



ORIGINAL ARTICLE

English translation and cross-cultural validation of the patient-reported outcome measurement-haemorrhoidal impact and satisfaction score (PROM-HISS)

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Abstract

Aim: The aim of this study was to translate the Dutch patient-reported outcome measurement-haemorrhoidal impact and satisfaction score (PROM-HISS) to English and perform a cross-cultural validation.

Method: The ISPOR good practice guidelines for the cross-cultural validation of PROMs were followed and included two steps: (1) Two forward and two backward translations. The forward translation concerned the translation from the source language (Dutch) to the target language (English), performed by two independent English speakers, one medical doctor and one nonmedical. Subsequently, a discussion about discrepancies in the reconciled version was performed by a stakeholder group. (2) Cognitive interviews were held with patients with haemorrhoidal disease (HD), probing the comprehensibility and comprehensiveness of the PROM-HISS.

Results: Discrepancies in the reconciled forward translation concerned the terminology of HD symptoms. Furthermore, special attention was paid to the response options, ranging from “not at all”, indicating minor symptoms, to “a lot”, implying many symptoms. Consensus among the stakeholder group about the final version of the translated PROM-HISS was reached. Interviews were conducted with 10 native English-speaking HD patients (30% female), with a mean age of 44 years (24–83) and primarily diagnosed with grade II HD (80%). The mean time to complete the PROM-HISS was 1 min 43 s. Patients showed a good understanding of the questions and response options, found all items relevant and did not miss important symptoms or topics.

Conclusion: The translated English language PROM-HISS is a valid tool to assess symptoms of HD, its impact on daily activities and patient satisfaction with HD treatment.

KEYWORDS

Haemorrhoidal Disease, Patient-Reported Outcome Measure, PROM

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INTRODUCTION

Haemorrhoidal disease (HD) is the most common type of anorectal complaint with prevalence rates up to 44% and it has a negative impact on patients' quality of life [1, 2]. Symptoms of HD include blood loss, prolapse, pain, itching and soiling [3]. Qualitative research indicates that patients with HD suffer from these symptoms and the symptoms have an impact on their daily life [4]. Furthermore, a patient's perspective on treatment success might vary from the perspective of the physician. The European Society of Coloproctology (ESCP) core outcome set (COS) for HD, published in 2019, emphasizes the importance of the patient's perspective in both daily practice and in research settings. The primary outcome of the COS are the symptoms of HD, and the secondary outcome is treatment satisfaction [5]. These outcomes are best measured by a patient-reported outcome measure (PROM), collecting the outcome directly from the patient without interpretation by healthcare professionals or others [6].

Recently, a PROM specifically for patients suffering from HD was developed and validated: The PROM-haemorrhoidal impact and satisfaction score (PROM-HISS) [7]. The PROM-HISS was based on interviews with HD patients and its development and testing closely followed the COSMIN-guidelines [4, 8]. The COSMIN-guidelines are a standardized tool used to guide the study design, or reporting of studies, on measurement properties [9]. The PROM-HISS was found to be a valid and reliable tool for evaluating the symptoms of HD, the disease's impact on daily activities and the patient's satisfaction with HD treatment [7].

Currently, the PROM-HISS is only available in Dutch. To ensure uptake of the primary outcome of the COS to as wide a geographical area as possible, the next step is the translation of the PROM-HISS into multiple languages. This study describes the English language translation and cross-cultural validation process of the PROM-HISS.

METHODS

The design of this study consisted of two parts: (1) Translation of the PROM-HISS from Dutch to English; and (2) the cross-cultural validation of the English language PROM-HISS in the UK. In the process of translation and cross-cultural validation, the formal guidelines for translation of PROMs were followed [10].

Translation

Patient evaluation is recommended during the translation process because cultural nuances may differ between countries [10]. The translation of the PROM-HISS entailed a forward and a backward translation. The forward translation from source language (Dutch) to target language (English) was performed by two people, of which one had a medical background (medical doctor) and the other did not (air traffic controller). Both were native English speakers who also

What does this paper add to the literature?

