MESTRADO INTEGRADO EM MEDICINA – TRABALHO FINAL

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TRANSLATION AND CROSS-CULTURAL ADAPTATION OF THE EULAR SYSTEMIC SCLEROSIS IMPACT OF DISEASE (ScleroID) INTO EUROPEAN PORTUGUESE LANGUAGE

ARTIGO CIENTÍFICO ORIGINAL

ÁREA CIENTÍFICA DE REUMATOLOGIA

Trabalho realizado sob a orientação de:

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MARÇO/2022

TITLE

TRANSLATION AND CROSS-CULTURAL ADAPTATION OF THE EULAR SYSTEMIC SCLEROSIS IMPACT OF DISEASE (ScleroID) INTO EUROPEAN PORTUGUESE LANGUAGE

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ABSTRACT

Introduction: Patient-reported outcome measures (PROMs) are important to integrate the patient's view into routine care. They are an integral part of clinical practice and research and required for registration of novel treatments. Therefore, a group of SSc experts from the European Alliance of Associations for Rheumatology (EULAR) developed and validated the EULAR Systemic Sclerosis Impact of Disease (ScleroID), which is a novel, brief, disease-specific, patient-derived, disease impact PROM, suitable for research and clinical use in SSc. The aim of this paper was to describe the translation and cross-cultural adaptation of the ScleroID questionnaire into European Portuguese among people with SSc and test the conceptual equivalence of the translated version in the Portuguese clinical context.

Material and Methods: The ScleroID was translated into European Portuguese and consequently back-translated into English, following forward-backward procedure. After the review of the portuguese version by an expert committee, the field test with cognitive debriefing involved a sample of 10 SSc patients with different ages, genders, disease duration, disease subsets and educational background.

Results: Ten patients in total (8 females, mean age of 58.4 ± 15.7 years) participated in the field test and cognitive debriefing, which showed that the items on the Portuguese version of the ScleroID were generally clear and easily understandable. The patients had minor difficulties with the wording of two items, which lead to changes in the wording to avoid misunderstandings.

Conclusion: The translated Portuguese ScleroID demonstrated acceptable linguistic validity and thus can be considered a valuable tool for use in both the clinical and research settings. Nevertheless, before European Portuguese version can be fully implemented, its psychometric properties (validity and reliability) need to be evaluated.

Keywords: Systemic sclerosis; ScleroID; quality of life; Health-related quality of life; Outcome research

RESUMO

Introdução: As *patient-reported outcome measures* (PROMs) são importantes para integrar a visão do doente na abordagem de rotina. São uma parte integral da prática clínica e da investigação e são necessárias para o registo de novas terapêuticas. Por isso, um grupo de especialistas em Esclerose Sistémica da Aliança Europeia de Associações de Reumatologia (EULAR) desenvolveu e validou a Escala de Avaliação do Impacto da Esclerose Sistémica na Qualidade de Vida (ScleroID), que é uma PROM nova, breve, específica para a esclerose sistémica, baseada no doente e no impacto da doença, sendo possível o seu uso em investigação e na prática clínica. O objectivo deste estudo foi o de descrever a tradução e adaptação cultural da escala ScleroID para a língua portuguesa e para os doentes com esclerose sistémica, testando a equivalência de conceitos da versão traduzida no contexto clínico português.

Material e Métodos: A ScleroID foi traduzida para português e consequentemente traduzida de volta para inglês, segundo o procedimento *forward-backward*. Após a reavaliação da versão portuguesa por um comité de especialistas, o teste de campo com o *debriefing* cognitivo envolveu uma amostra de 10 doentes com esclerose sistémica e de diferentes idades, géneros, duração da doença, subtipos de doença e nível de escolaridade.

Resultados: No total, dez doentes (8 mulheres, idade média de 58.4 ± 15.7 anos) participaram no teste de campo e *debriefing* cognitivo, que mostrou que os itens na versão portuguesa da ScleroID eram, em geral, claros e facilmente compreensíveis. Os doentes tiveram pequenas dificuldades com a expressão de dois dos itens, o que levou a alterações na expressão para evitar mal-entendidos.

Conclusão: A ScleroID traduzida para português demonstrou validade linguística aceitável e por isso pode ser considerada como uma ferramenta útil, tanto na prática clínica como na investigação. Todavia, as propriedades psicométricas (validade e confiabilidade) terão de ser avaliadas para que a versão portuguesa seja amplamente implementada.

