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Original research article

The translation and linguistic validation of the Revised Iowa Pain Thermometer into Czech for a clinical study involving Czech stroke patients

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Abstract
Aim: Patients with a stroke could benefit from vertical self-report pain instruments. Such instruments are not available in the Czech language. The aim was to translate and linguistically validate the Revised Iowa Pain Thermometer into Czech for use by Czech patients with a stroke.
Methods: Three translators, three nursing expert panels, and seven patients with a stroke participated in this methodological study that took place between January and April 2017. The International Society for Pharmacoeconomics and Outcomes Research guidelines were used to direct the process. This 10-phase process was supported by quantitative and qualitative methods, such as content validity indexing and modified kappa calculations, discussions with nursing experts, as well as cognitive debriefing with patients.
Results: Based on the content validity index, the modified kappa values, and the experts' feedback, a preliminary Czech version was developed. Cognitive debriefing revealed that most patients had some difficulty using the instrument.
Conclusions: The translation and linguistic validation process was demanding as it was difficult to recruit nurses and translators meeting the determined selection criteria; furthermore, many steps were required. However, using a less stringent methodology would have probably produced a Czech version that would not be as suitable for the intended target group – Czech patients with a stroke. The findings underscore the importance of involving representative users, i.e., patients with a specific health condition, in the translation and linguistic validation of self-report instruments. Psychometric properties of the Czech version will be established in a clinical study that will involve Czech patients with strokes.

Keywords: Nursing; Pain; Pain assessment; Self-report; Stroke

Introduction

The burden of a stroke is significant in many countries, including in the Czech Republic (CR) (Feigin et al., 2014; Sedova et al., 2017). Many stroke survivors experience pain, either due to the stroke itself or because of other co-morbidities (Harrison and Field, 2015; Nesbitt et al., 2015). Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (IASP, 2017).

Due to the subjective nature of pain, a person's self-report is considered the most accurate measure of pain (Hsiung et al., 2016). However, assessment of pain through self-report is frequently difficult, especially in patients with strokes as they may have aphasia and other cognitive problems (Nesbitt et al., 2015; Smith et al., 2013; Turner-Stokes and Jackson, 2006). Such deficits may complicate communication between the patient and the nurse and may hinder accurate and timely pain assessment (Nesbitt et al., 2015).

Nonetheless, various self-report pain intensity instruments have been used in patients with a stroke, e.g., the Numerical Rating Scale (NRS), the Faces Pain Scale (FPS), the Faces Pain Scale-Revised (FPS-R), and the Visual Analogue Scale (VAS) (Mandysová et al., 2017; Smith et al., 2013). Facial scales (without any pain descriptors) could be suitable especially for patients with a left-sided stroke who often have aphasia (Benaim et al., 2017). Conversely, patients with a right-sided stroke may be unable to interpret facial expressions (McCaffrey, 2008) and may have difficulties in using facial scales. Some experts advocate the use of vertical pain instruments, especially in cases of stroke-related visuospatial deficits. Examples include the vertically presented FPS (Benaim et al., 2017) and the ShoulderQ (Turner-Stokes and Jackson, 2006). However, a literature search conducted in January 2017 failed to identify evidence-based vertical pain instruments in Czech (Mandysová, 2017).

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Considering the mentioned facts, the Revised Iowa Pain Thermometer (IPT-R) could be a suitable vertical self-report pain instrument for patients with a stroke. A preliminary study aiming to conduct its psychometric evaluation involved older adults with varying levels of cognition (Ware et al., 2015). Similarly, most stroke patients are older and can have impaired cognition (Benaim et al., 2017; Sedova et al, 2017). The study of Ware et al. demonstrated good validity and reliability estimates for the IPT-R; furthermore, the participants preferred the IPT-R to the original 13-point Iowa Pain Thermometer (0–12 scale) and the NRS (Ware et al., 2015). However, the IPT-R is available only in English.

Translating foreign instruments into local languages

From a worldwide perspective, most instruments for nursing practice are published in English. Thus, nurses working with patients who speak languages other than English need to translate such instruments into their local language before putting them into practice. To support translational accuracy, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) has developed guidelines for the translation and linguistic validation of instruments (Wild et al., 2005). The guidelines have been used in many countries, e.g., Germany (Brammen et al., 2018), South Africa (Goggin et al., 2010), and Finland (Pudas-Tähkä et al., 2014). Similarly, the World Health Organization (WHO) stresses the importance of obtaining a translated version that is culturally equivalent to the original instrument (WHO, 2018). It recommends using forward-back translation to get a preliminary version, pre-testing it on target users, and subsequently obtaining their feedback, which is in line with the ISPOR guidelines (Wild et al., 2005).

