

Prospective multicentre validation study of a new standardized version of the 400 points hand assessment

Submission date

04/02/2019

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

07/02/2019

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

10/07/2020

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Background and study aims

Hand rehabilitation requires valid evaluation tools. The 400 points hand assessment is an exhaustive but not standardized tool. The aim of this study is to validate a new standardized version of this test.

Who can participate?

Patients over 18 years with unilateral hand injuries

What does the study involve?

The 400 points hand assessment is administered at the beginning and at the end of the patient's care (maximum 4 weeks). It is compared with another hand evaluation test (Jebsen hand function test) at the beginning and with questionnaires about quality of life (SF 36) and the upper limb (QuickDASH).

What are the possible benefits and risks of participating?

No risks are expected because these tests are not dangerous and if contraindications are present, they are not administered. These tests are used routinely in the field of hand rehabilitation.

Where is the study run from?

France: Institut de médecine physique et réadaptation, Nancy, and Centre médical Rocheplane, Saint Martin d'Hères

Switzerland: Clinique romande de réadaptation, Sion

Portugal: Hospital particular do Algarve, Faro

When is the study starting and how long is it expected to run for?

June 2011 to June 2015

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Dr Michel Konzelmann

Contact information

Type(s)
Scientific

Contact name
Dr Michel Konzelmann

Contact details
Clinique romande de réadaptation suva
Service de l'appareil locomoteur
Avenue du grand champsec 90
Sion
Switzerland
1950

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Prospective multicentre validation study of a new standardized version of the 400 points hand assessment

Study objectives
The standardized 400 points hand assessment has good psychometric properties: construct validity, criterion validity, internal consistency, intra- and inter-evaluator reliability, responsiveness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Switzerland: Commission cantonale valaisanne d'éthique médicale, ICHV Avenue du grand champsec 86, 1950 Sion (this committee no longer exists so an email address and a telephone number cannot be provided), 05/12/2012, ref: 050/12
2. France: Comité d'éthique de l'institut régional de médecine physique et réadaptation, 4 rue du

professeur Montaut 54690 Lay Saint Christophe, Email: Jean-marie.beis@ugecamne.fr
3. Portugal: Comissao de ethica para saude do hospital particular do Algarve, Urbanizacao casal de gambela lote 2 8005-226 Faro, 12/01/2013, ref: 01/2013

Study design

Validation prospective multicentre study of a hand assessment tool

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Hand injuries

Interventions

Data at admission: patients were screened for inclusion and exclusion criteria and received an information sheet. Patients who fulfilled inclusion criteria and willing to participate signed an informed consent. If the patient fulfilled the exclusion criteria or refused to participate, he was considered in the group of excluded patients. The following data were collected: birth date, sex, profession, school formation (under 9 years or over 9 years), pathology and type of lesions, hand dominance, hand side involved, injury date, surgical intervention date, beginning of rehabilitation date, hospitalized or ambulatory treatment, work incapacity, pain numerical rating scale (NRS) maximum and average in the last week.

Protocol at T0: For convergent and divergent construct validity the trialists used the Quick Disabilities Arm Shoulder and Hand questionnaire (QuickDASH) and the MOS-SF 36 in validated French and Portuguese versions. For criterion validity, the protocol for assessing 400 Points HA and Jebsen hand function test (JTHFT) was: pain numerical rating scale (NRS) from 0 to 10 before and after administration of 400 Points HA, administration of the 400 Points HA in one session (30 to 40 minutes), rest for 10 minutes, pain NRS before and after JTHFT, administration of JTHFT considered as comparator. The JTHFT is standardized and commercialized, and French and Portuguese versions are available. Each of the seven tests of the JTHFT is timed. For statistical analysis the time of the seven tests were compared to the norms of the JTHFT and summed up for each hand (injured and non-injured) and compared to the score of the 400 Points HA. The trialists compared only the time of JTHFT and 400 Points HA score for the injured hand. The hypothesis was: the lower the time to complete JTHFT is, the higher is the 400 PHA score. The two tests were administered by very seasoned occupational therapists, six at Nancy, five at Saint Martin d'Hères, three at Sion and one at Faro.

