

**Quality of life and discriminating power of two questionnaires in fibromyalgia patients: Fibromyalgia Impact Questionnaire and Medical Outcomes Study 36-Item Short-Form Health Survey**

**A qualidade de vida e o poder de discriminação de dois questionários em pacientes com fibromialgia: Fibromyalgia Impact Questionnaire e Medical Outcomes Study 36-Item Short-Form Health Survey**

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**ABSTRACT**

**BACKGROUND:** Fibromyalgia is a painful syndrome characterized by widespread chronic pain and associated symptoms with a negative impact on quality of life. **OBJECTIVES:** Considering the subjectivity of quality of life measurements, the aim of this study was to verify the discriminating power of two quality of life questionnaires in patients with fibromyalgia: the generic Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) and the specific Fibromyalgia Impact Questionnaire (FIQ). **METHODS:** A cross-sectional study was conducted on 150 participants divided into Fibromyalgia Group (FG) and Control Group (CG) (n=75 in each group). The participants were

evaluated using the SF-36 and the FIQ. The data were analyzed by the Student t-test ( $\alpha=0.05$ ) and inferential analysis using the Receiver Operating Characteristics (ROC) Curve - sensitivity, specificity and area under the curve (AUC). The significance level was 0.05.

**RESULTS:** The sample was similar for age (CG:  $47.8\pm 8.1$ ; FG:  $47.0\pm 7.7$  years). A significant difference was observed in quality of life assessment in all aspects of both questionnaires ( $p<0.05$ ). Higher sensibility, specificity and AUC were obtained by the FIQ (96%, 96%, 0.985, respectively), followed by the SF-36 (88%, 89% and 0.948 AUC).

**CONCLUSION:** The FIQ presented the highest sensibility, specificity and AUC showing the most discriminating power. However the SF-36 is also a good instrument to assess quality of life in fibromyalgia patients, and we suggest that both should be used in parallel because they evaluate relevant and complementary aspects of quality of life.

**Key words:** fibromyalgia; quality of life; questionnaires; disability evaluation; health status indicators.

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## RESUMO

**CONTEXTUALIZAÇÃO:** A fibromialgia é uma síndrome dolorosa caracterizada por dor espalhada e crônica e sintomas associados com um impacto negativo na qualidade de vida.

**OBJETIVOS:** Considerando a subjetividade da mensuração de qualidade de vida, o objetivo deste estudo foi avaliar o poder de discriminação de dois questionários que avaliam a qualidade de vida de pacientes com fibromialgia: o genérico Medical Short Form Healthy Survey (SF-36) e o específico Questionário do Impacto da Fibromialgia (QIF).

**MÉTODOS:** Foi conduzido um estudo transversal com 150 indivíduos, divididos em dois grupos: grupo fibromialgia (FM) e grupo controle (GC) ( $n=75$  em ambos). Os pacientes foram avaliados pelo SF-36 e pelo QIF. Na análise dos dados, utilizou-se o teste "*t de Student*" com  $\alpha=0,05$  e a Curva ROC (Receiver Operating Characteristics Curve).

**RESULTADOS:** As amostras foram estatisticamente semelhantes para a idade - 47,8 (8,1) no GC e 47,0 (7,7) no FM - e estatisticamente diferentes em todos os aspectos dos dois questionários (SF-36 e QIF). Alta sensibilidade, especificidade e área abaixo da curva (AUC) foram obtidas com o QIF (96%, 96%, 0,985 respectivamente), seguido pelo SF-36 (88%, 89% e 0,948 AUC).

**CONCLUSÃO:** O QIF mostrou-se mais discriminativo do que o SF-36 para avaliar a qualidade de vida de fibromiálgicos. No entanto, o SF-36 é também um bom instrumento de avaliação e

sugere-se que ambos sejam usados uma vez que avaliam aspectos relevantes e complementares da qualidade de vida.

**Palavras-chave:** fibromialgia; qualidade de vida; questionários; avaliação da deficiência; indicadores básicos de saúde.

