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Responsiveness of EQ-5D in Patients With a Distal Radius Fracture

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Abstract

Background: The EuroQol Group 5-Dimension (EQ-5D) questionnaire is frequently used as an outcome measure of general patient-reported health-related quality of life (HRQoL). We evaluated the internal and external responsiveness of EQ-5D (specifically EQ-$5D_{index}$ score) in patients with a surgically treated distal radius fracture. **Methods:** Within the context of a randomized controlled trial (RCT), 132 patients with a surgically treated distal radius fracture filled out EQ-5D and Patient-Rated Wrist Evaluation (PRWE-Swe) at baseline (preinjury state), and at 3 and 12 months. Internal responsiveness was evaluated by calculating mean change score and standardized response mean (SRM) of the EQ-$5D_{index}$ scores. External responsiveness was evaluated with PRWE-Swe as the external criterion. PRWE-Swe was used to define 4 subgroups of patients with different clinical outcomes. The ability of EQ-$5D_{index}$ change score to discriminate between these subgroups was analyzed with logistic regression, receiver operating characteristic (ROC) curves, and area under the ROC curves (AUROCs). Correlation analysis was made with Spearman's ρ test. **Results:** The mean change in EQ-$5D_{index}$ score from baseline to the 3-month follow-up was −16.1 and from the 3- to the 12-month follow-up was 7.6. The corresponding SRMs were large (0.93) and small to moderate (0.47). Analysis of external responsiveness displayed odds ratios >1 and AUROCs between 0.70 and 0.76 in all 4 subgroups. The proportion of patients correctly classified into the 4 subgroups by the EQ-$5D_{index}$ change scores was 78% to 94%. Spearman's ρ was 0.35. **Conclusion:** EQ-5D displayed an overall acceptable to good responsiveness in patients with a distal radius fracture. It may thus be used as a measure of HRQoL in this patient group.

Keywords: EQ-5D, EQ-$5D_{index}$ score, responsiveness, distal radius fracture, health-related quality of life (HRQoL), PRWE, PRWE-Swe, patient-reported outcome measure

Introduction

Distal radius fractures occur in all ages and are the most common of all fractures.[7,10,26] In a recent nationwide Swedish registry study, the incidence rate in the total population was 32/10 000 person-years.[26] Treatment of distal radius fractures is based on the fracture pattern as well as patient factors and may range from elastic bandage to advanced surgery.

Treatment outcome after musculoskeletal injury has traditionally been measured with radiographic appearance, range of motion, muscle strength, and frequency of complications.[3] These results may, however, differ from the patient's own assessment of the treatment outcome. In recent years, the interest in patient-reported outcome measures has increased. A large number of instruments have been developed, including disease- and anatomical region-specific questionnaires, and generic questionnaires that measure general health-related quality of life (HRQoL). For patients with disorders of the wrist, one of the most commonly used region-specific instruments is the Patient-Rated Wrist Evaluation (PRWE).[21] It is valid, reliable, and responsive.[22,23] It has been translated into Swedish (PRWE-Swe) and good validity, reliability, and responsiveness has been ascertained in a Swedish setting.[25,34]

Region- and disease-specific instruments do not allow comparison with injuries located in other anatomical regions, nor do they give information on the general aspects of the patient's health. For this purpose, generic HRQoL instruments are required. These instruments contribute to a more complete picture of how an injury or disease affects

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the general aspects of the patient's health, such as mobility, self-care, and psychological well-being. Owing to their design, generic HRQoL instruments may have limited responsiveness for a specific injury or disease. Responsiveness is defined as the ability of an instrument to detect clinically important change, reflected by a proportional change in the instrument's scale.[11,17] Internal responsiveness refers to the ability of the instrument to detect an expected change in a variable over time. External responsiveness refers to how well the instrument correlates to an external criterion (EC) (ie, another instrument used as a standard with ascertained reliability, validity, and responsiveness for a specific patient group). Before applying a generic instrument on a specific patient group, adequate responsiveness of the instrument for that specific patient group should be ascertained.