Protocol at T1 and T2: Some patients after T0 were randomly assessed for intra evaluator reliability (T1) or for inter evaluator reliability (T2). These patients were not the same. The trialists estimated the number of patients for T1 and T2 at 40 patients in each group. Because no international recommendations are available, they chose this number based on previous studies about 400 points HA and on other studies of functional hand tests. The ICC of first version of 400 points HA was good with 20 to 30 patients, so they expected the same result with 40 patients in each group. The 400 Points HA was administered 1 to 4 days after T0, by the same evaluator at T1 and by other evaluator at T2. They chose this interval because no improvement is expected in this short time.

Protocol at T3: T3 was between three to four weeks after T0 even if the treatment was not finished. All patients were evaluated by the same evaluator as T0. The protocol was: administration of QuickDASH questionnaire in French or Portuguese, Likert scale of 7 items (Patient global impression of change = PGIC) asking patients how their health status has improved following treatment (1 = worse than ever; 2 = much worsened; 3 = slightly worsened, 4 = unchanged, 5 = slightly improved; 6 = much improved; 7 = completely improved), pain NRS from 0 to 10 before and after administration of 400 Points HA and administration of the 400 Points HA in one time (30 to 40 minutes).

Data summary: All the data were summarized in an anonymous booklet with a number for each patient. When the booklet was finished each centre handed it to the Clinique Romande de Réadaptation in Switzerland and the booklet was verified and scanned directly in an anonymous Excel file.

Statistical analysis: the following analysis were scheduled.

Construct validity was assessed with Pearson's correlation coefficients (r) between 400 Points HA and QuickDASH, MOS-SF 36 physical component (PC) at T0 for convergent construct validity. The hypothesis was that there is a correlation between 400 Points HA and QuickDASH and MOS-SF 36 PC. For divergent construct validity: 400 Points HA was compared to MOS-SF 36 mental component (MC) and pain at T0. The hypothesis was that there is no correlation between the 400 Points HA and MOS-SF36 MC and pain.

Criterion validity was assessed with Spearman's correlation coefficients (r) between 400 points HA and JTHFT at T0. The hypothesis was that there is a correlation between the two tests.

Correlation was considered excellent if $r > 0.91$, good if r between 0.71 and 0.9, medium between 0.51 and 0.70, weak between 0.31 and 0.50 and no correlation if $r < 0.30$. Ninety five percent confidence intervals for the correlation coefficients were calculated by means of Fischer's transformation.

Internal consistency of the 400 Points HA was determined by Cronbach's α , which is a general coefficient of homogeneity between items. Values for α can range from 0 (no internal consistency) to 1 (perfect internal consistency). A value above 0.8 is considered acceptable. The trialists calculated Cronbach's α for each test and for the total score of 400 Points HA.

Intra and inter evaluator reliability was assessed with the intraclass coefficient correlation (ICC) and the Bland-Altman method. The mean of the two 400 Points HA test (1 to 4 days) were calculated between T0 and T1 for the intra evaluator reliability, and between T0 and T2 for inter evaluator reliability. The trialists expected 40 patients for both reliability measures. ICC was considered excellent if $r > 0.91$, good if r between 0.71 and 0.9, medium between 0.51 and 0.70, weak between 0.31 and 0.50 and no correlation if $r < 0.30$. The trialists chose the interval of one to four days for inter and intra evaluator reliability because they think patients do not improve in this short interval.

For responsiveness, different methods were used. First, the Anchor-based approach. The anchor used was the level of improvement based on subjective patients' feelings reported on the PGIC. The score was treated as a binary outcome (scores of 6 or 7 = "improved" versus scores of 1 through 5 = "not improved"). Minimal clinically important difference (MCID) of the 400 Points HA was estimated using the receiver operating characteristic (ROC) method by comparing patients with and without improvement. The optimal cutoff on the ROC curve was determined using the optimal Youden's Index. The trialists also calculated the mean change of score according to each

patient's response level on the PGIC. Revicki recommends that MCID must be based primarily on appropriate patient-based anchors that are correlated at ≥ 0.30 with the patient-reported outcome. To reinforce the validity of the anchor, the trialists calculated the Spearman correlation coefficient between the PGIC and delta scores.

