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Original article

Translation, cross-cultural adaptation, reliability, and validation of the italian version of the Foot and Ankle Disability Index (FADI)

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Summary. *Background and Aim of the work:* Foot-and-Ankle-Disability-Index (FADI) is one of the most widely used evaluation questionnaires for this anatomical district, but an italian validated version lacks and is necessary to properly evaluate italian people. In fact a correct interpretation of the items by patients is essential to obtain a precise subjective response, making the questionnaire valid to evaluate patients' satisfaction and wellness. Our purpose was to translate and culturally adapt into Italian the FADI questionnaire, and to check its reproducibility and validity. *Materials and Methods:* The original english version of FADI questionnaire was translated into Italian and checked for medical part coherence. It was submitted to 10 italian randomized patients to verify a correct cultural adaptation, and then to other 50 randomized patients operated at their ankle or hallux to assess intra- and inter-observer reproducibility by the Pearson's-Correlation-Coefficient (PCC) and the Intra-Class-Correlation (ICC) coefficient. Moreover, Short-Form-36 (SF36) questionnaire for Quality-of-Life and Visual-Analogue-Scale (VAS) for pain were also administered to the same 60 people and compared to italian-FADI to perform validation analysis by PCC and ICC coefficient. *Results:* Cultural adaptation of the translated version of the scale resulted good in terms of understandability by patients. An optimal correlation of the inter- and intra-observer reproducibility was obtained. The correlation obtained between FADI and SF-36 as well as between FADI and VAS indicates success in the validation process. *Conclusions:* Validation of the FADI italian version has been performed successfully, its use can be considered appropriate and is indicated in italian clinical practice. (www.actabiomedica.it)

Key words: evaluation scale, validation, cultural adaptation, foot, ankle, disability, Quality of Life, questionnaire, FADI, Italian.

Introduction

The importance of patient's perspective is recognized to be central for judging the effectiveness of a treatment in health care (1). Particularly for musculoskeletal disorders the response in terms of Quality of Life (QoL) of patients is important to obtain indication on functional limitation and disability before and after surgery (2). To this purpose several questionnaires were born to analyse patient's individual outcome. These tools can be divided into two groups: one dedicated to generic measures investigating overall health and wellness, designed to be applied to several diseases and body parts and to be widely used across

various population, whilst another group of questionnaires is dedicated to specific measures related to well defined anatomical regions (3).

Many specialistic questionnaires have been designed to investigate different orthopaedic conditions, encountering wide consent among doctors and healthcare professionals, because they can well investigate the impact of a specific disease and the direct consequence of therapeutic intervention on QoL and wellness state of patients (4).

One of the most widely used questionnaires for foot and ankle disorders is the Foot and Ankle Disability Index (FADI), first described in 1999 by Martin et al.: it consists of 22 activity related items and 4 pain related items (5).

The clinimetric qualities are extensively documented for the FADI, and in particular it has been considered a reliable and sensitive, patient-assessed tool to quantify functional disability in patients with chronic ankle instability (3).

A great advantage of FADI compared to other rating scales lies in the possibility of remote patient compilation.

However, its appropriate utilization is strongly limited by the english language in which it has been offered to scientific world. In fact, the validity of this tool in reporting the effective subjective response by patients cannot be separated from an adequate comprehension of the text of the items proposed inside the questionnaire. Moreover, the intervention of healthcare personnel to mediate or explain the questionnaire may generate interpretative bias causing loss of sincerity or misunderstanding, with consequent poor reproducibility invalidating the use of the questionnaire (6).

Therefore, the use of the questionnaire in the non-english language of the country where is administered, needs the translation for a full comprehension necessary for an adequate use. However it has been claimed that a simple translation cannot adequately respect the proper sense of the items, and a cross-cultural adaptation should be performed. The need to apply a scheduled procedure in which the questionnaire is not simply translated, but also culturally adapted to the language to maintain the same evaluation properties, was proposed by Guillemin et al. in 1993 (7).

Objective

In the present work we aimed to perform a translation of the FADI questionnaire into the italian language, to ascertain its cross-cultural adaptation and to verify its reliability and validity.

Materials and Methods

Characteristics of FADI questionnaire

The FADI specific questionnaire for foot and ankle consists in a total of 26 items, grouped into three different categories of questions: 16 items (1-16) related to walking, 6 items (17-22) to daily activity and 4 (23-26) to pain. Each item can be scored on a 5-points Likert scale (from zero to four), with a maximum total score of 104 points; the score can be transformed into percentage if a comparison with other questionnaires is needed.

The best possible score (104) corresponds to a complete absence of any difficulty in daily activities and no pain; the minimum score of zero (0) corresponds to the worst possible condition i.e. severe limitation in walking and daily activities as well as pain presence.