One of the most widely used generic instruments is the EuroQol Group 5-Dimension (EQ-5D).[5,6,13,29] An important application of EQ-5D is health economic evaluation, because it is commonly used as an estimate of the HRQoL component (ie, utility) in quality-adjusted life years (QALYs). QALYs are used in cost-benefit analyses, ie, to compare the cost and health benefit of different treatments and interventions. The results of cost-benefit analyses are used to determine resource allocation on a population level in many countries.[8,31] In a large review[14] of generic instruments for patient-reported HRQoL used in older patients (defined as aged ≥60 years, range 60-86 years) in different countries and clinical settings, EQ-5D proved to have good reliability, validity, and responsiveness in several patient groups. To the best of our knowledge, the responsiveness of EQ-5D has not been evaluated in patients treated for a distal radius fracture.

The objective of this study was to evaluate the internal and external responsiveness of EQ-5D in patients with a distal radius fracture (ie, to test its ability to detect clinically important change in HRQoL after an acute injury to the wrist). PRWE-Swe was used as the EC.

Materials and Methods

Study Population, Setting, and Design

The study population consisted of 132 individuals with a displaced distal radius fracture, who within the context of a single-center randomized controlled trial (RCT), underwent surgical treatment of their fracture and were thereafter followed for 12 months. The main object of the RCT was to compare the clinical, radiological, and functional outcome of 2 different surgical treatment regimens. The primary outcome measure was the upper extremity questionnaire Disability of the Arm, Shoulder and Hand (DASH).[1,15] Among the secondary outcomes were EQ-5D and PRWE. The RCT was registered at www.clinicaltrials.gov (NCT01034943, NCT01035359). The results are presented in detail elsewhere.[24]

The focus of the present study was to evaluate the responsiveness of EQ-5D in the patients participating in the RCT. A total of 1349 consecutive patients presenting at the Södersjukhuset Hospital in Stockholm between September 2009 and February 2013, with a dorsally displaced distal radius fracture scheduled for surgical treatment, were eligible for inclusion. Inclusion criteria for the RCT were patient age 50 to 74 years for women and 60 to 74 years for men; fall from a standing height; wrist radiography of ≥20° dorsal angulation and/or ≥5 mm axial shortening; good knowledge of the Swedish language; fracture diagnosis within 72 hours of injury; and residency in the Stockholm area. Exclusion criteria were former disability of either wrist; other concomitant injuries; rheumatoid arthritis or other severe joint disorders; moderate or severe cognitive impairment defined by a score of ≤5 on the 10-item Short Portable Mental Status Questionnaire[28]; drug or alcohol abuse; severe psychiatric disorder; dependency in activities of daily living; or a medical condition that did not allow general anesthesia.

Figure 1 contains an attrition flow diagram which visualizes the inclusion and exclusion process. Of the 1349 eligible patients, 1055 did not meet all of the inclusion criteria and/or met one or more of the exclusion criteria, 51 declined to participate, 86 were not included due to lack of available research personnel, and 17 were not included due to yet other reasons.

A power analysis was made for the RCT prior to start-up. The power was set to 80%. The number of patients needed to detect a minimally important difference (MID) of 10 points in the primary outcome (DASH) at the 1-year follow-up was 64 in each study arm. The anticipated dropout rate was 20%, resulting in a sample size of 160 patients. However, due to an unexpectedly high follow-up frequency of more than 95%, the RCT was closed at 140 patients.[24]

After written informed consent, patients were randomized to surgical treatment of their distal radius fracture by either internal fixation with a volar locking plate (n = 70), or wrist-spanning external fixation with optional addition of Kirschner wires (n = 70). Surgery was performed within 10 days from the fracture date. At inclusion, all patients were asked to fill out PRWE-Swe and the EQ-5D questionnaire, as recall of their preinjury status from the week before injury (baseline). At 3 and 12 months after surgery, current status was documented with the same questionnaires.