Second the Distribution-based approach. The trialists calculated the standard error of measurement (SEM) which is the variation in scores due to the unreliability of the scale used. A SEM value is based on the standard deviation (SD) of the sample and the reliability of the measurement instrument, expressed as $SEM = SD \text{ from the 1st test} \times (\sqrt{1-ICC})$. ICC is the result of intra evaluator reliability of 400 Points HA. Minimum detectable change (MDC) was also calculated. MDC refers to the minimal amount of change outside of error that reflects true change by a patient between two timepoints, rather than a variation in measurement. The trialists use this formula of $MDC = 1.96 \times SEM \times \sqrt{2}$. 1.96 was chosen to have a confidence interval of 95%. Effect size (ES) and standardized response mean (SRM) were also calculated. ES and SRM measure the magnitude of a treatment effect. $ES = \text{mean change of 400 Points HA T0-T3} / \text{SD of baseline score}$. $SRM = \text{mean difference of 400 Points HA T0-T3} / \text{SD of individual difference T0-T3}$. For ES and SRM the Cohen classification is usually used: small < 0.50 , medium from 0.51 to 0.80, large > 0.80 .

As a comparison, the MCID of the QuickDASH was also estimated. ICC for test-retest of DASH was 0.95 for the French version. All calculations were performed using the statistical package Stata 11.0 for Windows.

Intervention Type

Other

Primary outcome(s)

Criterion validity assessed with Spearman's correlation coefficients (r) between 400 points HA and JTHFT at T0

Key secondary outcome(s)

T0= first test , T and T2= 1 to 4 days after T0, T3= 3 to 4 weeks after T0

1. Construct validity assessed with Pearson's correlations coefficients between 400 points HA and QuickDASH, MOS SF36 physical component and mental component and pain at T0
2. Internal consistency assessed with Cronbach alpha of the 400 points HA for each test and for the total score at T0
3. Intra and inter evaluator reliability of the 400 points HA assessed with intraclass correlation coefficient (ICC) and Bland Altman method of the 400 points HA between T0 and T1 (intra) and T0 and T2 (inter)
4. Responsiveness assessed with:
 - 4.1. Anchor based approach: calculation of the MCID with ROC method and mean change of score of the 400 points HA and the QuickDASH between T0 and T3
 - 4.2. Distribution based approach: calculation of the standard error of measurement (SEM), minimum detectable change (MDC), effect size (ES), standardized response mean (SRM) for 400 points HA and QuickDASH, between T0 and T3

Completion date

28/06/2015

Eligibility

Key inclusion criteria

Patients over 18 years hospitalized or not with:

1. Unilateral traumatic hand impairment (fractures, tendons lesions, wounds, peripheral traumatic neuropathy)
2. Complex Regional Pain Syndrome (CRPS)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

176

Key exclusion criteria

1. Patients aged under 18 years
2. Bilateral hand impairment
3. Central neurological impairment
4. Severe psychiatric disorders
5. Patients unable to fulfilled the questionnaires or to understand the instructions of 400 Points HA
6. Impossibility to plan the 400 Points HA at the entry
7. Contraindication for the 400 Points HA at the entry (recent surgery)

Date of first enrolment

01/05/2013

Date of final enrolment

28/02/2015

Locations**Countries of recruitment**

France

Portugal

Switzerland

Study participating centre

Clinique romande de réadaptation suva service de réadaptation de l'appareil locomoteur
Avenue du grand champsec 90
sion
Switzerland
1950

Study participating centre

Institut régional de medecine physique et réadaptation
75 boulevard Lobeau, CS 34209
Nancy
France
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Study participating centre

Centre médical rocheplane
6 rue Massenet
Saint Martin D'Hères
France
38400

Study participating centre

Hospital particular do algarve
Urbanização Casal de Gambelas, Lote 2
Faro
Portugal
8005-226

Sponsor information

Organisation

Institut de recherche en réadaptation

ROR

<https://ror.org/04n404y68>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Michel Konzelmann. All the data are in his possession and are available any time and forever. All the data are in Excel files and are anonymized and store in the data bank at the research institute in Switzerland. Just two persons are authorized to access at this data: Dr Michel Konzelmann and one of his colleague who made the statistics. The consent of patients was obtained by signing a consent form as usual after an information about the study. These two files were approved by the ethics committees.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	10/07/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes