



Validation of a Simple Instrument of Fast Application to Track Disability in Leprosy Patients

Validação de um instrumento simples e de aplicação rápida para rastrear incapacidade em pacientes com hanseníase

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Abstract

Objective To evaluate a simple and fast diagnostic instrument to be used by any health professional to track the disability presented by leprosy patients.

Method Validation study of a diagnostic test performed in a sample of 156 leprosy patients to track functional disability through the shortened disabilities of arm, shoulder, and hand (QuickDASH) questionnaire. The simplified neurological assessment proposed by the World Health Organization was used as a reference. A receiver operating characteristic (ROC) curve was constructed to determine the cutoff point of QuickDASH that best discriminated patients with functional disability caused by leprosy.

Results We identified 86 (55.5%) patients with functional disability by simplified neurological evaluation. The performance of the QuickDASH instrument showed that, at a cut-off point of 30 points, the sensitivity and specificity were 72.1% and 68.1% (accuracy of 70.3%), respectively, to identify functional disability, with a positive predictive value of 73.8%.

Conclusion The QuickDASH instrument showed good accuracy to track functional disability in leprosy patients, and it may be useful in clinical practice of primary and general outpatient care, with the goal of identifying patients who need specialized reference for the prevention and treatment of this condition.

Keywords

- ▶ leprosy
- ▶ biomedical technology
- ▶ disability evaluation

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Resumo

Objetivo Avaliar um instrumento diagnóstico simples e rápido a ser utilizado por qualquer profissional da saúde para rastrear a incapacidade apresentada por pacientes com hanseníase.

Método Estudo de validação de teste de diagnóstico realizado em uma amostra de 156 pacientes com hanseníase para rastrear incapacidade funcional, por meio do questionário abreviado *disabilities of arm, shoulder, and hand* (QuickDASH). A avaliação neurológica simplificada proposta pela Organização Mundial da Saúde foi utilizada como referência. Construiu-se a curva de características operacionais do receptor (ROC) para determinação do ponto de corte do QuickDASH que melhor discriminou pacientes com incapacidade funcional provocada pela hanseníase.

Resultados Foram identificados 86 (55,5%) pacientes com incapacidade funcional pela avaliação neurológica simplificada. O desempenho do QuickDASH mostrou que, em ponto de corte de 30 pontos, a sensibilidade e a especificidade foram de 72,1% e 68,1% (acurácia de 70,3%), respectivamente, para identificar incapacidade funcional, com um valor preditivo positivo de 73,8%.

Palavras-chave

- ▶ hanseníase
- ▶ tecnologia biomédica
- ▶ avaliação da deficiência

Conclusão O instrumento QuickDASH mostrou boa acurácia para rastrear incapacidade funcional no paciente com hanseníase, podendo ser útil na prática clínica da atenção básica e ambulatorial geral, com o objetivo de identificar pacientes que necessitam de referência especializada para sua prevenção e tratamento.

Introduction

Leprosy is a chronic infectious disease of compulsory notification, caused by *Mycobacterium leprae* and characterized by peripheral neuropathy. In its evolution, especially in patients not adequately treated, leprosy can evolve with different skin and neural lesions, which can result in mutilations and different degrees of functional disability.¹ The Hansen bacillus presents tropism by the peripheral nerve, mainly by Schwann cell. The degeneration of nerve fibers, leading to a mixed neuropathy, which compromises sensory, motor, and autonomic nerve fibers. Neuropathic pain and neural thickening are consequent clinical manifestations, occurring in 45.8% of patients.²

If not addressed properly, neuromotor dysfunction will result in functional deficit in one or more segments of the body, known as leprosy-induced disabilities. Timely diagnosis and treatment are important actions for the prevention of disabilities. It is important to highlight that frequent anesthetic skin lesions are absent in the pure neuritic form of the disease, which can also lead to disability due to dysfunction of some nerve, which can occur in up to 60% of cases with neural impairment.²