Of the 140 patients included in the RCT, one had to be excluded shortly after randomization due to misclassification of the fracture at inclusion. A closer review of the radiographs revealed a nondisplaced fracture of the ulnar metaphysis in addition to the displaced distal radius fracture. Five patients were lost to follow-up, of whom 3 declined to participate further, 1 died, and 1 we were unable

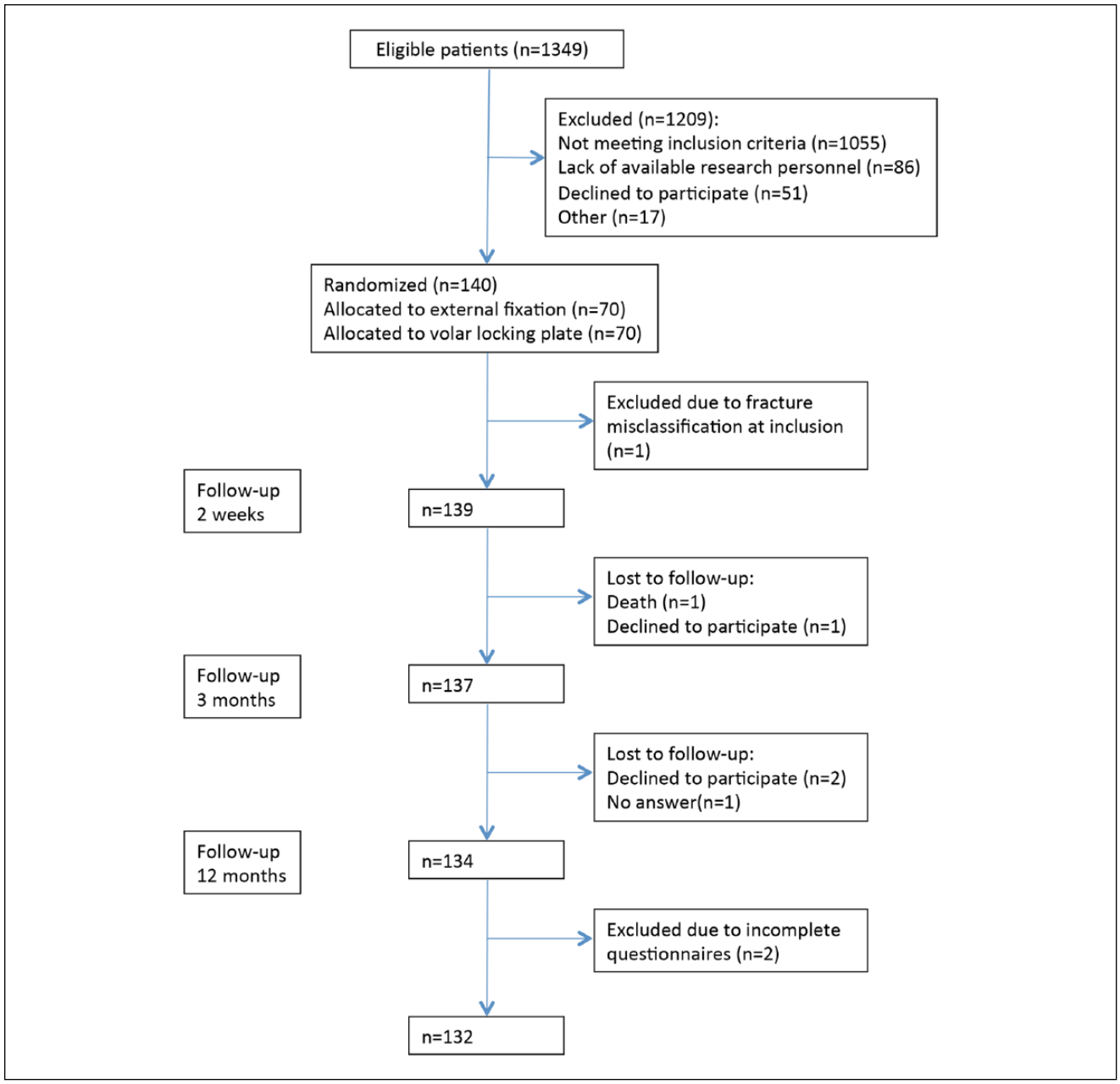

Figure 1. Attrition flow diagram.

to contact. A total of 134 patients completed the 12-month follow-up. Two of these had incomplete questionnaires and were excluded in the present study. Thus our study population consisted of the 132 individuals in the RCT who had fully completed both questionnaires at all 3 measuring points.