Ultimately, researchers should aim at conceptual equivalence (i.e., the instrument should measure the same theoretical construct in each culture) rather than literal (word-for-word) translations (Squires et al., 2013; WHO, 2018). To achieve this aim, various qualitative and quantitative methods should be used (Wild et al., 2009). Qualitative methods such as discussions, observations of users, questionnaires, and cognitive interviews enable developers to resolve any discrepancies between individual preliminary translations (Goggin et al., 2010), detect any difficulties in using the translated instrument (Ploughman et al., 2010), and elicit users' feedback (Brammen et al., 2018; Goggin et al., 2010; Piault et al., 2012; Ploughman et al., 2010). Quantitative methods may include various rating scales, as well as the item content validity index (I-CVI) and modified kappa statistics (Hsiung et al., 2016; Liu et al., 2011; Pudas-Tähkä et al., 2014). Content validity indexing is used to quantify the relevance of potential items for instrument development (Polit and Beck, 2006; Polit et al., 2007) and to evaluate the cross-cultural relevance and accuracy of instrument translations (Squires et al., 2013).

However, the methods used for translation and linguistic validation of instruments are inconsistent, and numerous problem areas exist (Squires et al., 2013). In the CR, forward-back translations are common; nonetheless, they are supported by only a limited number of methods (mainly discussions to resolve discrepancies between individual versions of translations), as revealed by a search of the literature published in the Czech language between 2012 and 2017 (Mandysová, 2017).

Study aims

The objective of the current study was to translate the IPT-R into Czech and to conduct its linguistic validation using a rigorous process based on the ISPOR guidelines (Wild et al., 2005). By doing so, the ultimate aim was to prepare a Czech version for psychometric evaluation in a subsequent clinical study that would involve Czech stroke patients.

Materials and methods

Study setting and design

This methodological study was conducted in the capital of the Pardubice region, Czech Republic; it took place between January and April 2017. The instrument translation and linguistic validation process was based primarily on the ISPOR guidelines (Wild et al., 2005). Table 1 provides a description of the methodology used (phases 1–10). This 10-phase process was supported by quantitative and qualitative methods used in other translation and linguistic validation studies: (1) Reconciliation (phase 3): Using a 3-point item accuracy scale adapted from Pudas-Tähkä et al. (2014), expert panel 1 evaluated the accuracy of the two preliminary Czech versions (1 = accurate; 2 = good but not entirely accurate; 3 = inaccurate). In each case, seven items were evaluated: instrument title (1 item), patient instructions (1 item), and individual pain descriptors (5 items). The experts' scores were analysed using the I-CVI and modified kappa (κ*) based on the methods described by Liu et al. (2011) and Polit et al. (2007). (2) Cognitive debriefing (phase 7): Using Ploughman et al.'s (2010) 5-item cognitive debriefing model (Comprehension, Retrieval, Judgment, Response, and Respondent Burden), patient observations by the researcher aimed at identifying instrument issues as the patients were asked to assess and record their pain intensity using a form with the translated IPT-R printed on it. After completing this task, each patient underwent a debriefing interview, based on Piault et al.'s (2012) procedure. Patients were to circle any words on the form that were difficult to understand and to explain why they found them difficult. Next, they were asked to paraphrase each item. Additionally, they could propose changes to the wording. Finally, the patients evaluated the feasibility of the translated instrument, using a 3-point feasibility scale (1 = very; 2 = maybe; 3 = not at all), adapted from Pudas-Tähkä et al. (2014). Specifically, they reported their opinion concerning: ease and time-burden of pain assessment using the instrument, clarity, appropriateness, and relevance of the instrument items, as well as the suitability of the graphic elements (the graduated thermometer and the numeric scale). Cognitive debriefing information was recorded on a form developed for this purpose.

Participants

Two translators (Translator A and B) conducted independent forward translations of the IPT-R into Czech (Table 1, phase 2); Translator C performed a back translation of the reconciled preliminary Czech version into English (Table 1, phase 4). All three translators met the inclusion criteria specified by the ISPOR guidelines (Wild et al., 2005) and the WHO (2018). Translator A was a professional translator; Translator B was a doctoral-level nurse with 25 years of experience in neuroscience nursing. She was familiar with pain terminology and knowledgeable of the English-speaking culture as she had completed her bachelor and master studies in North America. Both had experience in translating patient instruments, their mother tongue was Czech, and they resided in the CR. Translator C was a professional translator and native speaker of American English who was fluent in Czech (Supplementary Table 1.1).

Table 1. The translation and linguistic validation phases used according to the International Society for Pharmacoeconomics and Outcomes Research guidelines (Wild et al., 2005)