The proportion of new leprosy cases diagnosed with grade 2 disability is an important indicator for assessing late diagnosis of the disease.³ In 2015, of 14,000 new cases of the disease diagnosed worldwide, 12% already had a grade 2 disability. Brazil was the country that contributed the most to this proportion.⁴ This disability is identified by simplified neurological evaluation (SNE), considered as a reference for its diagnosis.⁵⁻⁷ Simplified neurological evaluation is classified as grade 0 (zero), when there is no evidence of neural

involvement in the eyes, hands, or feet; grade 1 if there is decreased or loss of sensitivity in any segment of the body; and grade 2 when there is presence of lagofalmo, disabilities and deformities, claws, bone resorption, loss of hands and/or feet, loss of vision, among others.⁸

For decades, public policies for the diagnosis of leprosy have focused on the search for dermatological signs rather than neurological symptoms.⁹ The identification of peripheral nerve disorder is important to guide the regular practice of self-care and relevant intervention.¹⁰ Although it is apparently simple to investigate, SNE requires great skill from the professional for its execution. The complete examination recommended by World Health Organization (WHO) requires time and patience from the examiner and the patient, in addition to the ability to perform the proposed techniques. Lack of this ability may result in a delay in the diagnosis of disability.¹¹ This justifies the need for simple, easy-to-apply resources that do not require a high degree of experience to track patients at an early stage of functional disability.

The disabilities of arm, shoulder, and hand (DASH) is an instrument that assesses both symptoms and upper limb function from the patient's perspective. It is a questionnaire that assesses the upper limb as a functional unit of the individual, regardless of the pathology or even its location.¹² It can also point to dysfunction of other organic segments or systems, whose positive predictive value reached 75%.¹³ Through 30 questions, the DASH instrument assesses the degree of difficulty in performing different physical activities using the the upper limbs, including activity-related pain, tingling, weakness, stiffness, and the impact of this difficulty on social activities, work, sleep, and self-image.¹³⁻¹⁵ Due to

the DASH questionnaire being extensive, another instrument was later proposed, being simpler and more widely applied. This new questionnaire, called QuickDASH, has already been translated and validated for Portuguese, and it is considered reliable when used in patients with traumatic and non-traumatic diseases.¹⁶ The instrument consists of 11 questions with 5 answer options scored on a Likert scale (**Box 1**).¹⁷ If at least 10 of the 11 items are answered, the points are added up to form a raw score and then converted to a range from 0 to 100 points. To do this, subtract a point from the sum of the answers and multiply the result by 25.^{17,18} The higher the score, the higher the functional deficiency.

Considering the need to identify the functional disability caused by leprosy early, as well as the lack of simple resources for its diagnosis, the present study aimed to validate the QuickDASH questionnaire as a tool to be used by any health professional to screen for functional disability presented by leprosy patients.

Materials and Method

This is a validation study of a diagnostic test conducted in a sample of 156 leprosy patients, treated or under treatment, and in clinical follow-up at the infectious diseases outpatient clinic of Hospital Universitário Júlio Müller (HJUM), located in Cuiabá, MT. It is a reference service for the diagnosis and treatment of leprosy in the state of Mato Grosso. The sample was convenient, with sequential intake of patients and with adequate size to represent the target population.¹⁹

Only patients over 18 years of age and who agreed to participate in the study were included after signing a free and informed consent form. Patients previously submitted to neurotic or other orthopedic alteration due to leprosy were not included. The initial clinical evaluation was per-

formed by two examiners (authors B. P. A. and M. M. F.), independently. Patients with agreement in these two clinical evaluations were included in the analysis. Then, a SNE was conducted, and the QuickDASH instrument was applied, originally proposed to be self-answered, but, in this study, it was applied in the form of an interview, due to low schooling of the patients.

The data were tabulated and described in their absolute and relative frequencies or in their statistical summaries in the Stata version 12.0 software (StataCorp, College Station, TX, USA). Using as reference the results of the SNE (gold standard) and establishing as 0 the absence and 1 the presence of some degree of functional disability identified in the patient, sensitivity, specificity, predictive values, and accuracy of the QuickDASH for the diagnosis of functional disability were determined. In addition, to evaluate the discriminating power of the QuickDASH instrument for groups with and without functional disability due to leprosy, a receiver operating characteristic (ROC) curve was represented graphically.