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## Introduction

"Health is [...] not simply the absence of disease; it is something positive, a joyful attitude toward life, and a cheerful acceptance of the responsibilities that life puts upon the individual"<sup>1</sup>. According to WHO<sup>2</sup>, quality of life refers to the perception that people have about their position in life, within a context of culture and system of values in which they live and in relation to their aims, expectations and social standards. Considering the chronic diseases, the role of healthcare in improving quality of life has been increasingly underlined, particularly as concerns the relief of pain and suffering<sup>3</sup>. As in other chronic syndromes, improving the quality of life of patients is the main objective of fibromyalgia management.

Fibromyalgia syndrome has been described as a frequent rheumatological disorder in the world's population<sup>4-7</sup> and in the primary healthcare system, representing 7% of all health complaints and increasing health costs<sup>8</sup>. According to the criteria of the American College of Rheumatology (ACR), it is a painful syndrome characterized by widespread and chronic musculoskeletal pain and by the presence of at least 11 of the 18 tender points. These symptoms are frequently associated with morning stiffness, sleep disorders, fatigue, chronic headache, anxiety, depression, and irritable bowel syndrome<sup>9</sup>.

Considering the role of the symptoms, the negative impact on quality of life is frequently reported<sup>10,11</sup>. According to White et al.<sup>12</sup>, this negative impact on the quality of life of active individuals leads to loss of function, affects work capacity and consequently lowers family income. Although the functional disability is not caused by movement restriction, the impact of the symptoms on all aspects of daily life (e.g. work, family life and leisure<sup>13</sup>) aggravates the psychological conditions, causing depression and anxiety<sup>14,15</sup> and increasing the impact on the patient's quality of life<sup>10,11</sup>.

As in other syndromes, accurate quality of life measurements play an important role in the scientific and clinical context because they allow the identification of patients' needs, serve as outcome measures in experimental studies and provide parameters for the cost-benefit and cost-effectiveness analysis of treatment<sup>16-18</sup>. In this sense, quality of life assessment has

great relevance, and the use of specific and generic instruments could improve the diagnosis, treatment efficacy and research results<sup>18,19</sup>. While the generic questionnaires are usually more representative of overall quality of life, the specific instruments have a higher discriminating power<sup>20</sup>. Consequently, it is important that quality of life instruments have a reliable discriminating power<sup>16,18</sup>. The aim of the present study was to verify the discriminating power of two instruments used to assess quality of life in patients with fibromyalgia: the generic Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) and the specific Fibromyalgia Impact Questionnaire (FIQ).

## **Methods**

### **Type of study**

This is a cross-sectional study.

### **Sample**

This study included 150 participants. Seventy-five participants had a diagnosis of fibromyalgia according to the ACR<sup>9</sup> criteria and were selected at the rheumatology outpatient service of Hospital das Clínicas, Faculdade de Medicina da Universidade de São Paulo (HC-FMUSP), Brazil. For the healthy control group (CG), another 75 participants without fibromyalgia were selected among workers doing different jobs at Universidade de São Paulo.

The inclusion criteria were age between 35 and 60 years. All eligible participants were evaluated until the desired sample was completed and any sample losses were recorded. The participants from the fibromyalgia group (FG) were already under medical treatment. The study was approved by the Ethics Committee of HC-FMUSP - Comissão para Análise de Projetos de Pesquisa (Cappesq) - protocol number 210/01. All participants gave written informed consent.

### **Instrument and proceedings**

All participants from both groups were evaluated at a single face-to-face interview regarding demographic data (age, height, weight, gender, educational level, occupational activity and medical diagnosis). Two physical therapists were previously trained to read the questions in a standard format and clarify any questions. Because of the participants' limited reading skills, especially in the FG, the researchers decided to read the questionnaires along with them, avoiding problems in the comprehension and completion of the questionnaires.