EQ-5D

EQ-5D is a generic instrument designed to measure self-reported HRQoL.[5,29] It has 3 components, of which the EQ-5D questionnaire is the most frequently used. The questionnaire is constructed to let the respondent classify his or her health according to 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is graded by the respondent as 1, no problems; 2, some or moderate problems; or 3, extreme problems. The 5-digit result of the EQ-5D questionnaire represents 1 of 243 (5^3) possible health states. Each health state can be converted into a single summary index score ($EQ\text{-}5D_{index}$ score), ranging from 0.00 to 1.00, by applying HRQoL weights from a valuation set. The valuation set

used in this study was the commonly used UK EQ-5D Index Tariff, which is based on a large sample from the UK population.[12,19] An EQ-5D$_{index}$ score of 0.00 equals the worst possible health state and 1.00 equals the best possible health state.

PRWE-Swe

PRWE-Swe,[25,34] as well as the original PRWE,[21-23] is a 15-item questionnaire designed to measure patient-rated wrist pain and disability in activities of daily living. It is divided into a pain subscale with 5 items and a function subscale with 10 items. The patients rate their level of wrist pain and function on a categorical scale from 0 to 10, where 0 equals "no pain"/"no difficulty," and 10 equals "worst pain ever"/"unable to do." The pain score equals the sum of the 5 items and can be 50 at worse. The function score is the sum of the 10 items divided by 2, and can be 50 at worse. The pain and the function scores are summed. The result of the PRWE is thus a number between 0 and 100, where 0 represents a fully functioning wrist with no pain and 100 represents a completely disabled and extremely painful wrist.

Scale Compatibility

To enable comparison between the PRWE-Swe score and the EQ-5D$_{index}$ score, both scoring scales were adjusted so that the best scores (most positive health state) were equal to 100. This was achieved by reversing the PRWE-Swe score and multiplying the EQ-5D$_{index}$ score by 100.

Hypothesis for Assessment of Internal and External Responsiveness

Because none of the patients included in this study had any preinjury wrist disability, the deterioration in patient-rated wrist function and HRQoL after injury measured at the 3-month follow-up was expected to be large, regardless of which treatment regimen the patients were allocated to. Furthermore, we expected an improvement—but not a complete return to baseline—in wrist function and HRQoL for most patients from the 3- to the 12-month follow-up. We therefore hypothesized that all patients would report a substantial decrease in EQ-5D$_{index}$ scores and PRWE-Swe scores at 3 months compared with the preinjury state (baseline). Equally, we supposed that most patients would report an increase (major or minor) in EQ-5D$_{index}$ scores and PRWE-Swe scores at the 12-month compared with the 3-month follow-up. However, a small group was expected to report further deterioration from the 3- to the 12-month follow-up due to reasons such as fracture-healing complications.

Assessment of Internal Responsiveness

Internal responsiveness of EQ-5D$_{index}$ score (ie, its ability to detect the hypothesized change in HRQoL over time) was evaluated by calculating the mean change score (ie, the observed change) and the standardized response mean (SRM) for EQ-5D$_{index}$ scores from baseline to the 3-month follow-up, and from the 3- to the 12-month follow-up. The SRM is defined as the mean change score divided by the standard deviation of the change score. The SRM is classified as large (>0.8), moderate (0.5-0.8), or small (<0.5).[9,32]

Assessment of External Responsiveness

External responsiveness of EQ-5D$_{index}$ score was evaluated by using PRWE-Swe as the EC (ie, the standard by which EQ-5D$_{index}$ score was compared). In other words, external responsiveness was measured by how well the EQ-5D$_{index}$ score corresponded to the changes in PRWE-Swe. PRWE-Swe change scores between the 3- and the 12-month follow-ups were used to discriminate between 4 subgroups of patients with different clinical outcomes: clearly improved, with an increase in change score of ≥10 points; marginally improved, with an increase in change score of <10 points; marginally deteriorated, with a negative change score of <10 points; and clearly deteriorated, with a negative change score of ≥10 points. This cutoff level of 10 points was chosen based on the MID reported in previous studies.[22] The MID is defined as the smallest change in a patient-reported outcome score that patients consider to be clinically important.[22,32] The MID for EQ-5D$_{index}$ score was set to 0.1, in accordance with previous studies.[32] After adjustment for scale compatibility, the MID was 10 points for both PRWE-Swe and EQ-5D$_{index}$ score. The external responsiveness of EQ-5D$_{index}$ score was analyzed with receiver operating characteristic (ROC) curves, area under the ROC curves (AUROCs), logistic regression, and correlation analysis.