The validity of a diagnostic resource is the ability of a test to discriminate between the presence and absence of the target condition, and it can be quantified by means of diagnostic accuracy measures, such as sensitivity, specificity, predictive values, and accuracy. For quantitative measurement resources, the analysis of the ROC curve represents the most appropriate tool for the establishment of these parameters.²⁰

The ROC analysis is a technique that assesses the ability of a diagnostic test to discriminate between patients who have and those who do not have a particular disease. The ROC curve is made by tracing the false positive rate on the "x" axis with the true positive rate on the "y" axis to a set of threshold values. The discriminatory capacity of a test can be calculated by the area under the ROC curve (AUC). An AUC of 1.0 indicates perfect discrimination, while an AUC of 0.50

Box 1 Items evaluated in the Quick-DASH instrument for the assessment of functional disability in patients with leprosy

Degree of difficulty in the performance	None	Little	Some	A lot	Incapable
1. To open a new or tightly closed bottle	1	2	3	4	5
2. To do heavy household chores (wash the floor)	1	2	3	4	5
3. to carry a shopping bag or a briefcase	1	2	3	4	5
4. To wash one's own back	1	2	3	4	5
5. To use a knife to cut food	1	2	3	4	5
6. To perform an activity that requires force (hammer, sickle, hoe)	1	2	3	4	5
Interference in everyday life	None	Little	Some	A lot	Total
7. To what extent have the above problems interfered with your social relationship with family, neighbors, friends, and others	1	2	3	4	5
8. To what extent have the above problems interfered with your ability to work or other tasks	1	2	3	4	5
Severity of symptoms in the last week	None	Little	Some	A lot	Extreme
9. Pain in the arm, shoulder, or hand	1	2	3	4	5
10. Numbness (tingling) in the arm, shoulder, or hand	1	2	3	4	5
11. Difficulty sleeping because of this pain	1	2	3	4	5

Adapted from Santos & Gonçalves, 2005.^{21,22}

represents no discriminatory power of the test. In clinical practice, an AUC ≥ 0.75 is generally considered clinically useful as a diagnostic resource.¹³

After AUC determination, a QuickDASH cut-off point was identified by the Liu²¹ method (2012), from which it is possible to diagnose, with satisfactory accuracy, the true positive and negative scans for functional disability caused by leprosy. This method identifies the value that produces the highest sensitivity and specificity values, along with the lowest probability of random occurrence.²¹

The present study was approved by the Ethics and Research Committee of Hospital Universitário Júlio Müller, under case number: 12777719.5.0000.5541.

Results

We studied 156 patients at different stages of clinical follow-up of leprosy, 82 (52.6%) males and 74 (47.4%) females. Their ages ranged from 18 to 86 years, with a mean (SD) of 49.6 (12.7) years and a higher frequency of patients between 40 and 60 years. Patients from urban areas (82.6%), with manual or domestic occupation (60.0%), with family income lower than 2 minimum wages (65.9%), and with low schooling (64.7%) (► **Table 1**) predominated.

The patients in the study were mostly classified as multi-bacillary (81.9%), 92 (59.0%) of them currently being treated with multidrug treatment (MDT). Thirty (19.2%) patients were receiving MDT for the second time (► **Table 1**).

It was observed that 86 (55.5%) patients presented some functional deficit by SNE, representing 140 dysfunctional manifestations, which were due to visual alterations in 31 patients, upper limbs in 49 patients, and lower limbs in 60 patients, which resulted in a final disability classification of 0, 1, and 2 for 70 (44.9%), 46 (29.5%), and 40 (25.6%) patients, respectively (► **Table 2**).

The score obtained from patients after the application of the QuickDASH instrument ranged from 0 to 81.8, with mean (SD) of 35.2 (24.1) points, median of 29.5 points. About 1/3 of the patients (30.8%) had a score ≥ 50 points and a 1/4 (25%) of them had a score ≥ 54.5 (► **Table 3**).