This study shows that the translated English patient-reported outcome measure-haemorrhoidal impact and satisfaction score (PROM-HISS) is a valid tool to assess symptoms of haemorrhoidal disease, impact on daily activities and satisfaction with treatment. The PROM-HISS can be used in clinical research and practice.

had an excellent understanding of the Dutch language. The translators were asked to file a report with their translation, highlighting challenging phrases or uncertainties.

The two translations were combined and if translations differed, consensus on the translation was sought in the stakeholder team through discussion. The stakeholder team consisted of a Dutch (SB) and a Scottish (but fluent in English) colorectal surgeon (AW), a specialty research doctor (RC), a Scottish-based resident in colorectal surgery (HO), a Dutch professor in health technology assessment (HTA), a Dutch senior researcher in HTA (MK), and a Dutch clinical researcher (SK). The combination of the two forward translations including the adjustments from the stakeholder team was named FT1-2 (forward translation from translator 1 and translator 2).

Subsequently, version FT1-2 was used for the backward translation, in which the questionnaire was translated from the target language (English) to the source language (Dutch), by two native Dutch speakers. One had a master's degree in the English language and literature and the second one was a professional English translator. Both had no medical background, were not informed about the explored concepts and were blind to the original version of the PROM-HISS. The combined backward translation was discussed in the stakeholder team and after consensus was reached on all items, this version was named BT1-2 (backward translation from translator 1 and translator 2). A written report of the synthesis of the two forward- and backward translations was stored.

The English-speaking stakeholder team members were asked about the relevance and comprehensiveness of the items in FT1-2 from their perspective, ensuring equivalence between the source and target version of the questionnaire [11]. Comments and adjustments proposed by the stakeholder team were discussed and used to create a prefinal version of the translated PROM-HISS, FT3, to be used in the subsequent steps of the cross-cultural validation.

Cross-cultural validation

The acceptability of the translated version for the target population was tested to ensure that the intended meaning of the PROM-HISS was not compromised by the translation. Interviews with patients were performed according to the "cognitive interview principle", in which the participant's comprehension of the questions and

their response options is evaluated [12, 13]. This formal research method makes thought processes more explicit as participants are prompted to think aloud as they complete the PROM-HISS. Patients were recruited from one hospital in the UK by their treating physician at the outpatient clinic. Patients were invited if they were older than 18 years old, diagnosed with HD grade I–IV and if they were equipped with sufficient understanding of the English language, both in writing and speaking. Eligible patients were only included if written informed consent was obtained. Participants were interviewed face-to-face by a native English-speaking specialty research doctor (RC).

Interviews were scheduled at the outpatient clinic and recorded with an audio recorder. Participants were asked to complete the questionnaire, after which they were interviewed about the comprehensiveness of the instructions, questions, and response options (face validity). Furthermore, patients were asked about item relevance and missing domains or items (content validity). Also, the time needed to fill out the questionnaire was recorded. Results of the cognitive interviews were summarized in a report and served as groundwork for the establishment of the final translated PROM-HISS (English).

RESULTS

Translation

The two forward translations were discussed in the stakeholder group and minor adjustments were made in the final translation of the PROM-HISS, which was named FT3.

Identical to the Dutch version of the PROM-HISS, the English version consists of three domains: (1) HD symptoms, (2) impact of HD on daily activities, and (3) satisfaction with treatment. The first domain comprises of five symptom-items, the second and the third domain contain one item.

One of the topics discussed concerned the difference between “affected” and “experienced” to indicate the burden of the five symptoms asked in the first domain. Even though “to affect” can be used to probe “a reaction to a thought or an experience”, the literal translation is “to influence” which does not match the Dutch source word. Furthermore, the stakeholder team agreed that the term “affected” could have negative implications and an emotional charge, which could steer the patient in its choices. Hence, the term “experienced” was selected.

Next, the five items in the first domain were evaluated. Blood loss and pain were translated identically by the two forward translators and therefore did not require attention by the stakeholder team. The third item, prolapse, was translated once into swelling/protrusion and once into lumps/swelling from the anus. Bearing in mind that “lumps” are usually associated with breast pathologies [14], the stakeholder team agreed on the alternative wording, “swelling/protrusion from the anus”. For the fourth item, “itching anus” was preferred over “irritable anus”, seeing that the latter can also

be interpreted as pruritis ani [15]. The fifth item was translated as “soiling” by the translator with a medical background, reflecting the medical term, while the native forward translator defined it as “fluid loss from the anus”. In view of the fact that the PROM-HISS is for patients without a medical background or functional illiteracy, the lay man's wording was elected [16].

