THERAPIES

HEADING: Clinical pharmacology

French translation and linguistic validation of the Raynaud's condition score

Translation of the Raynaud's Condition Score

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Summary

The Raynaud's condition score is a 11-point scale severity score used in Raynaud's phenomenon clinical trials since 1998. The Raynaud's condition score diary has been recommended for use in clinical trials assessing efficacy of interventions on scleroderma related Raynaud's phenomenon. However, this score has never been formally validated in French. We thus performed a translation and a linguistic validation of the Raynaud's condition score through a forward/backward translations process followed by an expert review and cognitive patient interviews. The translations led to a French version of the Raynaud's condition score that was linguistically valid, and conceptually equivalent to the original English version. This "Score de Raynaud" will be usable to perform and harmonize clinical trials in French-speaking patients with secondary Raynaud's phenomenon.

KEYWORDS

Raynaud's phenomenon; Systemic scleroderma

Abbreviations

PRO: patient-reported outcome

RCS: Raynaud's condition score

WHO: World Health Organization

Introduction

The Raynaud's condition score (RCS) is a 11-point scale severity score used in patients with Raynaud's phenomenon. It has been widely used as a patient-reported outcome (PRO) in clinical trials since 1998 [1]. This Raynaud's phenomenon severity score was validated and standardized by Merkel et al. in 2002 [2]. The RCS diary has been recommended for use in clinical trials assessing efficacy of interventions on scleroderma related RP and is usually used as a primary endpoint [3,4]. However, this score has never been formally validated in French and, to our knowledge, in other languages. The aim of the current study was to translate and perform a linguistic validation of the RCS in French.

Linguistic validation of a PRO is a process ensuring that concepts are equivalent and easily understood by people speaking other languages than that of the original version.

Method

Ethical approval was applied from the CPP Ile de France 10 (RCB: 2018-A01473-52) prior beginning the study.

The translation process was performed through a forward/backward validation process followed by an expert review and cognitive patient interviews, in accordance with the translation guidelines of the World Health Organization (WHO) [5,6].

The following four steps were taken and are synthetized in Fig. 1.

- **Forward translation:** The original RCS was translated by two French-native speaking translators. They performed this translation independently after receiving information about the goal of the RCS and on the way it has been used in research. The two versions were further conciliated and a synthetic version was produced (Version A).
- **Backward translation:** The harmonized version A was back-translated by a professional English-native speaking translator (Version B). The original RCS version and the back translated B version were compared, conciliated and a synthetic version was produced (Version C).

- **Clinicians experts validation:** The conciliated version C was sent to 4 clinical experts in the field in France (YA, SB, EH, PS). They were asked to review and comment the version C for expression and concepts. The results of the clinical expert feedback were synthetized and incorporated into the version C to produce the version D.
- **Patient cognitive interviews:** Finally the version D was presented in a face to face meeting to 5 scleroderma patients to ask for comprehension and commentaries. All remarks and commentaries were synthetized and used to produce the version E. A further 5 cognitive face to face interviews with patients were led. Findings were used to make the final French version of the RCS.

Results

The translation process led to a French version of the RCS that was linguistically validated and conceptually equivalent to the original English version. In the first step, we found that the two independent forward translations had different views on the language, which required discussion in order to reach consensus. Main discrepancies between the two translated versions were the use of “*Syndrome de Raynaud*” or “*Phénomène de Raynaud*” terms, and the translation of difficulty by “*difficulté*” or “*gêne*” in French. The “painful sores” translation was also absent from one version. Moreover, adding or not the concept of quantification to translate the English concept of “rating” was also thoroughly discussed during the conciliation process.

The comparison of the back translated version B to the original English version identified several words for which the meaning differed. “Difficulty” was back translated to “discomfort” and the emphasis “ALONE” (in capital letters) put on Raynaud’s phenomenon in the original version was lost in the backtranslation.

Then the version C was send to 4 clinicians experts in the field. Their comments were integrated to the version D. Mainly, more emphasis was put on the importance to rate daily symptoms by underlining “*au cours de la journée*” (“during the day”) in the French version. Moreover the French term “*à lui seul*” (“alone”) was also underlined to emphasize this point. The version D was first presented to 5 scleroderma patients in cognitive interviews. Their characteristics and comments are presented in Table 1. Mainly, the concept of daily rating was insufficiently understood. Furthermore, the isolation of Raynaud’s symptoms from other

hand related scleroderma symptoms (such as sclerodactyly or musculoskeletal disorders) was not easy for patients. A revised version was thus presented to 5 additional patients, and it was well understood by all of them with no further changes.

The original and the final versions of the RCS are presented in Table 2.

Discussion

In this study, we translated and linguistically validated the RCS into French.