Quality of life was assessed by two questionnaires: the FIQ<sup>16,17</sup> and the SF-36<sup>18,19</sup>. The FIQ<sup>21</sup> was used to assess the FG, and it

was translated to Portuguese and validated for the Brazilian population by Marques et al.<sup>22</sup>. The FIQ captures information on the following items: physical function, well-being, missed work, job difficulty, pain, fatigue, morning stiffness, morning tiredness, anxiety and depression. This questionnaire has been widely used in research and has shown good sensitivity, validity and reliability. Scores range from 0 to 100, and higher scores are associated with increased impact. As per Bennett, the mean value is 50, and severely affected patients have scores above 70<sup>23</sup>.

The SF-36 is a generic multidimensional instrument that assesses eight scales: Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional and Mental Health<sup>24</sup>. The score for each scale varies from 0 to 100, and the higher the score the better the quality of life. Two final measures are used: Physical Health and Mental Health<sup>17,25</sup>. A score based on the mean of the eight scales is reported in order to compare it with other questionnaires<sup>15</sup>. This partial score is used in the present study. The SF-36 has been widely used in research with excellent metric properties (sensitivity, validity and reliability)<sup>17,19</sup>, and it has been translated and validated for the Portuguese language<sup>26</sup>.

### **Statistical analysis**

All variables were tested for normality using Shapiro-Wilk's test. Only demographic data (age and BMI) had adherence to normality and were analyzed using a two-tailed t-test for independent samples. The questionnaire variables were analyzed with the non-parametric Mann-Whitney test. The significance level adopted was 0.05. The discriminating power of the questionnaires was assessed using the Receiver Operating Characteristics (ROC) curve with its sensitivity, specificity and area under the curve (AUC). For these analyses, we used the total FIQ score<sup>23</sup> and the partial SF-36 score, as used in a previous study<sup>15</sup>.

### **Results**

[Table 1](#) shows the patients' demographic data. The groups are similar for age, gender and body mass index (BMI). For educational level, the CG had more years of education than the FG, which may be related to the socioeconomic status of patients in a public hospital.

**Table 1.** Socio-demographic data of participants in the control group and fibromyalgia group.

Demographic data	Control group n=75 Mean (SD)	Fibromyalgia group n=75 Mean (SD)
Age (years)	47.8 (8.1)	47.0 (7.7)
Weight (Kg)	64.6 (11.7)	69.1 (14.5)
Height (m)	1.6 (0.8)	1.6 (0.7)
Body Mass Index (Kg/cm <sup>2</sup> )	25.2 (4.5)	26.8 (4.7)
Gender		
Female (%)	73 (97%)	73 (97%)
Male (%)	2 (3%)	2 (3%)
Educational level		
More than 12 years	57%	17%
9 to 11 years	26%	37%
0 to 8 years	17%	46%
Occupation		
Housekeeper	31%	37%
Retired	0%	14%
Other	69%	49%

The results obtained with the FIQ showed significant differences ( $p < 0.05$ ) between the CG and FG for all variables ([Table 2](#)). [Table 3](#) shows the results obtained with the SF-36. There were significant differences ( $p < 0.05$ ) between the CG and FG for all variables.

**Table 2.** Data from the Fibromyalgia Impact Questionnaire (FIQ) in the control group and fibromyalgia group.

FIQ variables	Control group n=75 Mean (SD)	Fibromyalgia group n=75 Mean (SD)	p
Physical function	4.7 (5.0)	12.7 (5.9)	<0.001*
Well-being	6.2 (1.8)	1.6 (1.9)	<0.001*
Missed work	0 (0.0)	0.2 (1.0)	<0.001*
Job difficulty	0.4 (1.0)	7.0 (2.5)	0.04*
Pain	0.8 (1.7)	7.6 (2.0)	<0.001*
Fatigue	2.3 (2.8)	7.6 (2.3)	<0.001*
Morning tiredness	1.5 (2.6)	7.1 (2.8)	<0.001*
Morning stiffness	0.7 (1.6)	6.6 (2.9)	<0.001*
Anxiety	3.5 (3.1)	7.7 (2.5)	<0.001*
Depression	1.8 (2.3)	6.0 (3.0)	<0.001*

\* Significantly different according to the Mann-Whitney Test.