The response options for the first domain are scored using a 5-point Likert scale and were defined as (1) “not at all”, (2) “very little”, (3) “somewhat”, (4) “quite a bit”, and (5) “a lot”. The wording “somewhat” was preferred over “reasonable” due to the greater comprehensibility in the English language.

Regarding the second domain, consensus was reached on the phrase “hindered by daily activities” instead of “influenced by daily activities”. The PROM-HISS aims to assess the burden of the symptoms of HD and “to hinder” relates more to limitations experienced by the patient but caused by the disease. This domain is scored on a numeric rating scale from 0 to 10, where 0 was indicated as “not hindered at all” and 10 as “very hindered”.

The third domain, satisfaction with HD treatment, was identically translated by the two forward translators. This domain is scored on a numeric rating scale from 0 to 10, where 0 was indicated as “not satisfied at all” and 10 as “very satisfied”. The term “very” was selected instead of “extremely” in the last response option, considering that the latter could be interpreted as an exaggeration.

Cross-cultural validation

Individual interviews were conducted with 10 native English-speaking HD patients (30% female), with a mean age of 44 years (24–83) and primarily diagnosed with grade II HD (80%). The mean time to complete the PROM-HISS was 1 min 43 s and instructions, items and response options were generally well understood. Some patients had difficulty understanding the item “fluid loss”, because they had not experienced this complaint. Patient E described it as: “[Fluid loss is] not so much that it is not relevant to haemorrhoids, probably something that was not relevant to my personal experience (...)” (patient E, male, 30 years old, grade II HD). As fluid loss is one of the five most prevalent HD symptoms, this item was not amended in the PROM-HISS [3].

Furthermore, one patient indicated that he had been trying to self-medicate for quite a long time before presenting at the hospital and wondered if over-the-counter remedies should be part of the questionnaire (patient I, female, 54 years old, grade II HD). As the main interest of the PROM-HISS is satisfaction of in-hospital HD treatment, questions about previous HD medications were not included.

Lastly, sometimes it was not clear for patients which timeframe was used in the PROM-HISS to recall their complaints of HD. Patient F stated the following about this: “(...) there's probably science or who knows the reasons for asking for a specific week, but if you had a lot of bleeding a few weeks ago (...) and then you haven't seen any for a few weeks, you might find the answer for that question, like

maximize the diversity within the study participants, based on age, gender, HD grading, and educational level. These criteria have been selected to ensure a wide variety of contrasting views and experiences within the study sample. Despite the fact that PROMs should be accessible and comprehensible for all sections of society, patients with low literacy skills and learning disabilities are often excluded from the development process [16]. In the validation process of the English language PROM-HISS, we included all degrees of educational level.

Lastly, as with all disease-specific PROMs, the PROM-HISS is restricted to its domains of relevance, that is, HD symptoms. Other important health-related quality of life domains are not measured. Thus, we strongly recommend health care providers use the PROM-HISS as a starting point to commence an open conversation with their patients.

With the translation of the PROM-HISS to English, we crossed a language border to implement the use of the PROM-HISS in international clinical settings and therefore help foster the communication between physician and patient. Future work will focus on multiple language iterations of the PROM-HISS to facilitate widespread utilization of this tool and to further test on the psychometric properties of the translated and validated questionnaires.

CONCLUSION

The translated PROM-HISS is a valid tool to assess symptoms of HD, impact on daily activities and satisfaction with treatment in English-speaking clinical HD practice and research settings.

AUTHOR CONTRIBUTIONS

All authors whose names appear on the submission (1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; (2) drafted the work or revised it critically for important intellectual content; (3) approved the version to be published; and (4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS APPROVAL

Ethical clearance for this study was obtained from the Maastricht University Medical Centre ethical review board (file number 2022-3042).

CONSENT TO PARTICIPATE

Informed consent was obtained from all individual participants included in the study.

CONSENT FOR PUBLICATION

Consent for publication was obtained from all participants.