The ROC curve created according to the QuickDASH score for discrimination of patients with and without functional deficit shows that the AUC of 0.76 represents the accuracy (76.0%) of this instrument for the diagnosis of functional disability caused by leprosy (► **Fig. 1**). By Liu's method²¹ (2012), the QuickDASH cutoff was estimated at 32.2 points, whose sensitivity and specificity were 66% and 75%, respectively, with accuracy of 71%. However, the analysis of the validity of different levels of the QuickDASH score showed that the cutoff of 30 points resulted in a better balance between sensitivity (72.1%) and specificity (68.1%), with accuracy of 70.3%, as well as positive and negative predictive values of 73.8% and 66.2%, respectively (► **Table 3**).

Discussion

In the present study, it was possible to demonstrate that the QuickDASH instrument was sensitive, specific, and accurate

Table 1 Demographic and clinical characteristics of patients

Feature		n	%
Age group (years)	18–30	11	7.0
	31–40	30	19.2
	41–50	33	21.2
	51–60	50	32.1
	> 60	32	20.5
Sex	Male	82	52.6
	Female	74	47.4
Occupation	Administrative	22	14.2
	Heavy work	62	40.0
	Housework	31	20.0
	Trade	26	16.8
	Health	14	9.0
Residence area	Rural	27	17.4
	Urban	129	82.6
Family income (minimum wage)	< 1	22	14.1
	1–2	84	53.8
	2–3	19	12.2
	≥ 3	31	19.9
Schooling (years)	0–8	79	50.6
	8–9	22	14.1
	9–12	33	21.2
	≥ 12	22	14.1
Operational classification (n = 155)*	Multibacilar	127	81.9
	Paucibacilar	28	18.1
Polychemotherapy	Current	92	59.0
	Previous	64	41.0
Retratamento	Yes	30	19.2
	No	126	80.8

*A patient without operational classification.

Table 2 Distribution of functional disabilities found in 86 leprosy patients, according to type and classification in the simplified neurological evaluation

Inability		n	%
Type*	Any deficit	86	55.5
	Visual	31	19.9
	Upper limbs	49	31.4
	Lower limbs	60	38.5
Degree of disability	0	70	44.9
	1	46	29.5
	2	40	25.6

*Some patients had multiple disabilities.

Table 3 Results of functional deficit assessment of leprosy patients by applying the Quick-DASH instrument

Cutoff point	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)	Accuracy (%)
15.0	87.2	42.0	65.2	72.5	67.1
20.0	84.9	46.4	66.4	71.1	67.7
25.0	77.9	58.0	69.8	67.8	69.0
30.0	72.1	68.1	73.8	66.2	70.3
35.0	66.3	75.4	77.0	64.2	70.3
40.0	59.3	79.7	78.5	61.1	68.4
45.0	57.0	82.6	80.6	60.6	68.4

Quick-DASH values: mean = 35.2; standard deviation = 24.1; median = 29.5; Cutoff point by the Liu method: 32.2 points (sensitivity = 66%, specificity = 75%, accuracy = 71%).

to track patients suspected of functional disability. It is a diagnostic resource of simple and fast application, already validated in portuguese for the diagnosis of functional deficit consequent to several other injuries and without any additional cost for its application. In addition, the positive predictive value of a score higher than 30 in the QuickDASH instrument was also high, to indicate those patients most in need of referral to a higher level of complexity. This finding demonstrates that the QuickDASH instrument, which can be applied by any health professional, may contribute to a timelier identification of leprosy functional disabilities.

The frequency of patients who presented any type of functional deficit by the SNE (55.5%), whether visual, upper, or lower limb, was high. This finding can be justified by its performance having taken place in a reference center, where more complex cases are referred to, and the sample includes individuals already treated and in retreatment (19.2%). However, it is important to consider that, every year, around 47,000 new leprosy cases are recorded in Brazil, of which 23.3% have disability grades I and II and may reach up to 70% on the date of diagnosis.²³

It was found that most patients in the study had socio-demographic characteristics common to the general population of leprosy patients. The most frequent ones being

onset in adulthood, proportional balance between genders, occupations that require physical exertion, residing in urban areas, low schooling, and precarious family income. This sociodemographic profile has already been observed by several authors, even in population-based studies.²⁴