Statistical Methods

All statistics were calculated with the IBM SPSS 22.0 software (IBM Inc, Armonk, New York). A paired-sampled 2-sided *t* test was used to compare mean change scores. The results were considered significant at $P < .05$. Confidence intervals (CIs) of 95% were calculated for the SRM.

ROC curves were used to demonstrate the ability of the change in EQ-5D$_{index}$ score between the 3- and the 12-month follow-ups to discriminate between the 4 subgroups specified by the EC. The ROC curves provided information on the sensitivity and specificity of EQ-5D$_{index}$ change scores. AUROCs were measured and correlated to the probability of correctly identifying patients in the 4 subgroups specified by the EC. AUROC can range from 0.5 (no discriminatory accuracy) to 1.0 (perfect accuracy). We hypothesized

Table 1. Baseline Data for Study Population (n = 132).

Variable	Result
Age at injury, y	
Mean (SD)	62.8 (6.6)
Median (range)	63 (50-74)
Sex female, n (%)	122 (92)
Smoker, n (%)	18 (14)
EQ-$5D_{index}$ score	
Mean (SD)	95.3 (11.1)
Median (range)	100 (41-100)
Floor effect, n (%)	0 (0)
Ceiling effect, n (%)	105 (80%)

Note. Floor effect = proportion of patients reporting lowest possible value on EQ-$5D_{index}$ score. Ceiling effect = proportion of patients reporting highest possible value on EQ-$5D_{index}$ score.

that EQ-$5D_{index}$ score would be able to significantly discriminate between the 4 subgroups defined by the EC. Comparisons were made between subgroups with differences of ≥10 points on the EC in order to ensure a clinically relevant difference between the reference group and the comparison group.

In the logistic regression analysis, odds ratios (ORs) were calculated with the EC as the dependent variable and the EQ-$5D_{index}$ change score as the independent variable. The patient group with the more favorable outcome was used as the reference. Thus, OR exceeding 1.0 indicated that the odds of belonging to the group with the less advantageous outcome increased among patients with a comparatively worse EQ-$5D_{index}$ score. Furthermore, the proportion of patients correctly classified by EQ-$5D_{index}$ change scores into the 4 subgroups defined by the EC was calculated. We predicted it to be larger than 50% (the proportion expected by chance).

The correlation analysis between EQ-$5D_{index}$ change score and PRWE-Swe change score between the 3- and the 12-month follow-ups was made by using the Spearman's ρ test. We predicted a positive direction of the correlation and the strength of the coefficient to be ≥0.30.

Results

Baseline data for the 132 patients in the study population are presented in Table 1. The ceiling effect, ie, the proportion of patients reporting the highest possible value of 100 on EQ-$5D_{index}$ score, was 80%. Correspondingly, the mean EQ-$5D_{index}$ score was 95.3 and the median value was 100.

Internal Responsiveness

The mean change score from preinjury state to the 3-month follow-up for the EQ-$5D_{index}$ score was −16.1 (SD = 17.4; $P < .001$). The corresponding SRM was 0.93 (95% CI, 0.75-1.10), categorized as large. The mean change score from the 3- to the 12-month follow-up for the EQ-$5D_{index}$ score was 7.6 (SD = 16.2; $P < .001$). The corresponding SRM was 0.47 (95% CI, 0.30-0.64), classified as small to moderate.

External Responsiveness

The mean change scores and SRMs of EQ-$5D_{index}$ score between the 3- and the 12-month follow-up for the 4 subgroups are presented in Table 2, as well as results of the independent *t* tests for each subgroup.