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APPENDIX A

Interview guide cross-cultural adaptation PROM-HISS 26th of July 2022

A.1. | Participants

Participants will be identified in the outpatient clinic at Raigmore Hospital, Inverness. Eligible participants are adult patients (m/f) diagnosed with haemorrhoidal disease (HD) grade I–IV. A purposive approach to sampling is selected with the aim of maximizing diversity within the study participants. The selected criteria aim to ensure that subsets within the study population that may express contrasting views and experiences are represented.

Key criteria are:

- Age
- Gender/sex
- Grading HD
- First language
- Level of education

A.2. | Patient interview

A cognitive interview approach will be used to explore a patient's experience with the PROM-HISS. Interviews will be recorded and transcribed verbatim.

A.3. | Interview guide

- Introduction:
 - Thank you for participating in the study.
 - The aim of today's interview with you is to ensure that the questionnaire that I will ask you to fill out in a moment is clear to you. This questionnaire, we call it the PROM-HISS, is a questionnaire about the experienced burden of symptoms of HD. At the moment, this questionnaire is only available in Dutch. In order to make this questionnaire also available to English speaking patients, we have translated the PROM-HISS from Dutch to English. Now, it is important to make sure that English and Dutch speaking patients have the same understanding of the questions and the response options, so that we can compare or combine the outcomes of their questionnaires. Furthermore, we are interested to see if you may miss a particular issue related to HD complaints in the questionnaire.
 - We ask you to complete the PROM-HISS and to think out loud, so to express what you are feeling when you are answering the questions. If you encounter any difficulties during completion of this questionnaire, you can indicate this. After completion, you can make further comments about the questionnaire and we will also ask you a few things.
 - We would like to audio-record this interview, is that ok with you?
- Completion of the PROM-HISS:
 - Audio-recording is started.
 - Patient completes the PROM-HISS in presence of Hannah O'Neill at the outpatient clinic of Raigmore Hospital, Inverness.
 - The patient is asked to "think aloud" as much as possible (i.e., express thoughts and feelings when reading the questions and selecting the response option)
 - Patients may raise any questions or difficulties about completing the questionnaire.
- After completing the PROM-HISS:
 - Were you able to complete the PROM-HISS? (Y/N)
 - Did you find it easy or difficult, or something in-between?
 - Did you read and understand the instructions in the questionnaire? (Y/N)
 - If no, which part or text component did you not understand and can you explain why? Do you have a suggestion what could be changed?
 - Did you read and understand the questions in the questionnaire? (Y/N)
 - If no, which question(s) or text component did you not understand and can you explain why? Do you have a suggestion what could be changed?
 - Did you understand the response options? (Y/N)
 - If no, which one(s) did you not understand and can you explain why? Do you have a suggestion what could be changed?
 - Did you miss any items or questions regarding your complaints of HD that are relevant for you?
 - If yes, which ones and could you try to explain why?

- Where there any items or questions that you found irrelevant?
 - If yes, which ones and could you try to explain why?
- These were our questions about the questionnaire. Is there anything else that you would like to say about the questionnaire?
- Thank you very much for your participation and time.

@ Rowena: How long did the completion of the PROM-HISS take. Please record this in minutes.

APPENDIX B

The questions below are about the symptoms you experience from haemorrhoids. There are no right or wrong answers.

To what extent have you experienced the symptoms listed below in the PAST WEEK?

(select the answer that applies)

	Not at all	Very little	Somewhat	Quite a bit	A lot
Blood loss from the anus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pain around the anus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Swelling/Protrusion out of the anus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Itching anus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fluid loss from the anus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Have the above symptoms hindered your daily activities in the past week? (e.g., taking care of yourself and others, household activities, work or exercise).

(place an X on the line below)

0	1	2	3	4	5	6	7	8	9	10	
Not hindered at all										Very hindered	

If you have recently undergone treatment for haemorrhoids in a hospital (e.g., elastic banding or an operation), how satisfied are you with the results regarding symptom reduction?

(Place an X on the line below)

Not applicable. I have not (yet) received hospital treatment.

0	1	2	3	4	5	6	7	8	9	10	
Not satisfied at all at all										Very satisfied	

Thank you for completing the questionnaire!