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Original article

Italian translation, cultural adaptation and validation of the "American Orthopaedic Foot and Ankle Society's (AOFAS) ankle-hindfoot scale"

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Summary. *Background and Aim of the work:* Ankle and hindfoot injuries are common and may lead to functional impairment, disability, exclusion from occupational and daily activities. It's necessary a standardized method for assessing treatment outcomes in people with same condition and disease. American-Orthopaedics-Foot-and-Ankle-Society's-Ankle-Hindfoot-Evaluation-Scale (AOFAS-AHES) is specific to estimate clinical problems of the ankle-hindfoot. Outcome evaluation scales should be translated and culturally adapted into the language of the investigated patient. Our purpose was to translate and culturally adapt into Italian AOFAS-AHES, and to check its reproducibility and validity. *Methods:* An Italian translation of the AOFAS-scale was retranslated into English by a native English and compared to the original to define a second correct Italian-version, that was submitted to 50 randomized patients operated at their ankle or hindfoot with a minimum follow-up of 6 months for cultural adaptation, and to 10 healthcare professionals to check comprehension of the medical part. To check intra and inter-observer reproducibility each patient underwent 2 interviews by interviewer-A and 1 by B. ShortForm(SF)-36-questionnaire for quality of life and Visual-Analogue-Scale (VAS) for pain were also compared for validation. The Pearson's-Correlation-Coefficient and the Intra-Class-Correlation coefficient were calculated to check inter and intra-observer reproducibility for validation. *Results:* Cultural adaptation revealed to be good. We obtained a good correlation of the inter and intra-observer reproducibility. Further validation of the Italian-AOFAS-AHES was obtained comparing AOFAS results to SF-36. *Conclusions:* Italian translation, cultural adaptation and validation of the AOFAS-AHES has been performed successfully and could be useful to improve assistance quality in care practice. (www.actabiomedica.it)

Key words: AOFAS score, evaluation scale, ankle, foot, italian validation, outcome, hindfoot, AOFAS

Introduction

Ankle and hindfoot injuries are common and may lead to functional impairment, disability, exclusion from occupational and daily activities (1).

A recent study (2) shows the prevalence of foot and ankle fractures in the U.S.A. from 2007 to 2011 using the National Trauma Data Bank. Patients involved in foot and ankle fracture or dislocation were 280.933 (119.787 females and 157.977 males); 43.576 patients had multiple foot and ankle fractures. The mean age of patients was 44 ±19 years. Shibuya et al. (2) reported also that, among all the foot and ankle fractures, the ankle ones were the most common

with an incidence of 56% of this sample, followed by hindfoot and forefoot fractures (both around 17%) and midfoot fractures (6,4%). Among ankle fractures, the bi-malleolar type was the most common. The tri-malleolar and medial uni-malleolar types had a similar frequency; the lateral uni-malleolar type was the least common pattern. Approximately 20% of all foot and ankle fractures were open fractures (2).

It is necessary, in scientific literature, a standardized method for assessing treatment outcomes in people with foot and ankle conditions, so that different treatments can be compared in patients with the same disease (1,3,4).

Several evaluation scales are used by healthcare professionals to evaluate ankle and foot problems. Indeed these tools help to find and organize homogeneous data about patients for allowing a more precise comparison at follow up and/or among patients with a similar pathologic condition.

There is currently a great concern not only for knowing whether a given treatment or surgical technique provides positive or negative results, but also for verifying the impact of those treatments on patients´ quality of life, regarding how they feel about their conditions and how they perform their daily life activities. The great challenge for researchers lies in how to quantify subjective data and which questions should be addressed by the different instruments assessing health-related quality of life (1).

When choosing an outcome questionnaire, clinicians and researchers should consider the targeted outcome, because no questionnaire can capture the full patient experience (5).

In the past, evaluations of a certain intervention were made upon clinical and X-ray criteria. Today, there is a consensus about the need of standardized systems for assessing physical/functional and quality of life-related aspects, allowing the comparison of the results of different treatment methods in patients with the same condition, and more reliably evaluating the effectiveness of a treatment modality (1,3,4).