In Table 3, the results of the ROC curve analysis and the logistic regression analysis of the EQ-$5D_{index}$ change scores between the 3- and the 12-month follow-ups are presented. Each of the 4 subgroups was compared with those of the other subgroups that differed ≥10 points on the EC. The AUROCs ranged from 0.70 to 0.76. The lower boundaries of the CIs for all groups were above 0.50, except for the marginally improved subgroup, in which it was 0.49. In the logistic regression analysis, all ORs exceeded 1.00 and were statistically significant. The proportion of patients correctly classified by EQ-$5D_{index}$ change scores into the 4 subgroups defined by the EC ranged from 78% to 94%.

The result of the Spearman's ρ test used in the correlation analysis of EQ-$5D_{index}$ change scores and PRWE-Swe change scores between the 3- and the 12-month follow-ups was Spearman's ρ 0.35 ($P < .001$). The correlation had a positive direction and the coefficient was, as predicted, stronger than 0.30.

Discussion

This study has ascertained that EQ-5D (specifically EQ-$5D_{index}$ score) has overall good internal and acceptable to good external responsiveness in patients with a surgically treated distal radius fracture in Sweden. In other words, it is responsive enough to detect clinically important change in HRQoL in patients with an acute distal radius fracture, and the subsequent surgical treatment and rehabilitation. EQ-5D may thus be used as a patient-reported outcome measure of HRQoL in clinical evaluation of this patient group. Furthermore, this allows health economic evaluations of this patient group by enabling calculation of QALYs and cost-benefit analyses.

Overall good internal responsiveness was supported by statistically significant change scores between baseline and the 3-month follow-up and between the 3- and the 12-month follow-ups, with corresponding large and small to moderate SRMs.

The overall results of the subgroup analyses for external responsiveness suggested that EQ-$5D_{index}$ score had an acceptable correspondence to the EC. The clearly improved group and the marginally improved group had mean change scores of approximately 12 and 6 points, respectively, with

Table 2. External Responsiveness of EQ-5D$_{index}$ Score.

EQ-5D$_{index}$ score	N (Total 132)	Observed change		P^a
		Mean (SD)	SRM (95% CI)	
Clearly improved[b]	61	12.1 (13.9)	0.87 (0.62-1.12)	<.001
Marginally improved[c]	50	5.9 (16.2)	0.36 (0.08-0.64)	<.05
Marginally deteriorated[d]	13	3.1 (12.5)	0.25 (−0.29-0.79)	NS
Clearly deteriorated[e]	8	−8.7 (24.7)	−0.35 (−1.04-0.34)	NS

Note. Change scores in the PRWE-Swe between the 3- and 12-month follow-ups were used as an external criterion (EC). EQ-5D = EuroQol Group 5-Dimension; SRM = standardized response mean; CI = confidence interval; NS = not significant; PRWE = Patient-Rated Wrist Evaluation.
[a]Paired samples 2-sided *t* test.
[b]Improvement in PRWE-Swe ≥ 10 points.
[c]Improvement in PRWE-Swe < 10 points.
[d]Deterioration in PRWE-Swe < 10 points.
[e]Deterioration in PRWE-Swe ≥ 10 points.

Table 3. External Responsiveness for EQ-5D$_{index}$ Change Scores.

EQ-5D$_{index}$ score	AUROC (95% CI)	Logistic regression	
		OR (95% CI)	Correctly classified, %
Clearly improved vs marginally/clearly deteriorated	0.75 (0.63-0.87)	1.06 (1.02-1.11)**	78
Marginally improved vs clearly deteriorated	0.70 (0.49-0.92)	1.05 (1.00-1.09)*	86
Marginally deteriorated vs clearly improved	0.71 (0.55-0.87)	1.05 (1.00-1.10)*	81
Clearly deteriorated vs marginally/clearly improved	0.76 (0.58-0.94)	1.06 (1.01-1.10)**	94