Phase	Description	Implementation
1	Preparation	Permission was obtained by the first author to translate and use the IPT-R from the copyright holder.
2	Forward translation	Two translators (Translator A and B) meeting the inclusion criteria independently translated the original IPT-R from English to Czech (Translator A completed preliminary version IPT-R-CZ-v1, and Translator B completed preliminary version IPT-R-CZ-v2).
3	Reconciliation	The two preliminary versions were evaluated by ten nursing experts (expert panel 1) using a 3-point item accuracy scale. The experts' scores were subsequently analysed using the I-CVI and modified kappa statistics. The obtained results were summarized, and four nursing experts (expert panel 2) and Translator B agreed on the final wording of the reconciled preliminary Czech version, IPT-R-CZ-v3. The final wording did not necessarily have to be contained in the two preliminary versions submitted by the translators.
4	Back translation	One translator (Translator C) meeting the inclusion criteria translated the reconciled preliminary Czech version into English.
5	Back translation review	Translator B reviewed the back translation against the original version while considering the back translator's comments and the original instrument copyright holder's comments.
6	Harmonization	Expert panel 3 (2 nursing experts) and Translator B discussed the results of the back translation review and agreed on how to resolve translation discrepancies that arose between the individual versions, which enabled them to obtain the final preliminary Czech version, IPT-R-CZ-v4.
7	Cognitive debriefing	Seven stroke patients (representative target users) were included in this phase, which consisted of patient observations, debriefing interviews (including item paraphrasing) and evaluation of the feasibility of the final preliminary Czech version, using a 3-point feasibility scale.
8	Review of cognitive debriefing results and finalization	The results of the cognitive review were reviewed by expert panel 3 and Translator B, and the copyright holder was consulted. All of them agreed on the changes arising from this review.
9	Proofreading	The final version, i.e., the IPT-R-CZ, was drafted and reviewed by expert panel 3 and the first author.
10	Final report	The final version was included in the final report, in Czech, which was part of an unpublished post-doctoral thesis.

I-CVI, item content validity index; IPT-R, the Revised Iowa Pain Thermometer.

Supplementary Table 1.1. Translator inclusion criteria

Forward translation (Translator A and B)			Back translation (Translator C)	
inclusion criteria (Wild et al., 2005; WHO, 2018)	*Criteria met?*		inclusion criteria (Wild et al., 2005; WHO, 2018)	*Criteria met?*
	T1	T2		T3
professional translator OR	yes	no	professional translator	yes
health professional[a]	no	yes	native speaker of the language of the source instrument (AmEn)	yes
native speaker of the target language (Cz)	yes	yes	fluent in the target language (Cz)	yes (B2)[c]
fluent in the source language (En)	yes	yes	does not have prior knowledge of the instrument	yes
resides in the target country (CR)[b]	yes	yes	has not seen the source (En) or any other language version before or during back translation	yes
has experience in the translation of patient instruments[b]	yes	yes		

[a] Has to be familiar with pain terminology and knowledgeable of the English-speaking culture.
[b] A preferred criterion (i.e., it is not obligatory).
[c] Level B2 according to the Common European Framework of Reference for Languages. At level B2, the person using Czech as a foreign language is an "independent user" and is able to describe medical symptoms and specify the location and type of pain as well as other symptoms (Adamovičová et al., 2005; Council of Europe, 2018).
AmEn, American English; Cz, Czech; CR, Czech Republic; En, English; T1–T3, translator 1–3.

Nursing experts (registered nurses) were recruited through a local university nursing school and a regional hospital affiliated with the university, for the purpose of evaluating the preliminary Czech versions (Table 1, phases 3, 6, 8, and 9). Based on Pudas-Tähkä et al.'s (2014) procedure, three expert panels were established (Supplementary Table 1.2). Ten nurses were involved in panel 1, which was in line with the number of experts used by other researchers for content validity indexing (Squires et al., 2013). Panel 1 experts were required to have sufficient English language skills. Three of them agreed to be on panel 2, whose members were required to have at least 6 months of experience with pain assessment in adult patients. As only one of the experts was experienced in assessing pain in stroke patients, an additional nurse was recruited through the neurological department of the hospital. Two of the panel 2 nurses with as different experience as possible (a senior nurse versus a junior nurse) agreed to be on panel 3 as well. This helped to ensure that different expert opinions would be voiced during the harmonization and finalization phases.

Supplementary Table 1.2. Characteristics of nurses on nursing expert panels

Inclusion criteria/ characteristics		Nursing experts (n = 11)										
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	N11
willing to participate		yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
expert panel membership		EP 1	EP 1	EP 1, 2	EP 1	EP 1	EP 1–3[d]	EP 1, 2	EP 1	EP 1	EP 1	EP 2, 3[d]
Expert Panel 1	doctoral nursing program graduate or student who has passed the English language exam[a] OR	yes[b]	yes[b]	no	yes[b]	yes[b]	yes[c]	yes[b]	yes[b]	yes[c]	yes[b]	n/a
	employed by the university as a lecturer of English-speaking nursing students	no	yes	yes	no	yes	no	yes	yes	yes	yes	n/a
Expert Panel 2	experience with pain assessment in adult patients	n/a	n/a	yes	n/a	n/a	yes	yes	n/a	n/a	n/a	yes
	length of nursing practice experience (years)	n/a	n/a	7	n/a	n/a	39	4	n/a	n/a	n/a	0.5
	clinical subspecialty	n/a	n/a	NICU/ AR	n/a	n/a	OR	ENT	n/a	n/a	n/a	NEU/ HC