Palavras-chave: Esclerose sistémica; ScleroID; qualidade de vida; qualidade de vida ligada à saúde; pesquisa baseada nos resultados

INTRODUCTION

Systemic sclerosis (SSc) is a rare inflammatory and multisystemic disease, with unknown aetiology, and it is characterised by immune system dysregulation, microangiopathy and fibrosis that mainly affects the skin and the internal organs[1,2]. This is a heterogeneous and challenging disease that can lead to a substantial decrease in quality of life (QoL) through physical, emotional and social impacts. People with SSc must cope often with a progressive and disabling condition and the persistent threat of an unpredictable course. Thus, patient-reported outcome measures (PROMs) are important to integrate the patient's view into routine care[3].

Recently, a novel patient-reported outcome measure for SSc aiming to cover the global disease burden— the EULAR Systemic Sclerosis Impact of Disease - hereafter referred to as ScleroID[4] - was developed and validated. It is comprised of 10 questions in which the patient is asked to rank, from 0 (no impact) to 10 (extreme impact), just how much different symptoms of SSc impacted their quality of life in the previous week. The 10 symptoms were selected of 17 possible ones, based on which symptoms the patients themselves reported as the most impactful.[5] During the development of ScleroID, each item was given a different weight, based on the rankings the patients gave to each, according to its impact on quality of life (the most impactful items carried more weight).[4] Thus, after the patient has ranked the 10 items, the clinician must weigh each according to the model set by the original developers to reach the final ScleroID score, which can range from 0 to 10.

In order to use this questionnaire in a clinical setting and ensure its content is equivalent in both the original language (English) and the European variant of Portuguese (the *lingua franca* of Portugal), the translation and cross-cultural adaptation of the ScleroID was carried out, according to the standards for conceptual equivalence across languages set for this purpose by Beaton et al. 2000.[6]

This study reports the translation and cross-cultural adaptation of the ScleroID into the European Portuguese language among people with SSc.

METHODS

Permission to translate the ScleroID questionnaire into European Portuguese was requested from the author (Dr. Oliver Distler) of the paper regarding the validation of the ScleroID before starting the adaptation (See Appendix 1).

This study received the approval from the Coimbra Hospital and University Centre's Ethics Committee (See Appendix 2). All participants gave were informed of the particulars of the study and gave written consent.

The translation and cross-cultural adaptation of the original scale, in its English version, was carried out over a period of seven months, from September 2021 to March 2022. The process was done according to the forward-backward method[6], consisting of 5 steps: translation, synthesis of the translation, back translation, expert committee review, and field test with cognitive debriefing

1. Translation

Three bilingual translators who are native European Portuguese speakers, V.O., A.R.A, and F.F., independently created forward translations of the ten items, response options and instructions of the ScleroID into European Portuguese. Two of the translators were aware of the medical background concepts of the questionnaire, but the other one was not aware. Each translator produced an independent written report, and they were also asked to register specific points where they had difficulties translating and what they settled for. Item content, response options and instructions were all translated.

2. Synthesis of the translation

The members of the Portuguese research team (T.S. and M.J.S.) then compared the 3 Portuguese versions, analysed the items that were more challenging, discussed and decided what would better fit into the Portuguese language and made some minor adjustments accordingly. At the end, the three versions were synthesised into a single consensual version.

3. Back translation

Two other bilingual translators (native speakers of English), T.S. and L.P. that were totally blind to both the medical concepts addressed in the questionnaire and the original scale, translated the synthesized version into the original English language.

4. Expert committee review

Finally, the expert committee (two rheumatologists T.S. and M.J.S) reviewed all of the translations. The objective of the committee was to reach a consensus on discrepancies and develop a pre-final version. The committee made decisions in order to ensure equivalence of the translation in four areas: semantic equivalence (i.e. ensuring that the words have the same meaning), idiomatic equivalence (i.e. formulating equivalence expressions for colloquialisms), experiential equivalence (i.e. replacing items that are not experienced in the target country by similar ones experienced in that country) and conceptual equivalence (i.e. ensuring the

concepts of the words are the same between cultures). Then, a pre-final European Portuguese ScleroID questionnaire was developed, to be given to patients in the next phase.

5. Field test with cognitive debriefing

The pre-final version was pre-tested in a representation sample of Portuguese patients with SSc. Patients covering a broad spectrum of socio-demographic background (age, gender, disease duration, education) were recruited from the Rheumatology Department of the Coimbra Hospital and University Centre. Patients were recruited according to the following inclusion criteria: (i) fulfilling the 2013 ACR/EULAR Classification criteria for SSc[8]; (ii) ability to understand and fill out the questionnaires; (iii) willingness to provide informed signed consent; and (iv) completed all the questionnaires required. Participants were excluded in the presence of severe comorbidities that could affect the completion of the questionnaire.