In literature there is a wide range of clinical outcome measurement tools that have been used in evaluating foot and ankle procedures, disorders, and outcomes. A systematic review (6) of all original clinical articles reporting on foot and/or ankle topics in six orthopaedic journals over a ten-year period (2002 to 2011) analysed a total of 878 clinical foot and ankle articles that used at least one patient-reported outcome measure: these articles were identified among 16,513 total articles published during the ten-year period. There were 139 unique clinical outcome scales used, and the five most popular scales (as a percentage of foot/ankle outcome articles) were the American Orthopaedic Foot & Ankle Society (AOFAS) scales (55.9%), Visual Analog Scale (VAS) for pain (22.9%), Short Form-36 (SF-36) Health Survey (13.7%), Foot Function Index (FFI) (5.5%), and American Academy of Orthopaedic Surgeons (AAOS) outcomes instruments (3.3%). The AOFAS scales continue to be used at a high rate relative to other scales that have been validated (6).

The AOFAS's Ankle-Hindfoot Evaluation Scale (AHES) is specific to the region of the ankle and hindfoot and it's the one of the four scales proposed on July 1994 in the journal "Foot & Ankle International" (3): the scale is strictly clinical and no radiologic images are necessary for the scoring; the evaluation scale is composed by the following nine items: pain, limitations in activities and support requirement, maximum walking distance in blocks, ability in walking surfaces, gait abnormality, sagittal and hindfoot motion, joint stability and alignment. The maximum and best possible score is 100 points and it consists in no pain (40 pt), no restraints in activities and no support (10 pt), ability in walking more than 6 blocks (5 pt), no difficulties of walking on any surface (5 pt), no gait abnormality or mild (8 pt), normal sagittal motion or slightly limited (8 pt), normal hindfoot mobility or slightly limited (6 pt), a stable joint (8 pt), good alignment, plantigrade foot, well-aligned forefoot and hindfoot (10 pt); the minimum score is 0 points and consists in the worst possible condition for our patients that will have a severe and almost always present pain, strong restraints in activities with use of supports, difficulties in walking on some surfaces, a strong gait abnormality, difficulty in walking for less than a block, strong limitation of joint mobility and its instability, non plantigrade foot with a bad alignment.

AOFAS-AHES grades ankle, subtalar, talonavicular and calcaneocuboid joint levels and could be used in ankle replacement, ankle arthrodesis, subtalar

instability operations, talonavicular arthrodesis, calcaneocuboid arthrodesis, calcaneal osteotomy, calcaneus, talus and ankle fracture (3).

Outcome evaluation scales are usually written in the English language and addressed to English speaking people. In order to be used worldwide, the scales should be translated and culturally adapted into the language spoken in the country where they are going to be applied. Subsequently, its measurement properties should be assessed with standards pre-established in literature in order to assure that the same characteristics are maintained in the new translated version (7,8).

To validate AOFAS questionnaire it is necessary to compare it with another one concerning individual general health aspects already validated and used in clinical practice and in the same language like the Short Form SF-36 (9-11).

The SF-36 questionnaire was already used in similar validation studies (1,12,13). It is composed of 36 questions that belong to eight domains: physical function, physical role, bodily pain, general health, vitality, social function, emotion role and mental health; each domain has a score from a minimum of 0 to a maximum of 100 points.

The purpose of this study was thus to translate and culturally adapt into Italian AOFAS Ankle-Hindfoot scale. It was also our intention to check its reproducibility and validity to use it hereafter as an assessment instrument of clinical and functional aspects in italian patients with ankle and/or hindfoot disorders.

Materials and methods

We performed a literature search through the Medline DataBase typing in the PubMed search service the keywords: "AOFAS score AND italian validation" in order to ascertain if previous italian validation of the AOFAS-AHES was already performed: the search didn't found any previous italian version.

We started translation and cultural adaptation following rules proposed and standardized by literature (7,8).

1) First Stage: a primary translation of the AOFAS scale, from English into Italian , was made by two translators aware of the study, namely a nursing student (P.J.) and an orthopaedic surgeon (M.L.); both translations were compared and discussed to obtain a unique version.

2) Second Stage: this Italian version was submitted to a native English translator, who was unaware of the study and of the original English version of the AOFAS scale; the translator had to back-translate the AOFAS scale 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. (table 1)

3) Third Stage: subsequently we proceeded to the cultural adaptation enlisting randomly 10 patients with ankle and hindfoot conditions retrieved from the hospital DataBase "AcceWeb" (Hi.Tech S.p.A. Software Engineering, via di Campigliano 51, 50012 Bagno a Ripoli, Firenze, Italy); no other particular conditions were required for enlistment like age, sex or nationality. To those who tested the second Italian version of AOFAS scale was added the question "difficult to understand ?" to each sentence. All patients gave their informed consent for participation in the research study. 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 AOFAS scale to 5 physiatrists and 5 orthopedic surgeons to check comprehension of the medical part that consists in: gait abnormality, sagittal and hindfoot mobility, ankle and hindfoot stability and alignment. The comprehension 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 this case, we should have to restart from first stage for searching a translation improvement.