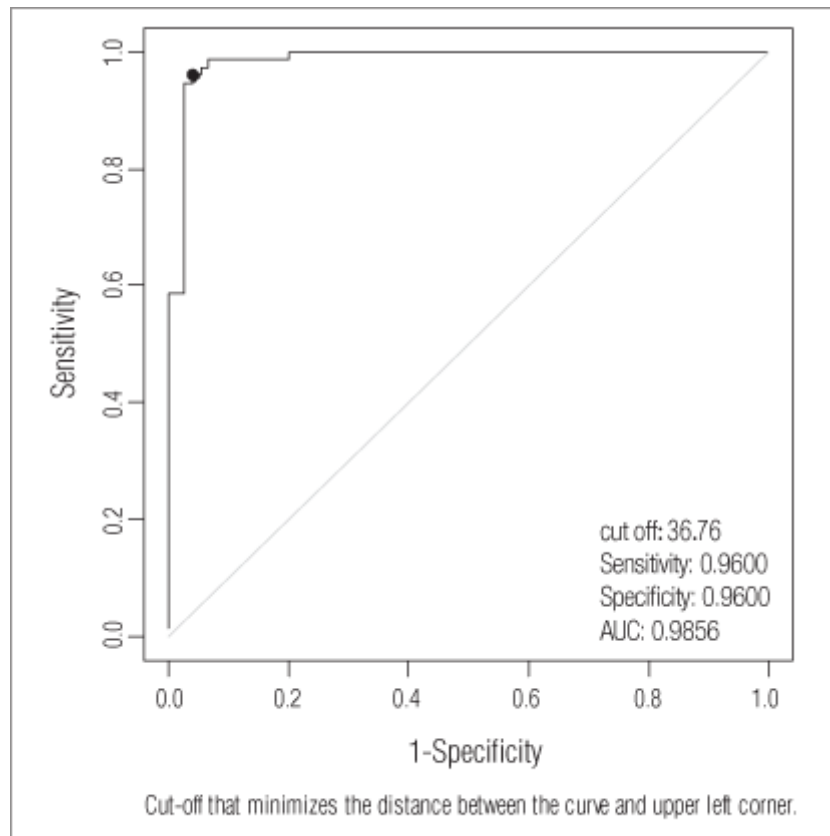
**Table 3.** Data from the Medical Outcomes Study 36-item Short Form Health Survey (SF-36) in the control group and fibromyalgia group.

SF-36 variables	Control group n=75 Mean (SD)	Fibromyalgia group n=75 Mean (SD)	p
Physical functioning	86.3 (15.8)	39.1 (23.2)	<0.001*
Role-physical	89.3 (24.0)	16.05 (30.1)	<0.001*
Bodily pain	79.3 (21.1)	30.1 (16.1)	<0.001*
General health	83.1 (18.3)	49.5 (25.9)	<0.001*
Vitality	70.2 (20.4)	36.3 (27.1)	<0.001*
Social functioning	84.2 (20.8)	46.6 (30.9)	<0.001*
Role-emotional	81.9 (35.1)	38.4 (40.4)	<0.001*
Mental health	77.3 (16.0)	48.75 (24.0)	<0.001*

\* Significantly different according to the Mann-Whitney Test.