During the course of a few weeks, 10 patients with SSc underwent a field test, having been given the questionnaire and asked to fill it in under supervision of a member of the Portuguese research team (M.V.), and then participating in a cognitive debriefing interview to assess the difficulties in filling in the questionnaire. Patients were asked to comment on its relevance and which items lead to confusion, explaining why they were misleading. The time taken to complete the questionnaire was also recorded for each patient.

In addition, information on age, gender, disease characteristics, including disease subset, autoimmunity, educational level, and working status were collected in a pre-established form.

To assess quality of life, the Scleroderma Health Assessment Questionnaire (SHAQ) and the EuroQoL Five Dimension Questionnaire (EQ5D), to evaluate health-related quality of life, were both given to the patients to fill in, along with ScleroID.

SHAQ scores range from 0 (no disability) to 3 (impossible to do). EQ5D includes the dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, and each is for each one level is picked: no problems, some problems, and severe problems.

Higher scores in the EQ5D represent a better self-perceived quality of life, while a higher score in the SHAQ denotes a more severe status of disease.

RESULTS

The final Portuguese version of the ScleroID questionnaire is shown in Appendix 3 and can be obtained from our department website (http://www.reumatologiachuc.pt).

Translation and cultural adaptation of ScleroID

The translation of the ScleroID scale into European Portuguese was mostly straightforward.

There were a few discrepancies, but they were due to different wording and thus the meaning of the sentence was not impacted. For example, level 10 "Extremely serious" was translated as "Extremamente grave", "Extremamente severo" and "Extremo"; after some discussion, the Portuguese research team decided on the term "Extremamente grave"

Item #2 was translated as both "Função das mãos" and "Funcionamento da mão"; "Função das mãos" was ultimately chosen.

Item #5 was translated as both "Fadiga" and "Cansaço/fadiga". Due to the word "cansaço" being more easily understood by patients, the second option was picked.

Item #6 was translated as both "Sintomas do aparelho digestivo inferior (ex. Sensação de inchaço abdominal, diarreia, prisão de ventre, incontinência anal)" and "Sintomas do sistema gastrointestinal inferior (por exemplo: sensação de "barriga inchada", diarreia, obstipação, incontinência fecal)". "Barriga inchada" é a more readily understandable term to patients, thus it was picked as the final option.

Some extra information was added by a few translators to emphasise the meaning of the items (p.e., "Mobilidade do corpo" instead of just "Mobilidade", but it was considered redundant by the Portuguese research team and therefore was removed from the final version.

Cognitive debriefing

Table 1 summarises the demographic and clinical characteristics of the participants. Ten patients with SSc were included (8 women and 2 men; mean age of 62 (±15.7) years; 6 with limited subset and 4 with diffuse subset).

Table 1 – Individual patients' characteristics

Patient ID	Gender	Age	SSc Subset	Disease duration since first Raynaud phenomenon (years)	SSc specific autoantibody	Working Status*	Years of formal education
P1	F	39	Limited	14	Centromere	1	12
P2	F	57	Diffuse	4	Anti-Scl 70+	2	12
P3	F	52	Limited	11	Centromere	1	9
P4	F	65	Diffuse	2	Anti-Scl 70+	2	6
P5	F	74	Limited	22	Neg	2	4

P6	F	61	Limited	14	Centromere	1	12
P7	F	27	Diffuse	2	Neg	1	16
P8	F	79	Limited	22	Centromere	2	4
P9	M	63	Limited	23	Centromere	2	4
P10	M	67	Diffuse	15	Neg	2	12

*working status: 1 = employed; 2 = retired

SSc, systemic sclerosis

The mean total score of the Sclero ID scale was 2.6 ± 2.18 (with a lower score indicating a lower impact of disease on quality of life) and ranged from 0.3 (one participant) to 6.9 (one participant).

The mean total score of the SHAQ was 0.6375 ± 0.66 (range 0 to 3, with a higher score indicating a worse health status).

The mean total score of the EQ5D was 0.56242 ± 0.3 (range -0.59 to 1.0, with a higher score indicating a perceived better health status) and ranged from 0.28 (two participants) to 1 (two participants).

Completion time for Sclero ID was 3.105 ± 1.64 (range 1.17 to 5.80) minutes.

Table 2 shows the calculated ScleroID score for each patient.