Note. Change scores from the PRWE-Swe between the 3- and 12-month follow-ups were used as EC. EQ-5D = EuroQol Group 5-Dimension; AUROC = area under receiver operating characteristic curve; CI = confidence interval; OR = odds ratio; PRWE = Patient-Rated Wrist Evaluation; EC = external criterion.
*P < .05. **P < .01.

corresponding large and small to moderate SRMs. Both groups had statistically significant changes. The marginally deteriorated group and the clearly deteriorated group had mean change scores of approximately 3 and −9 points, respectively, with corresponding small SRM's and nonsignificant changes in the score. As the number of patients in the marginally deteriorated and clearly deteriorated groups was low, we speculate that the nonsignificant results may be due to a subsequent lack of statistical power and recommend that these results are interpreted with caution. The ROC curve analysis with AUROCs ranging from 0.70 to 0.76 and CIs above 0.5 for all but 1 group confirmed our hypothesis by indicating a good ability of EQ-5D$_{index}$ score to discriminate between different outcomes in patients with a distal radius fracture. In the logistic regression analysis, all ORs exceeded 1.00 and were statistically significant. The proportion of patients correctly classified by EQ-5D$_{index}$ change scores into the 4 subgroups defined by the EC was 78% to 94%. This was far better than the 50% expected by chance, and in accordance with our hypothesis. Spearman's ρ test gave a statistically significant result of 0.35, showing a moderately strong correlation between EQ-5D$_{index}$ change scores and PRWE-Swe change scores. However, a full correlation between 2 instruments is never desirable, as it would suggest that they measure the exact same thing.

The study population was aged 50 to 74 years with a mean age of 63 years, and 92% of the patients were female. This is in accordance with the results of a Swedish nationwide registry study of patients with a distal radius fracture,[26] in which the mean age at the time of fracture was 62 years and the proportion female:male was 3:1 in the adult population. It may therefore be assumed that the results in this study are applicable in the average adult population of patients with a surgically treated distal radius fracture in Sweden. A further assumption may also be that EQ-5D$_{index}$ score can be used as a patient-reported outcome measure of HRQoL in Swedish patients with a nonsurgically treated distal radius fracture, as well as in patients with other injuries and disorders of the forearm, wrist and hand, with similar impact on HRQoL. However, further studies are needed to verify these assumptions.

The high ceiling effect of 80% in EQ-5D$_{index}$ score was expected. It reflects a high preinjury general HRQoL in the study population and to some extent corresponds to the fact that none of the study patients had any wrist disability prior to their wrist fracture.

Of the 140 patients included in the original RCT, 134 were followed for 12 months, and 132 of these had fully completed PRWE-Swe and the EQ-5D questionnaire at all 3 measuring points and were included in the present study. Excluded patients were either lost to follow-up along the way and/or had missing values of various magnitude and reasons in their questionnaires. These values were considered to be missing at random. Because missing values occurred in not more than approximately 5% of the patients included in the RCT, these patients were excluded in the present study. The risk of introducing confounding bias in doing so was judged to be low.

PRWE-Swe was chosen as the EC over DASH,[1,15] which in fact was the primary outcome in the RCT. The reason for this is, first, that PRWE is specific for injuries of the wrist while DASH covers the whole upper extremity. Second, PRWE has been ascertained to have better responsiveness in patients with a distal radius fracture than DASH.[22] Third, PRWE has a lower response burden, ie, fewer questions for the patient to answer, which may reduce missing values.

Besides the observed change, the SRM was used as one of the measures of internal responsiveness in this study. The SRM was chosen over the also well-known standardized effect size (SES). The SRM is determined by the mean change score (ie, score difference) divided by the standard deviation of the change score, while the SES is determined by the mean change score divided by the standard deviation of the baseline score. By using the standard deviation of the change score as the denominator instead of the baseline score, the SRM better reflects change over time than the SES.[2]

Responsiveness of EQ-$5D_{index}$ score has previously been studied in patients with a wide range of injuries and medical conditions, such as proximal humeral fractures,[27] femoral neck fractures,[30] anxiety disorders,[20] breast cancer,[18] and stroke.[16] Olerud et al[27] reported a deterioration in EQ-$5D_{index}$ score of 21 from baseline to the 4-month follow-up in patients with a proximal humeral fracture, while Tidermark et al[30] found a deterioration of as much as 26 in patients with a displaced femoral neck fracture. These results are in agreement with our clinical experience that a proximal humeral fracture is more disabling than a distal radius fracture, and a femoral neck fracture affects the patient's HRQoL even more. These findings also confirm the discriminative ability of EQ-$5D_{index}$ score in patients with injuries of the musculoskeletal system.