### Discriminating power of the questionnaires

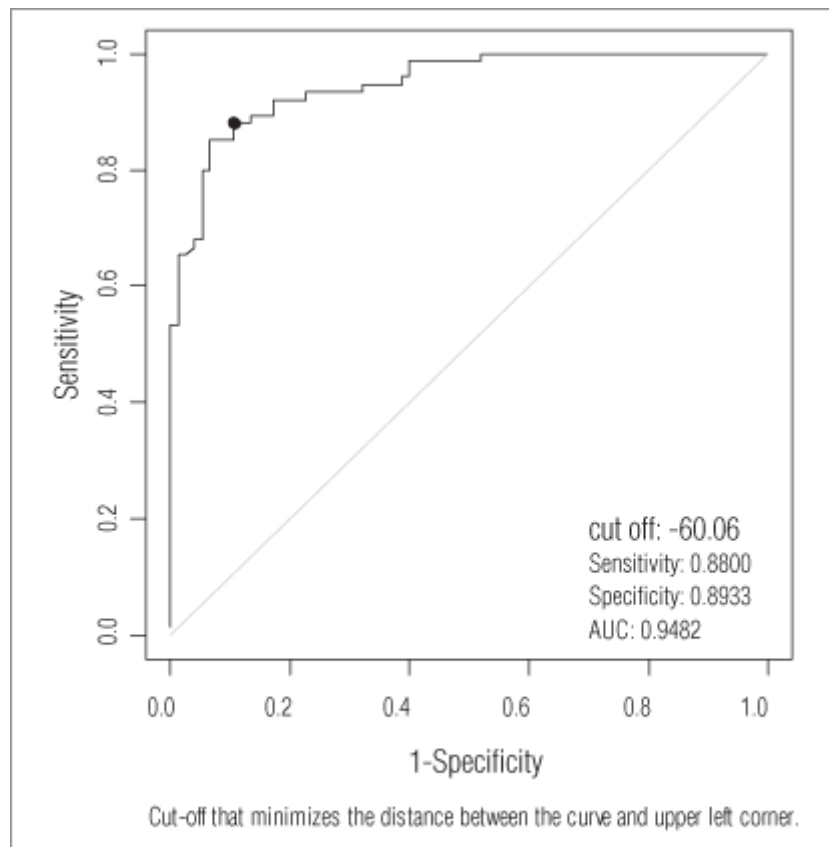
The FIQ was applied to the FG and CG. In the ROC analysis, the AUC was 0.985 (95% CI: 0.969 - 1.000). The cut-off score of 36.76 for the FIQ gave a sensitivity of 96% and specificity of 96% ([Figure 1](#)).



**Figure 1.** ROC curve for the Fibromyalgia Impact Questionnaire (FIQ).

The SF-36 was applied to both groups. In the ROC analysis, the AUC was 0.948 (95% CI: 0.917 - 0.980). The cut-off score of 60.06 for the SF-36 gave a sensitivity of 88% and specificity of 89% ([Figure 2](#)).





**Figure 2.** ROC curve for the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36).

## Discussion

The main objective of the present study was to analyze the discriminating power of two quality of life questionnaires. The results showed that the FIQ and the SF-36 are efficient to measure quality of life and to discriminate between participants with fibromyalgia and healthy participants, with excellent metric properties. Currently, the improvement in the quality of life of patients is one of the main objectives of treatments for several health conditions<sup>16</sup>. However, it is difficult to measure quality of life because it is related to a perception of living in terms of health, socioeconomic, psychological and cultural aspects<sup>1</sup>. In this sense, questionnaires are the most important instruments to indirectly quantify quality of life<sup>17,19,23</sup>.

Several studies have reported a negative impact of fibromyalgia on quality of life<sup>10,11</sup>. The combination of physical and mental symptoms interferes in different aspects of living such as work, family and leisure<sup>13,27,28</sup>. As in other syndromes, questionnaires are the most important form of assessing quality of life in order to compare patients with fibromyalgia and other chronic diseases<sup>18,29</sup> to healthy subjects<sup>30</sup> and to quantify the effectiveness of treatments<sup>20,25,31</sup>. Therefore, knowledge of the

metric properties of the questionnaires is essential to evaluate their efficacy.