[a] Part of the doctoral nursing program curriculum; [b] PhD program student; [c] PhD program graduate; [d] For EP 3, the most senior nurse and the most junior nurse were included (see Length of nursing practice experience).
AR, anaesthesia and resuscitation; ENT, ear, nose, and throat; EP, expert panel; HC, home Care; N1–N11, nursing expert 1–11; n/a, not applicable; NEU, neurology; NICU, neurological intensive care unit; OR, operating room

As for cognitive debriefing, Wild et al. (2005) recommend involving 5–8 patients from the target population. Thus, this was the planned sample size. Patients were recruited via convenience sampling during a 2-week period in April 2017, using the same setting and inclusion criteria that were planned for the subsequent clinical study (Table 1, phase 7). Specifically, the participants were recruited in the neurological department of a regional hospital, and the inclusion criteria were: clinically stable; Glasgow Coma Scale score ≥ 14; willing and able to sign the informed consent; able to cooperate and understand simple instructions; and native speakers of Czech. The Mini-Cog was used to determine the participants' cognitive function (0–2 = abnormal; 3–5 = normal) (Borson et al., 2006).

The Revised Iowa Pain Thermometer

The IPT-R contains a combination of a graphic, graduated thermometer (from white to red), vertical numeric scale (0–10), and five pain descriptors, as depicted in Ware et al.'s (2015) article. The translation and linguistic validation focused on the translation of the instrument title (translation item 1), the instruction for use: *"Circle a number on the Pain Thermometer below that best represents the intensity of your pain right now"*, (translation item 2), and the 5 pain descriptors: *"No Pain"*, *"Mild Pain"*, *"Moderate Pain"*, *"Severe Pain"*, and *"The Most Intense Pain Imaginable"* (translation items 3–7).

Data analysis

For each preliminary Czech version, 70 item accuracy ratings were obtained (seven translation items by ten panel 1 nurses). Subsequently, for each translation item, I-CVI and κ* were calculated and interpreted, based on the formulas described by Polit et al. (2007) and Liu et al. (2011). Specifically, I-CVI = number of experts giving an accuracy rating of 1 to a translation item/total number of experts, and κ* = (I-CVI – Pc)/1 – Pc (Pc is the probability of a chance agreement that the accuracy rating of a translation item = 1); Pc = [10! / A! × (10 – A)!] × 0.510 (Liu et al., 2011; Polit et al., 2007). An I-CVI score of ≥0.78 on each item was considered ideal; the κ* values were interpreted as follows: fair = κ* of 0.40–0.59, good = κ* of 0.60–0.74, and excellent = κ* > 0.74 (Polit et al., 2007). The obtained values guided panel 2 as they determined the final wording of the reconciled preliminary Czech version.

Any issues noticed by the researcher during patient observations were classified into one of the five categories based on Ploughman et al.'s (2010) procedure. The results of paraphrasing were used to calculate Item comprehension rate (ItCR) using Piault et al.'s (2012) method: ItCR = (number of patients who paraphrased item correctly/total number of patients) × 100 (Piault et al., 2012). Panel 3 evaluated the results, together with the patients' instrument feasibility ratings and their suggestions on how to change the instrument, which helped them to finalize the Czech version.

Results

Translation process

There was a limited agreement between Translators A and B, as they proposed identical wording for only two items: *"No Pain"* and *"Mild Pain"* (Supplementary Table 1.3). While Translator B retained the word *"thermometer"* (*"teploměr"* in Czech) in the title and the instruction for use, Translator A replaced it with *"scale"* (*"škála"*).

I-CVI scores and κ* values determined by panel 1 nurses concerning preliminary version 1 (IPT-R-CZ-v1) ranged from 0.1 and 0.09 (for item *"Severe Pain"*), respectively, to 1.0 for items *"Mild Pain"* and *"No Pain"* (Table 2). As for preliminary version 2 (IPT-R-CZ-v2), panel 1 nurses' I-CVI scores and κ* values ranged from 0.5 and 0.34 (for the instrument title), respectively, to 1.0 for items *"Severe Pain"*, *"Mild Pain"*, and *"No Pain"*.