Compared with Short Form 36 Health Survey (SF-36),[4,33] another widely used generic instrument for evaluation of HRQoL, the EQ-5D questionnaire is considered to be shorter, easier, and have a lower response burden. However, with only 5 dimensions of health represented and only 3 levels of response in each dimension, there is a risk that EQ-5D fails to capture subtle but significant changes in health status, and thus may not adequately reflect the respondent's HRQoL. In a previous study evaluating the responsiveness of SF-36, DASH, and PRWE in patients with a distal radius fracture using SRM, the responsiveness of PRWE was better than that of DASH, and the responsiveness of DASH was better than that of SF-36.[22] This indicates that instruments that are more specific to the wrist are more responsive in patients with a distal radius fracture. A recent review of 40 studies using EQ-5D as the patient-reported outcome measure of HRQoL in a wide variety of patients confirmed that EQ-5D was more responsive when larger changes in health status was expected, such as after lower back surgery, stroke rehabilitation, and high-dose chemotherapy for breast cancer.[31] A majority of the studies in the review had a poor to moderate responsiveness, based on SRM.

One limitation in this study was that the mean change score for the EQ-$5D_{index}$ score between the 3- and the 12-month follow-ups in the internal responsiveness analysis was slightly smaller than the MID of EQ-5D: 7.6 compared with 10. In the subgroup analysis of the 4 patient groups with different clinical outcome between the 3- and the 12-month follow-ups (Table 2), only the mean change score for the EQ-$5D_{index}$ score in the clearly improved group was above the MID of EQ-5D, at 12.1. MID refers to the smallest change in an instruments scale that correlates to a clinically relevant change in the patient. This indicates that the EQ-5D questionnaire may be too blunt to detect subtle changes in HRQoL, such as those occurring in our study population of high-functioning individuals with a distal radius fracture between the 3- and 12-month follow-ups. However, given the nature of EQ-5D as a brief questionnaire measuring general HRQoL and the expected moderately low impact of a distal radius fracture on general HRQoL between these measuring points, the results are not completely surprising and in accordance with previous studies.[31]

Another limitation may be that the valuation set (UK EQ-5D Index Tariff) used in this study to weigh different health states into the summary index score (EQ-$5D_{index}$ score) was based on the general population in Britain. The fact that healthy persons generally tend to rate HRQoL of hypothetical diseases and injuries worse than actual patients suffering from the same condition, as well as the fact that the British and Swedish population may differ, could introduce confounding bias. However, up until very recently,[8] no Swedish value set has existed for EQ-5D, and the UK valuation set has therefore been predominantly used in Sweden.

A weakness in this study was the risk of recall bias at baseline when patients at inclusion were asked to fill out PRWE-Swe and the EQ-5D questionnaire for their preinjury status as of the week before injury. However, due to the study design, the preinjury period was never more than 10 days previous. Furthermore, it is reasonable to assume that

the magnitude of this potential recall bias would be the same in both questionnaires in each individual patient.

Conclusion

This study showed that EQ-5D (specifically EQ-$5D_{index}$ score) displays an overall acceptable to good responsiveness in patients with a surgically treated distal radius fracture in Sweden. It may thus be used as a patient-reported outcome measure of HRQoL in this patient group, and assumingly also in patients with nonsurgically treated distal radius fractures or similar injuries to the forearm and hand. Furthermore, this enables calculation of QALYs and the subsequent cost-benefit analyses in health economic evaluations in this patient group, as well as comparison of HRQoL with other patient groups.

Ethical Approval

This study was approved by the regional ethics committee in Stockholm (Ref 2016/2207-32).

Statement of Human and Animal Rights

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Statement of Informed Consent

Informed consent was obtained from all patients for being included in the original RCT.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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