In the present study, both questionnaires showed a significant difference in quality of life between the FG and the CG ( $p < 0.05$ ) in all aspects of the FIQ and SF-36. Studies in the literature report similar results supporting the negative impact of fibromyalgia, assessed with specific<sup>14,15,23</sup> and generic<sup>3,10,11</sup> instruments. For the FIQ, the ROC curve analyses show an AUC of 0.985, a cut-off score of 36.76, a sensitivity of 96%, and specificity of 96%. These data demonstrate the excellent metric properties and the high discriminating power of this questionnaire. The efficacy of the FIQ has been demonstrated for comparisons with healthy subjects<sup>32</sup>, with other diseases<sup>33</sup>, when comparing subjects before and after a treatment program<sup>23,31</sup> and in prospective studies<sup>34</sup>.

The FIQ is certainly the most widely used quality of life instrument in studies on fibromyalgia, which can be attributed to the fact that it is a specific questionnaire measuring all aspects of the syndrome. According to Bennett<sup>23</sup>, the FIQ has credible construct validity, reliable test-retest characteristics and good sensitivity in demonstrating therapeutic change. In the same study, the author noted that the average score for fibromyalgia patients is around 50 and that severely affected patients usually score 70 or above. In our study, the cut-off score between the CG and the FG was 36.76. In addition, the FIQ is short and easy to apply, thus allowing brief and efficient records.

For the SF-36, the ROC analysis showed an AUC of 0.948, a sensitivity of 89% and specificity of 89%. The SF-36 is the most generic instrument used to assess quality of life<sup>17,24</sup>. For fibromyalgia patients, this instrument have been widely used for comparisons with other diseases<sup>10,11,35</sup>, other kinds of pain and healthy subjects<sup>12,13,36</sup>. However, its discriminating properties in fibromyalgia were not described in the same way as they were in psychiatric disorders<sup>37,38</sup>. Our results have shown that the SF-36 was an excellent instrument for screening the FG and CG, with a cut-off score of 60.06.

When compared, both instruments provided objective and direct measures of quality of life and good discriminating power to distinguish fibromyalgia patients from healthy individuals. According to Contopoulos-Ioannidis et al.<sup>25</sup>, the data from quality of life and health surveys should be used more systematically in randomized trials. In this sense, the qualities of both disease-specific and generic instruments can be useful<sup>25</sup>. In fibromyalgia patients, quality of life instruments can even detect subgroups of the syndrome<sup>39,40</sup>. Oswald et al.<sup>39</sup> showed that the SF-36 was able to distinguish a psychological dysfunction subgroup among fibromyalgia patients and that this subgroup did not differ in terms of the physical well-being scores. The FIQ cluster analysis also found two subgroups among fibromyalgia patients. Pain and stiffness are universal symptoms for these patients but psychological distress was a feature only in some of them<sup>40</sup>.

In our study, the FIQ was the most sensitive and specific instrument for assessing quality of life in individuals with fibromyalgia. Similar results have been reported by Garratt et al.<sup>41</sup> and Gliklich and Hilinski<sup>42</sup>, who compared the SF-36 with specific instruments and observed a higher efficacy of the specific questionnaire. However, the authors emphasized the discriminating power of the SF-36. For chronic pain, Angst et al.<sup>18</sup> suggest that, although specific questionnaires are more responsive than the SF-36, the generic one is recommended for comprehension of the biological, psychological and social effects of pain.

In the present study, the SF-36 had less discriminating power, however it was efficient in identifying poor quality of life in individuals with fibromyalgia and in screening for fibromyalgia in control subjects. Considering the WHO definition of quality of life, social and psychological aspects are important when assessing quality of life, therefore generic and specific questionnaires provide complementary evaluations and should be applied in parallel<sup>43</sup>.

## **Conclusions**

The participants with fibromyalgia presented a poorer quality of life than the healthy participants, demonstrating that fibromyalgia interferes with quality of life. The FIQ presented the highest sensitivity, specificity and AUC, with greater discriminating power, however the SF-36 was also a good instrument for assessing quality of life in the participants with fibromyalgia and for discriminating participants with fibromyalgia from healthy participants. We suggest that both instruments be used in parallel because the SF-36 evaluates relevant aspects not evaluated in the FIQ.

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