Exclusion of existence of previous Italian validated FADI

To assure that an italian translation of FADI was not already available for valid use, a Medline database search was performed typing in the PubMed service (National Center for Biotechnology Information - NCBI, National Library of Medicine - NLM, National Institutes of Health - NIH, USA) the keywords "Italian FADI" and the search didn't find any previous italian validated version. The same result was obtained by the Scopus (Elsevier) and Web of Science databases.

Translation and cultural adaptation

Translation and cultural adaptation were performed according to the different stages process proposed by Guillemin (7, 8), and already used for AOFAS Italian validation (9, 10).

1) First Stage: a primary *translation* of the FADI questionnaire from English into Italian was made by two translators aware of the study, namely an orthopaedic surgeon (M.L.), and a university student in-

volved in non-medical disciplines (A.C.); both translations were compared and discussed to obtain a unique version.

2) Second Stage: the first italian version was submitted to a native English translator who was unaware of the study and of the original english version of the questionnaire; the translator had to *back-translate* the FADI questionnaire from Italian to English. We gained a new english version from the native translator and we compared this one to the original to define a second correct italian version: this step is important to verify eventual change or shift of significance related to linguistic expression during translation procedure (6).

3) Third Stage for *cultural adaptation* of the translated questionnaire: we randomly enlisted 10 patients with regular informed consent who had undergone a surgical procedure at our institution for the treatment of hallux valgus or limitus, or bimalleolar fracture from 1-1-2016 to 31-12-2017, retrieved from the hospital database "AcceWeb" (Hi.Tech S.p.A. Software Engineering, Firenze, Italy), typing the ICD-9 codes (International Classification of Diseases, 9th edition) 735.0 for Hallux valgus, 735.2 for Hallux rigidus/limitus, 824.4 for Bimalleolar-closed fracture and 824.5 Bimalleolar-open fracture. These pathologies were chosen as their outcomes are among the most representative situations for the use of FADI.

To those who tested the second italian version of FADI questionnaire was added the question "difficult to understand?" to each sentence. We posed the limit of 90% of patients understanding the italian questionnaire to indicate a good translation; otherwise we should have to restart from the first step of the process to try to improve the cultural adaptation.

We also submitted the FADI questionnaire to 10 healthcare professionals (3 orthopaedists, 2 physiotherapists, 2 medical residents, 3 nurses) to check the comprehension of the items and professional approval of the indication used in the several items as appropriate in analysing foot and ankle disability. The comprehension and acceptance of the text by healthcare professionals had to be, as for patients, with a positive feedback of at least 90% to continue with the following steps, otherwise, even in these cases, we should have to restart from first stage for searching a translation improvement.

4) Assessment of reproducibility and validity of the Italian version of the FADI questionnaire. The definitive italian FADI questionnaire (Tab.1) was administered to a randomized group of 60 patients including, and with the same criteria as, the 10 patients previously recruited to assess the cultural adaptation of the evaluation scale. Each patient of the group underwent three interviews made by two previously trained and independent interviewers (interviewers A and B). The first interview was made from A and the same day after 30 minutes it was made from B: this step was necessary to check the inter-observer reproducibility. Within 15 days, interviewer A (A bis) reassessed all the patients with the Italian FADI questionnaires to check the intra-observer reproducibility. At the moment of the first interview, interviewer A also submitted the Short Form 36 (SF-36) questionnaire for QoL and the Visual Analogue Scale (VAS) to measure pain, in order to gain data to proceed to FADI scale validation.

Statistical Analysis

Demographic and clinical data of the assessed patients were characterized.

Data scores and statistics indices related to the FADI items are reported grouped in three domains, characterizing the FADI questionnaire: walking (items 1-16), daily activity (items 17-22), pain (items 23-26).

The Pearson's Correlation Coefficient (PCC) and the Intra-Class Correlation (ICC) coefficient were calculated to check the inter and intra-observer reproducibility for validation.

PCC evaluation results will be read as follows: $0 < PCC < 0.3$: weak correlation; $0.3 < PCC < 0.7$: moderate correlation, $0.7 < PCC < 1.0$: good correlation.

All statistical procedures were performed by STATA 13.0 statistical program.

Results

Translation and cultural adaptation

During the dispensing of the questionnaire for checking the cultural adaptation, five patients out of the ten, found difficulties to understand the ninth item related to the term "rollata", while three out of ten in-

Table 1. Italian version of the Foot and Ankle Questionnaire (FADI)
Indice di disabilità di piede e caviglia (FADI)
Prego risponda ad ogni domanda con una risposta che descriva più appropriatamente la sua condizione nell'ultima settimana. Se l'attività in questione è limitata da qualcos'altro oltre al suo piede o caviglia, segni 0.