Since its first use in 1998 by Wigley et al. the RCS has been widely used in clinical trials, in combination with the frequency and the duration of RP attacks, to assess the efficacy of pharmacological interventions on RP. In 2002 Merkel et al. in a study on 148 scleroderma patients highlighted that the dimension covered by the RCS differed from crisis duration and frequency, thus highlighting the complementarity of the outcomes. Another study conducted in a cohort of patients with primary and secondary RP study further established the minimally important difference for the RCS at 1.4, and patient acceptable symptom state at 3.4, on a 0-10 scale [7]. The cognitive interviews also highlighted the difficulty for the patients to individualize Raynaud's symptoms from other scleroderma hand related symptoms such as sclerodactyly and skin fibrosis. This difficulty is probably more important in late stage scleroderma patients with less paroxysmal RP crises. However, that difficulty is inherent to this global score and is also expected in the original English version [8].

One of the main limitation of the study is the limited number of included patients for cognitive interviews and the absence of primary Raynaud's phenomenon patients. However, the translated version has been promptly well understood by patients and no primary RP patients were included in the original validation study [2].

Conclusion

In this study we translated and validated in French the most used and recommended severity score, the RCS, to assess the efficacy of intervention on scleroderma related RP in clinical trials. This "Score de Raynaud" will be usable to perform and harmonize clinical trials enrolling French-speaking patients with secondary RP.

Disclosure of interest

Authors have no competing interest to declare

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Table 1. Characteristics of included patients. The main triggering factor and Raynaud's phenomenon locations are in bold.

Patient characteristics				Raynaud's Phenomenon					Ulcers	Linguistic validation		
Age	Gender	Type of scleroderma	Year of diagnosis	Triggering factor	Frequency		Mean crisis duration	Locations	Sores / finger ulcer	Score de Raynaud	Formulation clear and understandable	Comments
					Winter	Summer						
50	F	Diffuse	2003	Temperature variation	>5/ day	<1/ week	<10min	Hand / foot	YES	2	YES	
47	F	Diffuse	2011	Cold / moisture	>5/ day	<1/ week	60min	Hand / foot	YES recurring every winter	0	NO	"Today" should be emphasized (write it at the beginning)
49	F	Limited cutaneous	2004	Cold / moisture/ uncaused	>5/ day	1 to 5/ day	20 min (winter) / more fleeting in summer	Hand / foot / nose	NO	8	YES	
57	F	Limited cutaneous	2008	Cold / stress	>5/ day	1 to 5/ day	20 to 25 min	Hand / foot	NO	5	YES	

48	F	Diffuse	2013	Cold	>5/ day	<1/ week	10 min	Hand / foot	NO	0	YES	No crisis during the summer
63	M	NA	2013	Cold	>5/ day	1 à 5/ day	20 to 30 min	Hand / foot/ ears	YES	1 to 2	YES	
55	F	Diffuse	2015	Cold	1 to 5/ day	<1/ week	20 min	Hand	YES	0	YES	
84	F	Limited cutaneous	1999	Cold	1 to 5/ day	<1/ week	10 min	Hand/foot	YES	8	YES	
60	F	Diffuse	1990	Cold	1 to 5/ day	<1/ week	15 min	Hand/foot	YES	5	NO	No crisis but permanent disability
56	F	Limited cutaneous	2002	Cold/moisture	1 to 5/ day	<1/ week	10 min to 1h	Hand	YES	5	YES	

Table 2. Original English and French final translated version of the Raynaud's condition score.

Original version	French version
<p><u>Raynaud's condition score</u></p> <p>The Raynaud's condition score is your rating of how much difficulty you had with your Raynaud's TODAY. Consider how many attacks you had and how long they lasted.</p> <p>Consider how much pain, numbness, or other symptoms the Raynaud's caused in your fingers (including painful sores) and how much the Raynaud's ALONE affected the use of your hands today.</p> <p>CIRCLE below the number that best indicates the difficulty you had today with your Raynaud's condition</p> <p>No difficulty 0 1 2 3 4 5 6 7 8 9 10 extreme difficulty</p>	<p><u>Score de Raynaud</u></p> <p>Nous souhaiterions connaître votre propre évaluation de la gêne ressentie <u>au cours de la journée</u> à cause du phénomène de Raynaud.</p> <p>Prenez en compte le nombre de crises que vous avez eues <u>aujourd'hui</u> ainsi que leur durée; prenez aussi en compte la douleur, l'engourdissement ou tout autre symptôme (y compris les plaies douloureuses), et à quel point le phénomène de Raynaud <u>à lui seul</u> gêne l'usage de vos mains.</p> <p>Entourez ci-dessous le chiffre qui indique le mieux la gêne que vous avez ressentie aujourd'hui à cause de votre phénomène de Raynaud</p> <p>Aucune gêne 0 1 2 3 4 5 6 7 8 9 10 Gêne extrême</p>

Legend of figure

Figure 1. Flow chart of the translation and the linguistic validation process.