Assessment of reproducibility and validity of the Italian version of the AOFAS ankle and hindfoot scale

The Italian AOFAS-AHES (table 1) was administered to a randomized group of 50 patients (with regular informed consent as above mentioned) who had undergone a surgical procedure at our institution for the treatment of ankle or foot injuries (table 2).

Table 1. Italian version of the "AOFAS Ankle-Hindfoot evaluation scale"

Categoria	Variabile	Punti
Dolore (40 punti)	Nessuno	40
	Lieve, sporadico	30
	Moderato, quotidiano	20
	Severo, quasi sempre presente	0
Funzione (50 punti)		
- Limitazioni nelle attività, necessità di ausili	Nessuna limitazione, nessun ausilio	10
	Nessuna limitazione nelle attività quotidiane, limitazioni nelle attività ricreative, nessun ausilio	7
	Attività quotidiane e ricreative limitate, bastone	4
	Seria limitazione nelle attività quotidiane e ricreative, deambulatore, stampelle, sedia a rotelle, tutore ortopedico	0
- Massima distanza che riesce a percorrere, in centinaia di metri	>6	5
	4-6	4
	1-3	2
	<1	0
-Superfici percorribili	Nessuna difficoltà su qualsiasi superficie	5
	Qualche difficoltà su terreno irregolare, scale, pendenze, gradini	3
	Seria difficoltà su terreno irregolare, scale, pendenze, gradini	0
- Anormalità nell'andatura	Nessuna, lieve	8
	Evidente	4
	Marcata	0
- Movimento sagittale (flessione + estensione)	Normale/leggera restrizione(≥30°)	8
	Restrizione moderata(15°-29°)	4
	Restrizione marcata(≤15°)	0
- Movimento del retropiede (inversione + eversione)	Normale/leggera restrizione(75%-100% del normale)	6
	Restrizione moderata(25%-74% del normale)	3
	Restrizione marcata(<25% del normale)	0
- Stabilità della caviglia e retropiede (anteroposteriore, varo, valgo)	Stabile	8
	Decisamente instabile	0
Allineamento (10 punti)	Buono, piede plantigrado, caviglia e retropiede ben allineato	10
	Discreto, piede plantigrado, si osserva qualche segno di mal allineamento della caviglia e retropiede, nessun sintomo	5
	Scarso, piede non plantigrado, grave mal allineamento, presenza di sintomi	0

Scala AOFAS per Caviglia e retro piede, versione italiana (Leigheb et al.)
Migliore (max) risultato = 100 punti
Peggiore (min) risultato = 0 punti

All these patients underwent standard surgical and rehabilitative treatment according to hospital protocols. We considered a minimum follow-up of 6 months and thus included patients operated from 13/08/2012 to 30/01/2014. The 10 patients previously recruited to assess the cultural adaptation of the evaluation scale were also included in this group. Each patient of the group was submitted to three interviews made by two previously trained and independent interviewers (interviewer A and B). The first and second interviews were randomly made by A and by B respectively at 30 minutes of distance: this step was necessary to check the

inter-observer reproducibility. Within 21 days, interviewer A had to reassess (3rd interview) all the patients with the Italian AOFAS questionnaire to check the intra-observer reproducibility. At the moment of the first interview, interviewer A also submitted the SF-36 questionnaire for quality of life and Visual Analogue Scale (VAS) to measure pain in order to gain data to proceed to AOFAS scale validation.

The descriptive statistical analysis was performed to characterize clinical and demographic data of the assessed patients. The intra-interviewer reproducibility (test and re-test), inter-interviewer reproducibility, and validation were assessed by using the Pearson´s correlation coefficient. The Intra-Class Correlation coefficient (ICC) was also employed to assess intra- and inter-interviewer reproducibility.

Results

We enlisted 50 patients (tables 2 and 2.1) including 36 females (72%) and 14 males (28%), with the following diagnoses/fractures according to ICD-9 (International Classification of Deseases, 9th edition): 4 (8%) medial malleolus closed, 12 (24%) lateral malleolus closed, 15 (30%) bimalleolar closed, 2 (4%) bimalleolar open, 14 (28%) trimalleolar closed, 1 (2%) trimalleolar open and 2 (4%) calcanues closed.