Table 2 – ScleroID final score

Patient ID	ScleroID score
P1	1.2
P2	2.2
P3	0.3
P4	4.9
P5	6.9
P6	1.2
P7	6.1
P8	0.8
P9	2.9
P10	3.7

The cognitive debriefing showed that the patients found the questionnaire generally easily understandable, clear, and easy to fill out. The patients had slight difficulties with the wording of two items in particular, namely the two which use specific medical terms: a few patients could not understand what either Item #1 "Fenómeno de Raynaud" and Item #10 "Úlceras digitais" referred to. The patients, with a range of different educational backgrounds and disease statuses and progression, showed a good understanding of what each item entailed and how they should answer according to their own disease experience.

DISCUSSION

The ScleroID, a global measurement tool to assess the disease burden in SSc patients, was successfully translated and culturally adapted into European Portuguese. It was found to provide a good way to measure how much systemic sclerosis impacted the patients' quality of life, by way of 10 clinical aspects commonly associated with the disease.

Some misunderstandings caused on a few patients by items #1 "Fenómeno de Raynaud" and #10 "Úlceras digitais" point to a need to alter those items, perhaps detailing what each one entails (p.e., "Fenómeno de Raynaud" could be explained as "Dedos alternam de cor entre pálidos, vermelhos e roxos quando expostos ao frio ou ao stress" and "Úlceras digitais" could be explained as "Lesões nos dedos").

The short completion time (approximately 3 minutes) makes this questionnaire highly useful in a quick but effective measuring of the impact of the disease on quality of life. Because of its non-reliance on additional resources and lack of a need for medical training to calculate the final score, ScleroID poses itself as a well-fitted candidate for use in both medical and clinical settings.

In a near future, this disease-specific questionnaire could be used in clinical trials and in clinical practice in SSc to cover different disease features of this multiorgan autoimmune disease capturing the burden of disease that is most important to patients. Therefore, ScleroID can be used to integrate patient experience to improve decision making in clinical practice.

Further studies are underway to test the psychometric properties of this new questionnaire.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication.

Margarida Vieira (M.V.) and Tânia Santiago (T.S.) had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design: Margarida Vieira (MV), Tânia Santiago (TS), José António Pereira da Silva (JAPS), Maria João Salvador Daniel dos Santos Henriques (MJS)

Acquisition of data: Margarida Vieira (MV), Tânia Santiago (TS), Maria João Salvador Daniel dos Santos Henriques (MJS)

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APPENDIX 1

Dobrota Rucsandra
Re: Permission to Translation and Cross-cultural adaptation to Portugal - EULAR ScleroID questionnaire.
To: Tânia Santiago, Becker Mike Oliver, Cc: Dra Maria João Salvador, Margarida Vieira, Distler Oliver

27 September 2021 at 17:54

Details

Dear Tania,

Thank you for reaching out, we look forward to collaborating with you!
I have attached the latest version of the ScleroID manuscript and the supplement. You should find all the information there. We are currently working on a second revision.
Let us know should you need any support, me and Mike are happy to help!

Best wishes,
Rucsandra

No dia 04/09/2021, às 10:30, Distler Oliver <Oliver.Distler@usz.ch> escreveu:

Dear Tanja
We are very open for these kind of cooperations. The main paper is currently in revision at Annals. Rucsandra or Mike can send you the most recent version. Please keep us updated on progress and dont hesitate to ask us for any support.
Best wishes, Oliver

APPENDIX 2

REPÚBLICA
PORTUGUESA
SAÚDE

SNS SERVIÇO NACIONAL
DE SAÚDE

CHUC
CENTRO HOSPITALAR
E UNIVERSITÁRIO
DE COIMBRA

Comissão de Ética para a Saúde

Visto/ A U.I.D.
para difusão
Dr. Nuno Deveza
Diretor Clínico
SUA REFERÊNCIA .U.C. - EPE   SUA COMUNICAÇÃO DE

Exmo. Senhor
Dr. Nuno Deveza
Digm° Diretor Clínico do CHUC

NOSSA REFERÊNCIA   DATA

N.° 432/CES   02-12-2021

Proc.N°   OBS.SF.174-2021

PI OBS.SF.174-2021 "TRADUÇÃO E ADAPTAÇÃO CULTURAL DO QUESTIONÁRIO DE AVALIAÇÃO DO IMPACTO
DA ESCLEROSE SISTÉMICA NA QUALIDADE DE VIDA"
Entrada na UID: 13-09-2021
Entrada na CES: 15-10-2021
Investigador/a/es: Margarida Maria Carvalho Vieira - Aluna do 6° ano do Mestrado Integrado em Medicina
Coordenador/a/es: Maria João Henriques Salvador
Co-Investigador/a/es: José António Pereira da Silva
Promotor: Não se aplica
Serviço de Realização: Serviço de Reumatologia do Centro Hospitalar e Universitário de Coimbra
(CHUC)