Early diagnosis is essential to prevent functional disability and to decrease the chain of transmission of the disease. It can be inferred that the frequency of functional disability caused by leprosy at the time of its diagnosis is a marker of the quality of health care work. Initial treatments of the disease for patients with grade-2 disability mean delay in diagnosis and inefficiency of screening made by the services. Some factors are widely known as causes of this delay, such as late patient demand, difficulty in accessing health services, and lack of specific training by health professionals. On the latter, it is known that the quality of leprosy control actions performed by health professionals produces effects in all indicator's disease monitoring.²⁵ Therefore, the importance of permanent training of professionals who care for leprosy patients is unquestionable. Diagnostic resources that are simple and of rapid application become fundamental to contribute to coping with this important health problem.

The satisfactory performance of the QuickDASH instrument for screening functional disability in leprosy patients was demonstrated in this study when the result of the instrument reached 30 points, with the correct classification (accuracy) of patients in 71% of cases. Even though it is a proposed instrument for functional evaluation of the upper body segment, the QuickDASH instrument proved sensitive in the screening of other health conditions, such as insomnia, depression, rheumatoid arthritis, and postoperative pain.²⁶⁻²⁸ Because leprosy affects more than one body segment simultaneously and in different proportions or stages, the instrument may be able to detect changes that are taking place in various sites in addition to the upper limbs.

Studies state that an accuracy $\geq 70\%$ in the ROC curve should be considered appropriate to indicate tests for the screening of health conditions.²⁹ There are several circumstances in which a test can be chosen for its high sensitivity, even having low specificity (or vice versa), if it is cheaper, simple to perform, or more accessible.²⁰ Such tests are generally used for the screening of various health conditions.

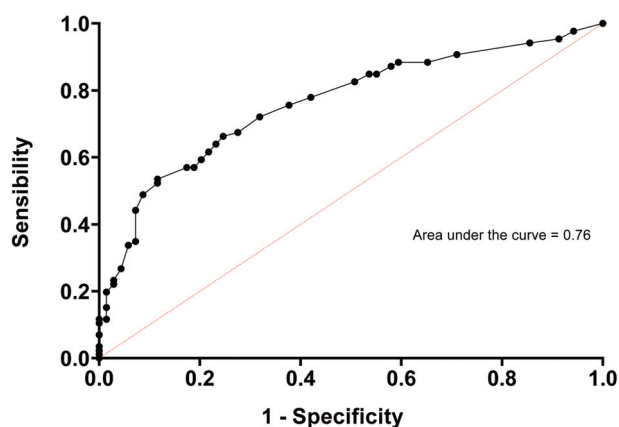


Fig. 1 ROC curve of the Quick-DASH score values for diagnosis of functional disability of leprosy patients.

In Brazil, technology policies for health have been implemented since 1994.³⁰ Health tools are being increasingly used and can be any type of electronic device, monitoring system, or an instrument that can be applied by health professionals in clinical practice with the objective of characterizing, diagnosing, monitoring, or improving the health status of individuals.³¹ The main finding of the present study includes this policy, since it proposes a simple and rapid application resource to be incorporated into primary care scenarios or in the outpatient health care network. The use of this diagnostic screening feature may contribute to the appropriate and timely referral of leprosy patients to confirm their actual situation in relation to the functional disability caused by the disease.

Some limitations should be considered in the interpretation of the results of this study. The inclusion of patients from a reference outpatient clinic may overestimate the frequency of disabilities. Although a high prevalence of the event of interest has an impact on the predictive value of diagnostic resources, this frequency measurement does not interfere with the sensitivity or specificity and, consequently, has no effect on the accuracy of the test.²⁹ Although the QuickDASH was originally extracted from the DASH instrument, which is a resource focused on upper member evaluation, this instrument turned out to be sensitive to screening for other pathologies such as insomnia, rheumatoid arthritis, and postoperative pain.^{26–28}

Conclusion

The QuickDASH showed good accuracy to track functional disability in leprosy patients, which may be useful in clinical practice in order to identify patients who require specialized referral for the prevention and treatment of this condition.

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Conflict of Interests

The authors declare that there is no conflict of interests.

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