	Difficoltà in attività	**Nessuna difficoltà 4**	**Leggera difficoltà 3**	**Moderata difficoltà 2**	**Estrema difficoltà 1**	**Incapace ad eseguire 0**
1	Stare in piedi					
2	Camminare su superficie regolare					
3	Camminare su superficie regolare senza scarpe					
4	Camminare in salita					
5	Camminare in discesa					
6	Salire le scale					
7	Scendere le scale					
8	Camminare su superficie irregolare/disconnessa					
9	Fare il passo completo con appoggio e spinta					
10	Accovacciarsi					
11	Dormire					
12	Salire in punta di piedi					
13	Iniziare a camminare					
14	Camminare 5 minuti o meno					
15	Camminare circa 10 minuti					
16	Camminare 15 minuti o più					
17	Lavori domestici					
18	Attività di vita quotidiana					
19	Igiene personale					
20	Lavoro da leggero a moderato (stare in piedi, camminare)					
21	Lavoro pesante (spingere/tirare, arrampicarsi, portare pesi)					
22	Attività ricreative					
	Dolore	Nessun dolore 4	Lieve 3	Moderato 2	Severo 1	Insostenibile 0
23	Livello generale di dolore					
24	Dolore a riposo					
25	Dolore durante la sua normale attività					
26	Dolore appena sveglio					
Cognome e Nome:		**Data:**			**Totale: …/104**	

dicated as confounding the same term, for which they required explanations.

Therefore, this item of the scale did invalidate the proposal of good comprehension level settled at 90% of patients. Because in any other item the patients showed to have difficulty to understand and no improper translation was revealed, only the item number 9 was subject to re-evaluation in its cultural adaptation and this process brought to delete the term indicated as not adequately comprehensible (Table 2). Any observation emerged by healthcare professionals interviewed for checking the medical part comprehension.

Statistical reproducibility and validity of the italian version of the FADI questionnaire

The 60 patients randomly enlisted to assess the validity of the questionnaire, were represented by: 77% (N=46) females and 23% (N=14) males, with average

Table 2. Different translation of the ninth item to better perform the cultural adaptation of the item

First translation of the voice "Stepping up and down curves" of the FADI questionnaire						
	Difficoltà in attività	Nessuna difficoltà 4	Leggera difficoltà 3	Moderata difficoltà 2	Estrema difficoltà 1	Incapace ad eseguire 0
9	Fare il passo completo con appoggio e spinta (rollata)					
Second translation culturally adapted of the voice "Stepping up and down curves" of the FADI questionnaire						
	Difficoltà in attività	Nessuna difficoltà 4	Leggera difficoltà 3	Moderata difficoltà 2	Estrema difficoltà 1	Incapace ad eseguire 0
9	Fare il passo completo con appoggio e spinta					

age 62 ±12 years, ranging from 38 to 80 years; 50% (N=30) with previous diagnoses of hallux valgus, 17% (N=10) hallux limitus and 33% (N=20) bimalleolar fracture, of which 17 closed and 3 open.

The time elapsed between the two interviews performed by the interviewer A was not the same for each patient, but all were interviewed after a minimum interval of 7 days and a maximum of 15 days.

The data for every item of the FADI questionnaire, collected by interviewer at first interview, are detailed in Table 3; whereas the comparison of the total scores collected by the interviewer A in the first and in the second time and by the interviewer B are resumed in Table 4.

The analysis related to the reproducibility of scale outcomes, concerning inter- and intra-interviewer variability is resumed in Table 5.

The reproducibility evaluated by PCC shows an optimal correlation for the several items of FADI questionnaire as evidenced by the domains. The intra-interviewer and inter-interviewer coefficients are very similar evidencing a very high coherence of response obtainable with the scale (Table 5). The ICC coefficient used to assess the reproducibility was compared with the PCC (Table 6); the analysis confirms the occurrence of a strong link among the different scores detected by interviewer A vs. Abis and A vs. B, allowing us to judge optimal the correlation in terms of in-

Table 3. FADI scores at the first interview.

FADI Questions/Items	Mean	SD	Minimum detected	Maximum detected
Walking (items 1 – 16)	3.7	0.6	0	4
Daily activity (items 17 – 22)	3.8	0.5	0	4
Pain (items 23 – 26)	3.7	0.6	0	4

Table 4. FADI total scores detected following the different interview performed on patients.

INTERVIEWER	Mean ± SD	CL 95%
A	96.0 ± 14.5	92.3 – 99.7
A bis	95.8 ± 14.2	92.2 – 96.4
B	98.9 ± 14.3	92.3 – 99.5

Table 5. Assessment of intra and inter-interviewer reproducibility of FADI questionnaire with Pearson correlation coefficient.

