were males, with an average age of 35 ± 11 years, a proportion of 2.5 women
172 for each man.
173
174 The patients' ages varied from 12 to 60 years old; 46.8% were between 31 and 40 years old.
175 The average time since diagnosis was 7.8 years for men and 5.3 years for women. The patients'
176 characteristics, shown in Table 1, did not present statistically significant differences; however,
177 women were predominant in the sample.
178
179 **Table 1.** Epidemiological characteristics of patients diagnosed with MS at the Demyelinating
180 Diseases Service in Manaus, Amazonas, Brazil, between January 2010 and December 2015
181

Variables	N=32	
	Men (n = 09)	Women (n = 23)
Proportion (%)	26%	74%
Age group (years ±SD)	35 ± 11	35 ± 12
Time since diagnosis (years)	7.8	5.3

182 *SD = standard deviation*
183
184 Table 2 exhibits comparative data with the average total FIM, mobility and locomotion scores
185 and their standard deviation for gender, age group and time since diagnosis. Women presented
186 higher average scores, and these values were statistically significant ($p = 0.03$) for both the total
187 FIM score (115 ± 7) and the mobility score (20 ± 1). This showed that women had lower
188 functional dependence when compared to men, whose average total FIM score was 100 ± 29,
189 with a score of 17 ± 6 in the mobility domain.
190
191 **Table 2.** Mean values for scores on the FIM. Total score and scores for mobility and locomotion
192 domains for patients diagnosed with MS at the Demyelinating Diseases Service in Manaus,
193 Amazonas, Brazil, between January 2010 and December 2015
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Variables	FIM	FIM	FIM
	Score +SD		
Sample (n=32)	110.9 ± 17.5		
Gender			
Female (n=23)	115 ± 7*	20 ± 1*	13 ± 1
Male (n=9)	100 ± 29	17 ± 6	11 ± 4
Age group (years)			
Less than 30(n =09)	110 ± 17	19 ± 2	13 ± 2
31 to 40 (n= 15)	115 ± 7	20 ± 0.7	13 ± 0.8
More than 40 (n= 08)	103 ± 28	18 ± 6	11 ± 4
Time since diagnosis (years)			
1 to 4 (n = 11)	115 ± 8	20 ± 0.9	13 ± 1
5 to 9 (n = 16)	112 ± 12	20 ± 2	13 ± 1
10 or more (n = 05)	94 ± 33	16 ± 7	10 ± 5

195 *p=0.03; SD = standard deviation
196
197 Regarding the functional profile of the sample, the comparison of average total FIM scores
198 among the variables revealed that most of these patients got scores near the maximum value
199 (126 points); it was observed that these people had the capacity to perform their activities and
200 needed little assistance. There was no statistical significance for age group and time since
201 diagnosis among the patients in any of the three FIM categories, but the lowest average values
202 were found for patients aged more than 40 years old with a time since diagnosis of 10 years or
203 more. This result points to the hypothesis that older patients with more time since diagnosis
204 present a functionally more dependent profile when compared to people who do not present
205 these characteristics.
206
207 **DISCUSSION**
208
209 In the North region of Brazil, including the city of Manaus, there are few studies focused on the
210 clinical and epidemiological aspects of MS, let alone its prevalence and incidence. The present
211 study provides information at one point in time for a specialized public service in Manaus that is
212 considered a reference center for demyelinating diseases. As such, it provides a situational
213 diagnosis of the epidemiology and functionality of people with MS.
214
215 Analysis of the epidemiological data shows a predominance of MS cases in females (74%). This
216 is in accordance with an experiment carried out in Uberaba, Minas Gerais by Ribeiro et al.[27] who
217 observed a predominance of women (71.4%) in a sample similar in number (35 patients) to the
218 one described in the present paper (35 patients). Ferreira et al.[12] Negreiros et al.[28] and Cardoso
219 et al.[6] also obtained comparable results regarding gender predominance in cities in
220 Pernambuco, Paraíba and São Paulo, respectively, confirming a higher propensity of women
221 for developing MS. As for average age, the findings of the present study were consistent with
222 most of the literature for both genders, corroborating the fact that MS affects mainly young
223 adults.
224
225 Several instruments have been used to assess functional skills in patients with MS. Most studies
226 describe the use of Kurtzke's Expanded Disability Status Scale (EDSS); however, because of
227 its limitations, researchers tend to complement it with other functional scales.[21,22] In the present
228 study, the authors opted for the FIM instrument, which was developed as an assessment tool
229 that can be used to measure the current functional level of patients. The drawback of its use is
230 the difficulty of comparing its results with the findings of other studies.

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To evaluate the functionality of patients, cutoff values for analysis of the total FIM scores were based on those used by Riberto et al.[24] The following score intervals were chosen: 18, complete dependence (total assistance); 19 – 60, modified dependence (assistance of up to 50% in an activity); 61 – 103, modified dependence (assistance of up to 25% in an activity); 104 – 126, complete/modified independence. Hence, the lower the score, the higher the level of dependence.

The average total FIM score of 110.9 ± 17.5 showed a population characterized by complete/modified independence. Gender analysis, however, showed that female patients were mainly responsible for this result, with an average score of 115 ± 7; the male patients obtained an average score of 100 ± 29, which puts them at the level of modified dependence, needing up to 25% of assistance to complete an activity. According to a study by Tremlett et al.[17] in which the female participants showed a 30% lower risk of obtaining low scores in the EDSS scale, even although MS is more frequent in females, the worst prognoses of long-term incapacity were made for affected men. Nevertheless, this conclusion still needs deeper analysis, and new investigations focused on the functional state of patients need to be carried out.[14,23,24]

Regarding age group, patients more than 40 years old and with a time since diagnosis of more than ten years were categorized as requiring modified dependence and assistance of 25%, unlike younger patients, who showed complete/modified independence, as well as those diagnosed between 1 and 4 years ago. This finding suggests that age and time since diagnosis may interfere with clinical progression for these patients, particularly level of dependence. However, in order to confirm this hypothesis, other clinical factors of the disease need to be investigated.

A systematic review by Vasconcelos et al.[29] shows that there are prognostic aspects associated with demographic and clinical characteristics directly related to the progression of MS, and consequently, to functional performance, that are not limited to the data collected in the present study. The prognostic factors that are more commonly addressed and associated with clinical progression are, in addition to gender: the outbreak frequency in the first years of the disease; the residual deficit after the initial outbreak; the time interval between the first two outbreaks; and ethnicity.

This set of information is paramount for accurately characterizing samples, given that MS is an illness with fluctuating clinical features and has stability phases that determine the impairment of patients' capacities. This applies to recent research about MS in Brazil: Several studies have described the sociodemographic and epidemiological characteristics of patients with MS, but lack assessment of their functionality in addition to their clinical condition. That is why the analyses in the present study are based more on clinical reasoning in comparison with other research.

As for clinical and demographic information, the present study revealed a few limitations during data collection. Nonetheless, it is hoped that it will contribute to unveiling the reality of MS in Manaus, Amazonas and the North region, so that the disease can be better mapped through incidence and prevalence studies in the near future. Also, since the study is based on data from a single public service, it does not reflect the situation of the state or the region. However, the objective of the present investigation was to describe the epidemiological and functional features of patients with MS from Manaus, where there is a center of reference for the treatment of this condition that admits patients from the entire state.

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281 Hence, it is hoped that the study will encourage researchers to carry out more epidemiological
282 and clinical studies on MS that allow assessment of the functional state of patients in other
283 regions of the country, especially in states in the region, an area that lacks investigation of this
284 topic.
285

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