During the dispensing of the questionnaire for checking the cultural adaptation, only one patient out of the ten (10%) found some difficulties to understand the item of the italian AOFAS evaluation scale concerning restraints in activities: so we had a good comprehension level of the evaluation scale by 90% of patients of the group; all healthcare professionals interviewed for checking the medical part comprehension didn't found any difficulty.

The time elapsed between the two interviews by the same interviewer A was comprehended between 14 and 21days (average 17,5 days).

The mean values with standard deviation and range for every item of the AOFAS-AHES collected by interviewer A are reported in table 3.

The results concerning inter and intra-observer reproducibility calculated with the Pearson's correlation coefficient (PCC) (table 4) show that the inter-observer coefficients are generally higher than the intra-observer's ones, with good levels of reproducibility for most of the variables. The Intra-Class Correlation (ICC) coefficient used to assess the reproducibility were compared with the Pearson's correlation coefficient (table 5) allowing us to note very similar values.

Analysis of Italian validation of AOFAS-AHES is represented in table 6 where interviewer A AOFAS results are compared to the 8 domains of SF-36 health

Table 2. Types of fractures in the sample using ICD-9 (International Classification of Diseases, 9th edition), with relative number (N) and percentage

ICD-9	Fracture description	N	(%)
824.0	Medial malleolus, closed	4	(8)
824.2	Lateral malleolus, closed	12	(24)
824.4	Bimalleolar, closed	15	(30)
824.5	Bimalleolar, open	2	(4)
824.6	Trimalleolar, closed	14	(28)
824.7	Trimalleolar, open	1	(2)
825.0	Calcaneus, closed	2	(4)
Total		50	(100)

Table 2.1. Characteristics of the 50 patients included on the translation and validation process of the AOFAS' scale for ankle and hindfoot

Sociodemographic aspects	Values
Male gender	28%
Female gender	72%
Age (years): average	60,38
Age (years): range	24 - 88
Ethnicity: Caucasian	96%
Ethnicity: Non Caucasian	4%
Elapsed time after surgery (in months): average	15,41

Table 3. AOFAS scores at the first interview

AOFAS Questions/Items	Average	SD	Maximum	Minimum
Pain	31	10,15	40	0
Activities limitations	8,3	2,95	10	0
Maximum walking distance	4,2	1,68	5	0
Walking surfaces	3,44	1,59	5	0
Gait abnormality	6,8	2,59	8	0
Sagittal motion	7,24	1,76	8	0
Hindfoot motion	5,28	1,55	6	0
Stability	6,88	2,80	8	0
Alignment	9,2	1,85	10	5

Table 4. Assessment of intra and inter-interviewer reproducibility of AOFAS ankle-hindfoot scale with Pearson correlation coefficient

AOFAS Questions/Items	Pearson Correlation Coefficient	
	Intra-observer	Inter-observer
Pain	0,8537	0,9800
Activities limitations	0,9693	0,9896
Maximum walking distance	0,9710	1,0
Walking surfaces	0,9465	1,0
Gait abnormality	0,9579	0,9545
Sagittal motion	0,7676	0,8244
Hindfoot motion	0,8990	0,8990
Stability	1,0	1,0
Alignment	0,8461	0,9245

Table 5. Analysis of the reproducibility by means of the Pearson's correlation coefficient and of the intra-class correlation coefficient values for the total score of the AOFAS ankle-hindfoot assessment scale

	Intra-Interviewer	Inter-Interviewer
Pearson's Coefficient	0,950#	0,993#
Intra-Class Coefficient	0,949*	0,991**

# $p < 0.001$; * CI = 95% (0.92 – 0.98);
** CI = 95% (0.987 – 0.996)

Table 6. Correlation with Pearson's coefficient, of the 8 domains of SF-36 with AOFAS results obtained from interviewer A the first time

SF-36 domains	Pearson's coefficient
Physical function	0,8171
Role physical	0,6895
Bodily pain	0,7402
General health	0,7647
Vitality	0,6986
Social function	0,7446
Role emotion	0,5185
Mental health	0,71

quality survey through the Pearson Correlation Coefficient (PCC); in the same manner we compared the interviewer A AOFAS scale results with the VAS values for pain, obtaining a PCC of -0,71 ($P<0.001$); in the end, comparing results of pain from AOFAS scale with those from VAS scale we obtained a PCC of -0,9 ($P<0.001$).