Supplementary Table 1.3. Preliminary and final Czech versions of the IPT-R

Translation item	Item type	Original IPT-R (Ware et al., 2015)	Czech versions of the IPT-R				
			Preliminary version 1 (IPT-R-CZ-v1)	Preliminary version 2 (IPT-R-CZ-v2)	Preliminary reconciled version (IPT-R-CZ-v3)	Final preliminary version (IPT-R-CZ-v4)	Final version (IPT-R-CZ)
1	title	The Iowa Pain Thermometer-Revised	Iowská škála bolesti – revidovaná verze	Revidovaný Iowský teploměr bolesti	Revidovaná verze Iowské stupnice bolesti	Revidovaná verze Iowské stupnice bolesti	Stupnice bolesti
2	instruction for use	Circle a number on the Pain Thermometer below that best represents the intensity of your pain right now	Na níže znázorněné škále bolesti zakroužkujte číslo, které právě teď nejlépe odpovídá intenzitě Vaší bolesti	Zakroužkujte na níže uvedeném teploměru bolesti číslo, které nejlépe vyjadřuje intenzitu Vaší bolesti, kterou právě teď máte	Zakroužkujte na níže uvedené stupnici bolesti číslo, které nejlépe vyjadřuje intenzitu Vaší aktuální bolesti	Zakroužkujte na níže uvedené stupnici bolesti číslo, které nejlépe vyjadřuje intenzitu Vaší aktuální bolesti	Na stupnici bolesti zakroužkujte číslo podle toho, jak silnou bolest máte PRÁVĚ TEĎ
3	pain descriptor	the most intense pain imaginable	největší představitelná bolest	nejsilnější bolest, jakou si dovedu představit	nejsilnější bolest, jakou si dovedu představit	nejsilnější bolest, jakou si dovedu představit	nejsilnější bolest, jakou si dovedu představit
4	pain descriptor	severe pain	prudká bolest	silná bolest	silná bolest	silná bolest	silná bolest
5	pain descriptor	moderate pain	střední bolest	středně silná bolest	středně silná bolest	středně silná bolest	středně silná bolest
6	pain descriptor	mild pain	mírná bolest	mírná bolest	mírná bolest	mírná bolest	mírná bolest
7	pain descriptor	no pain	žádná bolest	žádná bolest	žádná bolest	žádná bolest	žádná bolest

IPT-R, the Revised Iowa Pain Thermometer

Table 2. Quantitative analysis of Preliminary Czech versions 1 and 2 by panel 1 experts (*N* = 10)

	TI[b]	PV1–1	PV1–2	PV1–3	PV1–4	PV1–5	PV1–6	PV1–7	PV2–1	PV2–2	PV2–3	PV2–4	PV2–5	PV2–6	PV2–7
	Item type	T	IU	PD	PD	PD	PD	PD	T	IU	PD	PD	PD	PD	PD
Accuracy ratings[a]	N1	2	2	1	2	1	1	1	1	1	1	1	2	1	1
	N2	2	2	2	2	1	1	1	2	1	1	1	1	1	1
	N3	2	2	2	2	1	1	1	1	1	1	1	1	1	1
	N4	2	2	2	1	1	1	1	1	1	1	1	1	1	1
	N5	2	2	1	2	2	1	1	1	1	1	1	1	1	1
	N6	1	1	2	2	2	1	1	2	2	1	1	1	1	1
	N7	2	2	1	2	1	1	1	1	1	2	1	2	1	1
	N8	1	1	2	2	2	1	1	2	1	1	1	1	1	1
	N9	2	2	2	3	1	1	1	2	2	2	1	2	1	1
	N10	1	1	1	2	1	1	1	2	2	2	1	2	1	1
	A	3	3	4	1	7	10	10	5	7	7	10	6	10	10
	I-CVI	0.30	0.30	0.40	0.10	0.70	1.00	1.00	0.50	0.70	0.70	1.00	0.60	1.00	1.00
	Pc	0.117	0.117	0.205	0.010	0.117	0.001	0.001	0.246	0.117	0.117	0.001	0.205	0.001	0.001
	κ*	0.21	0.21	0.25	0.09	0.66	1.00	1.00	0.34	0.66	0.66	1.00	0.50	1.00	1.00

[a] Using an item accuracy rating scale: 1 = accurate; 2 good but not entirely accurate; 3 = inaccurate; [b] Pain descriptors are ordered from *"The Most Intense Pain Imaginable"* (translation items PV1-3 and PV2-3) to *"No Pain"* (translation items PV1-7 and PV2-7). A, number of experts who gave an accuracy rating of 1; I-CVI, item content validity index; IU, instruction for use; κ*, modified kappa; *N*, total number of experts; N1–N10, nursing expert 1–10; Pc, the probability of chance agreement; PD, pain descriptor; PV, preliminary version; T, title; TI, translation item

For the preliminary reconciled version (IPT-R-CZ-v3), panel 2 experts retained the wording of the two pain descriptors translated identically by both translators and accepted the remaining pain descriptor translations contained in IPT-R-CZ-v2. As for the title, they agreed on replacing *"thermometer"* with *"scale"*, using yet a different Czech term (*"stupnice"*), meaning *"graduated scale"*. They agreed on changing the wording of the instruction for use by replacing *"pain right now"* with *"current pain"*. The described changes were reflected in the back translation. Apart from this, there were only minor discrepancies between the original and the back-translated versions of the IPT-R, which were resolved in the harmonization phase, and the final preliminary Czech version (IPT-R-CZ-v4) was formulated.