Cumpre informar Vossa Ex.ª que a CES - Comissão de Ética para a Saúde do Centro
Hospitalar e Universitário de Coimbra, reunida em 17 de Novembro de 2021, após reapreciação do
projeto de investigação supra identificado, emitiu o seguinte parecer:

" A Comissão considera que se encontram respeitados os requisitos éticos adequados à
realização do estudo, pelo que emite parecer favorável ao seu desenvolvimento no CHUC. Solicita,
contudo, o envio do questionário em falta, para encerramento do processo administrativo".

Mais informa que a CES do CHUC deverá ser semestralmente atualizada em relação ao
desenvolvimento dos estudos favoravelmente analisados e informada da data da conclusão dos
mesmos, que deverá ser acompanhada de relatório final.

Com os melhores cumprimentos,

A Comissão de Ética para a Saúde do CHUC, E.P.E.

Prof. Doutora Margarida Silvestre
Presidente

1/1

Impacto da Doença - Esclerose Sistémica – Questionário EULAR ScleroID

Tendo em conta as diferentes dimensões da esclerose sistémica, indique o quanto é que elas o/a afetaram, durante a semana passada.

Por favor, responda usando a escala, e escolhendo o número que melhor quantifica cada uma das seguintes dimensões:

1- Fenómeno de Raynaud:
Faça um círculo à volta do número que melhor descreve a gravidade do seu fenómeno de Raynaud, durante a semana passada.

Nenhuma	0	1	2	3	4	5	6	7	8	9	10	Extremamente grave

2- Função das mãos:
Faça um círculo à volta do número que melhor descreve as limitações na função das mãos, devido à sua esclerose sistémica, durante a semana passada:

Nenhuma limitação	0	1	2	3	4	5	6	7	8	9	10	Limitação grave

3- Sintomas do sistema gastrointestinal superior (por exemplo: dificuldades em engolir, refluxo, vómitos):
Faça um círculo à volta do número que melhor descreve a gravidade dos sintomas do sistema gastrointestinal superior, devido à sua esclerose sistémica, durante a semana passada:

Nenhuma	0	1	2	3	4	5	6	7	8	9	10	Extremamente grave

4- Dor:
Faça um círculo à volta do número que melhor descreve a intensidade da dor que sentiu, devido à sua esclerose sistémica, durante a semana passada:

Nenhuma	0	1	2	3	4	5	6	7	8	9	10	Extremamente grave

5- Cansaço/Fadiga:
Faça um círculo à volta do número que melhor descreve a fadiga/cansaço geral que sentiu, devido à sua esclerose sistémica, durante a semana passada:

Nenhum	0	1	2	3	4	5	6	7	8	9	10	Extremamente grave

6- Sintomas do sistema gastrointestinal inferior (por exemplo: sensação de "barriga inchada", diarreia, obstipação, incontinência fecal):

Faça um círculo à volta do número que melhor descreve a gravidade dos sintomas do sistema gastrointestinal inferior, devido à sua esclerose sistémica, durante a semana passada:

Nenhuma	0	1	2	3	4	5	6	7	8	9	10	Extremamente grave

7- Quais as limitações nas atividades diárias e opções de vida (por exemplo: atividades da vida social, cuidados pessoais, trabalho):

Faça um círculo à volta do número que melhor descreve a gravidade das limitações nas atividades de vida diária e opções de vida, devido à sua esclerose sistémica, durante a semana passada:

Nenhuma	0	1	2	3	4	5	6	7	8	9	10	Extremamente grave

8- Mobilidade:

Faça um círculo à volta do número que melhor descreve, o quanto a mobilidade do seu corpo foi afetada pela esclerose sistémica, durante a semana passada:

Nada	0	1	2	3	4	5	6	7	8	9	10	Extremamente grave

9- Falta de ar:

Faça um círculo à volta do número que melhor descreve a gravidade da falta de ar que sentiu, devido à esclerose sistémica, durante a semana passada:

Nenhuma	0	1	2	3	4	5	6	7	8	9	10	Extremamente grave

10-Úlceras Digitais:

Faça um círculo à volta do número que melhor descreve o quanto as suas úlceras digitais o afetaram de um modo geral, durante a semana passada.

Nada	0	1	2	3	4	5	6	7	8	9	10	Extremamente grave