Discussion

A key-point of this work was to find an instrument for healthcare professionals, that could check the impact of a treatment in patient quality of life (14), assessing the most influential areas that regard mostly daily life activities; an instrument with this kind of claims is certainly useful for healthcare givers who work closely with patients that are mainly affected by foot and ankle illness.

The AOFAS foot scores are four related outcome instruments based on the use of quantitative interval data and have seen increasing use in the literature. The mathematical construction of the scales is particularly notable for a very small number of intervals available to answer each component item and for quantitatively unequal intervals for some items. Minor changes in a patient's response to a series of correlated questions can potentially make a drastic difference in their total score (15).

The AOFAS scale does not take into consideration any of following factors/items: patient's return to work with satisfaction, running ability, stair-walking ability, alignment in degrees, range of sagittal motion in degrees, swelling, tenderness and neuropathy. However, this doesn't mean that these factors are negligible or should not be considered when evaluating functional outcomes. Patients with ankle and hindfoot diseases often are affected by these factors and they should be reported and matched to the clinical score for a better rating comprehension. Difficulties in the interpretation of the AOFAS scale might arise in the assessment of patients who have ankle and hindfoot complaints not caused by local conditions (e.g. rheumatoid patients with hip and/or knee affected by the systemic disease) (3).

Researchers might find difficulties in choosing or creating instruments with questions that help to quantify subjective data; moreover, these instruments are often written in English and therefore not understood by many people. Very often there is the need to apply evaluation scales but only few times there is an available validated version in the specific language. Although there is large amount of evaluation scales, the long process necessary to obtain validated and culturally adapted versions conditions their applicability to any patient.

The fact that almost all patients understood our questions about daily life activities renders our translation and cultural adaptation functional; we think that these results are possible because patients could read on their own all items and they had some time to think about the meaning and answer as they felt. We didn't inquire about education school level of the patients because they were randomized and so if the questionnaire results understandable for the sample the same is expected for the population to which it is addressed. Moreover if the AOFAS-AHES is administered as interviews, potential interpretation errors are minimized (1,16).

Regarding cultural adaptation work, we found some difficulties with the translation of the question about the maximum walking distance in blocks: the term "block" in fact is tipically American and it was very difficult to find an Italian word that could be compared and used correctly to express the same concept; in Italy blocks are different from those in the United States because cities are structured differently and if we talk about blocks many Italian people could misunderstand the term. Therefore we found a compromise choosing to change a little the sentence asking about "maximum walking distance in hundreds of meters". During the dispensing of the evaluation scale we discovered that this small change had a positive reply: all patients had a good comprehension of the item and nobody had any difficulty in understanding.

The pain item has a strong impact on AOFAS scale because it establishes 40% of the total score, therefore a strong pain would reduce a lot the total score. In our sample, during the first administration of the AOFAS scale, we obtained an average result for pain of 31 points with SD 10,15 and an average VAS result of 1,82 with SD 2,16: Pearson correlation coefficient between AOFAS total results and VAS is -0,71 while between AOFAS pain item alone and VAS is -0,9, demonstrating a good correlation of pain also to the total AOFAS score.

About inter and intra-observer reproducibility we can say that the results found with the use of Pearson correlation coefficient (table 4) show that inter-observer reproducibility is higher than the intra-observer one probably because the questionnaire was re-administered after only 30 minutes by the second interviewer while after several days by the first interviewer again; this explains also the different pain value referred 2 to 3 weeks after even if it's a chronic pain and thus can't change in such a short time; in fact, as well known, the pain level cannot be so sharply estimated.

Moreover ankle stability has shown an ideal reproducibility with a coefficient of 1,0 for both intra- and inter-observer (table 4); we found maximal inter-observer reproducibility (PCC = 1) also for "maximum walking distance" and "walking surfaces" (table 4). Correlation coefficients compared on table V show very similar values and therefore they further denote very good results about inter and intra-interviewer reproducibility.

Conclusions

On the basis of the obtained results, we can affirm that Italian translation, cultural adaptation and validation of the AOFAS Ankle-Hindfoot scale has been performed successfully.

We believe that its popularization and use in Italy will help in improving the care of patients affected by ankle and hindfoot problems under several aspects, which include a more precise monitoring of the rehabilitation process as well as a more effective comparison of clinical series.

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