Table 3. Patient demographic and clinical characteristics (*N* = 7)

Characteristics	P1	P2	P3	P4	P5	P6	P7
type of stroke[a]	I	I	I	H	I	I	I
gender[a]	M	M	F	M	M	F	M
age (years)[a]	74	66	61	68	70	66	63
educational level[b]	SV	SP	SV	SV	SV	SV	SV
GCS (score)[c]	15	15	14	15	15	15	15
mini-cog (score)[c]	3	1	1	3	3	4	2

[a] Data obtained from the medical records; [b] Verbal information provided by the patients; [c] Data obtained by testing the patients. Mini-Cog scoring: 0–2 = abnormal; 3–5 = normal (Borson et al., 2006).
F, female; GCS, Glasgow Coma Scale; H, haemorrhagic; I, ischaemic; M, male; *N*, total number of patients; P1–P7, patient 1–7; SP, secondary professional; SV, secondary vocational

Linguistic validation process

As for cognitive debriefing, seven stroke patients were involved (5 men; average age 67.3 ± 4.4) (Table 3). Six patients had a GCS score = 15; one patient had a GCS = 14. Four patients had a normal Mini-Cog result.

Patient observations revealed various issues as they used the IPT-R-CZ-v4 (Table 4). The highest and lowest comprehension rate was for pain descriptor *"The Most Intense Pain Imaginable"* (85.7%) and instrument title (14.3%), respectively (Table 5). Three patients merely repeated the pain descriptors *"Severe Pain"*, *"Mild Pain"*, and *"No Pain"*, and two patients did so for the pain descriptor *"Moderate Pain"*. Verbal feedback revealed that three patients found the instrument title difficult to understand and recommended changing it. One patient mistakenly read the word "Iowa" as "lowa" (replaced letter "i" with letter "l"). One patient recommended deleting *"No Pain"* (and deleting "0" from the numeric scale) as he thought "no pain" was irrelevant. Feasibility ratings indicated a favourable attitude concerning most aspects of the instrument (Table 6).

Based on the obtained results, the final Czech version (IPT-R-CZ) was formulated. While the title was retained for professional communication, it was simplified for patient use to *"pain scale"*. The instruction for use was simplified by replacing the term *"current pain"* with *"pain right now"*, written in uppercase letters for emphasis (Supplementary Chart 1).

Table 4. Summary of instrument issues experienced by patients (*N* = 7)

Domain assessed (Ploughman et al., 2010)	Observed issues	Patient
comprehension	Patient did not read the instruction for use independently.	P1, P2, P3, P4, P5, P6
	Required re-explanation of the instruction for use.	P1, P2, P3, P5
retrieval (relevant and correct information)	Described pain intensity concerning an incorrect moment.	P5, P6, P7
judgment (formulation of response)	Response formulated using a pain descriptor rather than the provided numeric scale.	P4
response (matching the response to the category or "best fit")	Unsure of the selected pain intensity.	P1, P3, P4
respondent burden (cognitive, navigational, and temporal effort required)	Had to be re-orientated to the numeric scale.	P1, P2, P3, P5
	Had difficulty using the required documentation method (circling a number).	P2, P3, P5
	Excessive temporal burden (required > 5 minutes).	P3

N, total number of patients; P1–P7, patient 1–7.

Table 5. Paraphrasing results and patients' opinion on item wording (*N* = 7)

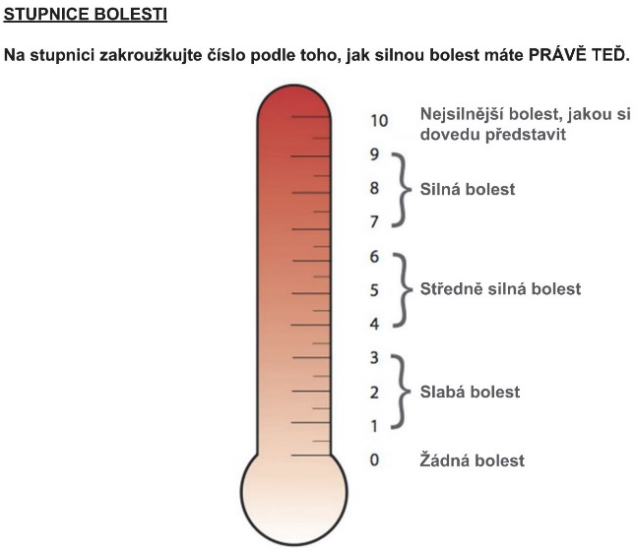
		Paraphrasing		Opinion on wording		
TI[a]	Item type	Correctly paraphrased (*n*)	ItCR (%)[b]	Wording unsuitable (*n*)	Wording is suitable (*n*)	No opinion on wording (*n*)
1	T	1	14.3	3	3	1
2	IU	2	28.6	1	4	2
3	PD	6	85.7	0	6	1
4	PD	3	42.9	0	7	0
5	PD	4	57.1	0	6	1
6	PD	3	42.9	0	6	1
7	PD	3	42.9	1	5	1

[a] Pain descriptors are ordered from *"The Most Intense Pain Imaginable"* (translation item 3) to *"No Pain"* (translation item 7); [b] Patient P3 did not understand the task and her responses are not included in the calculation of the Item comprehension rate. ItCR, Item comprehension rate; IU, instruction for use; *N*, total number of patients; n, number of patients; PD, pain descriptor; T, title; TI, translation item.