FADI Questions/Items	Pearson Correlation Coefficient	
	Intra-Interviewer	Inter-Interviewer
Walking (items 1 – 16)	0.9962	0.9983
Daily activity (items 17 – 22)	0.9863	0.9957
Pain (items 23 – 26)	0.9907	0.9958

Table 6. Analysis of the reproducibility by means of the Pearson's Correlation Coefficient (PCC) and of the Intra-Class Correlation coefficient (ICCc) values for the total score of the FADI assessment scale.

	Intra-Interviewer	CL 95%	Inter-Interviewer	CL 95%
PCC	0.9972		0.9988	
ICCc, individual	0.99868	0.99780 – 0.99921	0.99868	0.99780 – 0.99921
ICCc, average	0.99934	0.99890 – 0.99960	0.99934	0.99890 – 0.99960

ter and intra- interviewer variability. In conclusion the analysis evidences an optimal level of reproducibility, indicating the italian version of FADI questionnaire as adequate for the use by different interviewers.

The validation of the italian version of FADI questionnaire was performed comparing the total FADI score to the 8 domains of SF-36 health quality survey by the PCC (Table 7).

The PCC coefficients show a prevalence of a moderate correlation in the single domains in which is subdivided the SF-36 scale; they are rather similar (mean PCC = 0.503 ± 0.071) showing the occurrence of a limited internal variability of FADI questionnaire values.

For further control, we compared the FADI questionnaire total value of the interviewer A with the VAS scale; similarly, we compared the items related to pain of the italian version of FADI questionnaire (items 23-26) with VAS scale, being these items related to the same concept of the VAS i.e. the pain; the results are resumed in Table 8.

In both cases we obtained a good correlation, indicative of a strong influence of pain status in determining the values of the response.

Table 7. Correlation through Pearson's coefficient, of the FADI total score with the 8 domains and the total of the SF-36 results, obtained by observer A at the first interview.

SF-36 domains	Pearson's coefficient
Physical functions	0.4693
Role physical	0.4366
Bodily pain	0.4145
General health	0.5748
Vitality	0.4880
Social function	0.5103
Role emotion	0.6318
Mental health	0.4986
SF-36 TOTAL	0.6043

Table 8. Correlation with Pearson's coefficient of the VAS scale for FADI-total score and FADI-pain results obtained from interviewer A the first time.

FADI scores, interviewer A	Pearson's coefficient
Total	- 0.7399
Pain (items 23 – 26)	-0.7034

The negative sign in the PCC coefficient indicates that the value sequence of the two evaluation scales are displayed in opposite direction.

Discussion

In order to better understand and treat our patients, it is essential to evaluate effectively the impact of a disease and the effect of therapy on patient's well-being and Quality of Life. Every medical intervention has its real efficacy in the amelioration of patients' condition to reach satisfaction and wellness (11).

In this contest numerous questionnaires investigating patients' wellness were born. The increasing spread of specific questionnaires facilitates physicians to investigate specific diseases and related therapeutic interventions (12).

These questionnaires are gaining wide success and use, and thus need a proper cultural adaptation into the current language of the country in which it is applied, and a proper analysis for reproducibility and scientific validation (9, 10).

In our case the Italian culturally adapted FADI questionnaire has revealed a high level of reproducibility as assessed by the correlation indexes (Pearson CC and Intra-Class CC) of the statistical analysis. This finding brings us to introduce the use of the adapted FADI questionnaire as a reliable tool that can be used in clinical practice.

Moreover, the validity of the adapted FADI questionnaire has been assessed by the correlation analysis, with PCC, with the 8 domains characterizing the items of the SF36 health survey questionnaire which has been found to be reliable, valid, and responsive for a variety of medical diagnoses (13), and is eligible for our validity analysis (9, 10).

However, this comparison procedure, even if widely adopted, has a limit due to the different architecture of the evaluation scales born to investigate different topics. Therefore, the moderate values obtained in our PCC analysis can be anyway considered a good result that supports the validity of the italian adapted FADI questionnaire.

A further PCC analysis was performed with VAS scale which is one of the most eligible scales for pain

assessment in patients' subjective outcome. It is an evaluation index less rigorous than results of SF-36 questionnaire, but equally valid. Correlation analysis of italian FADI with VAS scale is used to confirm validity by an adequate PCC index, resulted even higher in our study than the one obtained in relation with SF-36. From this double check we obtained a further confirm of validity of our italian adapted FADI questionnaire.

The comparison with VAS scale is also used to detect the influence that pain has on the psychological state of patients and then their response (14, 15). The good level of values detected by PCC analysis, also in relationships to pain specific items of FADI, evidences that patients' pain is an important determinant in orienting the spontaneous response of patients.

In **conclusion**, validation and cross-cultural adaptation of the italian version of FADI questionnaire has been performed successfully and its use can be considered appropriate and suggested in Italian clinical practice.

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