Table 6. Instrument feasibility ratings expressed by patients (*N* = 7)

Pain assessment using the translated IPT-R	1 – very	2 – maybe	3 – not at all
method is easy	P1, P4	P2, P5, P6, P7	
method is quick	P1, P2, P4, P5, P6	P7	
method is clear	P1, P2, P4, P5, P6	P7	
method is appropriate	P1, P4, P5, P6	P7	P2
all parts of the instrument are relevant	P1, P2, P4, P5, P6, P7		
graphic elements (the graduated thermometer and the numeric scale) are suitable	P1, P2, P4, P6, P7	P5	

IPT-R, the Revised Iowa Pain Thermometer; *N*, total number of patients; P1–P7, patient 1–7.



Supplementary Chart 1. The Revised Iowa Pain Thermometer-Czech (IPT-R-CZ)

IPT-R, the Revised Iowa Pain Thermometer
The IPT-R (Ware et al., 2015) was translated and printed with permission. © Keela Herr, College of Nursing, The University of Iowa, USA.

Discussion

This study examined our experiences of using the 10-phase ISPOR guidelines to translate the IPT-R into Czech and to linguistically validate it, by involving a mix of professionals (translators and nursing experts) and a group of target users – stroke patients. The process was lengthy and required language skills and nursing knowledge. Similar experiences have been described by other authors (Brammen et al., 2018; Goggin et al., 2010).

The limited agreement between Translators A and B reinforces the importance of using more than one forward translator. The obtained item content validity index and κ* values suggest that IPT-R-CZ-v2, created by Translator B (i.e., a health professional), was more accurate than IPT-R-CZ-v1. These findings underscore the importance of involving, in the translation process, a health professional with solid source language skills and good knowledge of the target country clinical terminology, which is in line with Wild et al.'s (2005) recommendations to carry out one of the forward translations by a target-country person who comes from a healthcare background (Wild et al., 2005). In fact, panel 2 agreed on a reconciled version (IPT-R-CZ-v3) that retained the wording of all five pain descriptors contained in IPT-R-CZ-v2 and of only 2 pain descriptors contained in IPT-R-CZ-v1. Their decision not to accept the wording of items with low I-CVI and κ* is in agreement with Squires et al.'s (2013) comment that content validity indexing consistently predicts challenging translation items. On the other hand, not all expert panel decisions were appropriate, and just like in Brammen et al.'s (2018) study, unintentional modification of translations occurred. Specifically, panel 2 rejected the Czech wording *"právě teď"* (meaning pain *"right now"*) contained in the instruction for use and employed by both Translator A and B and replaced it with *"aktuální"* (meaning *"current"* pain). This wording appeared not only in IPT-R-CZ-v3 but also in IPT-R-CZ-v4, developed by panel 3. Nevertheless, based on cognitive debriefing results with patients, this specific wording was changed back to *"right now"* in the final version. This experience underscores the importance of involving representative users, i.e., patients with a specific health condition, as nurses may become blinded to wording that may be perceived, by patients, as difficult.

Using several cognitive debriefing methods enabled developers to compare and contrast the results obtained for individual patients across the methods and for the entire patient group obtained through each method. Some results were consistent, e.g., the title was too difficult based on paraphrasing as well as the patients' subjective opinion. Similarly, six patients did not read the instruction for use independently, four patients required its re-explanation, and only two paraphrased it correctly. Nonetheless, most patients found the wording of the instruction for use suitable. It is possible that more patients would have read the instruction for use independently if the researcher had not been present during the task. Likewise, while instrument feasibility ratings were favourable, and all seven patients thought that all parts of the instrument were "very relevant", cognitive interview revealed that one patient found *"No pain"* irrelevant and recommended deleting this item. The positive feasibility ratings could have been caused by the patients' desire to please the researcher who was recording their scores.

Overall, paraphrasing was difficult. One patient with the lowest GCS score (= 14) of all the patients and a low Mini-Cog score (= 1) did not understand the task and provided irrelevant information, although she was able to respond adequately to the remaining tasks. Some patients tended to repeat relatively "easy" items (most pain descriptors) even though they were able to paraphrase some of the more complicated items correctly. Thus, their comments that the meaning of such items

was "clear" or that they "lacked the words" suitable for paraphrasing could have been an accurate explanation of their reasons and attitude. These findings are in contrast to Piault et al.'s (2012) study, in which the obtained ItCR exceeded 90% for most of the paraphrased items, including the instrument title, instructions, questions, and response options. However, their subjects were patients with self-reported urinary problems and no cognitive problems.

Despite the mentioned difficulties with paraphrasing, the findings were valuable in that they revealed that the patients tended to think concretely. The individual pain intensity descriptors were likened to specific conditions that, in the patients' opinion, produced pain at that particular level. For example, *"The Most Intense Pain Imaginable"* was compared to pain experience after a "leg amputation" or "fractured limb". These findings supported the decision to retain the word *"scale"* rather than *"thermometer"* in the title and instruction for use, as *"thermometer"* could confuse stroke patients and could make them think that they should report their temperature rather than pain. This decision was in line with the mentioned recommendation to ensure the conceptual equivalence of the translated text while avoiding any ambiguities (WHO, 2018; Wild et al., 2005).

Limitations

The ISPOR guidelines expect involvement of a rather large team whose members need to assume various roles and meet specific selection criteria, which was difficult to achieve. Thus, the first author accepted several roles. However, measures were taken to limit the possible effect of such multiple involvements. Specifically, as she performed one of the translations (as Translator B), she did not see Translator A's version before completing her version in order not to be influenced. Next, she was not involved in the evaluation of her version. Finally, the identity of the translators was not revealed to any other person involved in the process.

It could also be argued that the title of the instrument should not have been included in the translation and linguistic validation process, as the form with the original IPT-R, provided by the copyright holder, did not include the title. If it had not been included, the results would have been more favourable. Similarly, the methodology of translation of the FPS-R focuses solely on the translation of the instruction for use, not the title (IASP, 2018). However, some experts translate titles of instruments intended for patient use, e.g., Piault et al. (2012).

Conclusions

ISPOR guidelines were used to translate the IPT-R into Czech. The process was demanding, as it was difficult to recruit nurses and translators meeting the determined selection criteria; furthermore, many steps were required. However, using a less stringent methodology would have probably produced a Czech version that would not be as suitable for the intended target group, i.e., Czech stroke patients. Other authors have described such findings as well.

The findings are relevant to nursing researchers worldwide as they underscore the importance of involving representative users, e.g., patients with a specific health condition, in the translation and linguistic validation of instruments intended for self-report. Patient involvement can help identify problem areas that may not be recognized by nurses and other experts involved in the process. Nurses need to consider whether it is appropriate to translate titles of instruments intended for patient use – the ISPOR guidelines do not address this specific issue. Although the recommendation arising from our findings is not to burden patients with difficult titles, we think that nurses should know the official title, to promote evidence-based practice.

Conflict of interests

The authors have no conflict of interests to disclose.

Ethical aspects

The ethics committee of the regional hospital where the study took place approved the study, in January 2017. The participants gave written informed consent before the initiation of data collection. They were assured of their anonymity and confidentiality, and it was explained that they could withdraw at any time without any consequences.

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Překlad Revidované verze Iowské stupnice bolesti do českého jazyka a její lingvistická validace pro výzkumné šetření zaměřené na české pacienty s cévní mozkovou příhodou

Souhrn

Cíl: Pro pacienty s cévní mozkovou příhodou by mohlo být přínosem využití vertikálně prezentovaných sebehodnoticích škál bolesti. Tyto škály nejsou v českém jazyce k dispozici. Cílem bylo do českého jazyka přeložit Revidovanou verzi Iowské stupnice bolesti a provést její lingvistickou validaci tak, aby mohla být využita českými pacienty s cévní mozkovou příhodou.

Metoda: Do této metodologické studie, probíhající od ledna do dubna 2017, byli zapojeni tři překladatelé, tři panely odborníků z oboru ošetřovatelství a sedm pacientů s cévní mozkovou příhodou. Celý proces byl řízen v souladu s guidelines International Society for Pharmacoeconomics and Outcomes Research. Tento proces, skládající se z 10 fází, byl podpořen kvantitativními a kvalitativními metodami, jako jsou index obsahové validity a výpočty modifikovaného koeficientu kappa, diskuse s odborníky z oboru ošetřovatelství i kognitivní rozhovor s pacienty.

Výsledky: Předběžná česká verze byla vytvořena na základě indexu obsahové validity, hodnot modifikovaného koeficientu kappa a zpětné vazby od odborníků. Kognitivní rozhovor ukázal, že většina pacientů měla s použitím nástroje potíže.

Závěr: Proces překladu a lingvistické validace byl náročný, protože bylo obtížné provést nábor sester a překladatelů splňujících stanovená výběrová kritéria; navíc se proces skládal z mnoha kroků. Avšak využití méně striktní metodologie by pravděpodobně vedlo k tvorbě české verze, která by pro zamýšlenou cílovou skupinu – české pacienty s cévní mozkovou příhodou – nebyla tak vhodná. Naše zjištění zdůrazňují, že je důležité do procesu překladu a lingvistické validace sebehodnoticích nástrojů zapojit reprezentativní uživatele, to znamená pacienty s konkrétním onemocněním. Psychometrické vlastnosti české verze budou zjišťovány ve výzkumném šetření, které bude zaměřené na české pacienty s cévní mozkovou příhodou.

Klíčová slova: Ošetřovatelství; Bolest; Posuzování bolesti; Sebehodnocení; Cévní mozková příhoda

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