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Comparing 15D and SF-6D Performance in Fragility Wrist and Hip Fracture Patients in a Two-Year Follow-Up Case-Control Study

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ABSTRACT

Objectives: To examine and compare the two utility and health-related quality-of-life (HRQOL) measures 15D and (SF-6D) in fragility wrist and hip fracture patients and controls, study the responsiveness of 15D and SF-6D, and examine the impact of these fractures on changes in 15D and SF-6D scores over 2 years. **Methods:** A total of 152 wrist fracture patients and 164 controls and 61 hip fracture patients and 61 controls with 15D and SF-6D scores were studied. **Results:** The mean 15D score decreased significantly in wrist fracture patients between baseline and 2-year follow-up ($P = 0.003$). A wrist fracture was a significant predictor of a decrease in 15D scores 2 years after fracture ($B = -0.016$; $P = 0.049$), along with low body mass index ($B = -0.002$; $P = 0.009$). In hip fracture patients, both 15D and SF-6D scores decreased significantly ($P < 0.001$). A hip fracture was a significant predictor of a decrease in 15D ($B = -0.060$; $P = 0.001$) and SF-6D ($B = -0.096$; $P = 0.001$) scores. **Conclusions:** Our data suggest that a fragility wrist fracture has a long-term negative effect on HRQOL, but not as strong as for fragility hip fractures. 15D seems to be more responsive than SF-6D when assessing HRQOL in patients with fragility fractures.

Keywords: decision making, 15D, health-related quality of life, SF-36, osteoporosis.

Introduction

Fragility fractures may be devastating for the individual, challenging for the health care system due to the increased demand of health care, and a burden to society because of increased costs [1]. The most frequent sites for nonvertebral fragility fractures are wrist and hip. Previous studies have consistently reported that patients with a fragility fracture at hip experience a long-term negative impact on health-related quality of life (HRQOL) and the patients do not regain prefracture HRQOL levels [2–6]. For fragility wrist fracture, however, several studies indicate no long-term negative effects on HRQOL [7–9].

HRQOL can be used for economic evaluation (cost-utility analysis), and several generic utility instruments (e.g., 15D, six-dimensional health state short form [derived from short form 36 health survey (SF-36)] [SF-6D], and EuroQol five-dimensional [EQ-5D] questionnaire) have been developed. The underlying idea is that the utility (value) of a health state can be measured on a scale from death (0.0) to perfect health (1.0). Such utility measures can also be used to calculate quality-adjusted life-years [10,11]. The ability of the instruments to detect clinically important differences and changes is vital to their usefulness and applicability in clinical practice. This ability may be assessed by exploring the responsiveness of the instruments, which may be considered as one form of validity [12,13].

There is a general lack of knowledge regarding changes in HRQOL in patients with fragility fractures compared with individuals from the general population, in particular as assessed by utility instruments [2,11]. Apart from two studies, no previous studies of patients with fragility fractures have compared results from utility-measures with those of other generic HRQOL measures such as SF-36 [2,14].

From a prospective case-control study, we have recently published long-term SF-36 (HRQOL) data in patients with fragility wrist and hip fracture, reporting long-term reduction in SF-36 HRQOL in hip fracture patients after 2 years [15] but no long-term reduction in SF-36 HRQOL in patients with wrist fracture after 1 year [9].

From this same study population of wrist and hip fracture patients and controls, we aimed to examine and compare the two utility measures 15D and SF-6D. Furthermore, our aim was to study the responsiveness of 15D and SF-6D and examine the impact of a fragility wrist or hip fracture on changes in 15D and SF-6D scores after 1 and 2 years.

Methods

Study Population and Data Collection

Patients aged 50 years and older with fragility wrist or hip fractures attending a regional hospital in the southern part of Norway in a

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2-year period were invited to the Osteoporosis Center for assessment of bone mineral density (BMD) and health status and participation in a 2-year prospective case-control study. The controls were recruited consecutively from the same geographic area. Patients with confusion or dementia, serious infection, patients not capable of giving informed consent, patients unable to speak Norwegian, and tourists were excluded. Study design, data collection, and demographic, clinical, bone density, and SF-36 (HRQOL) data from this study have previously been described in detail [9,16,17]. For the wrist fracture patients, only 1-year follow-up data have been published previously [9]. In our study, wrist fracture, also called distal radius fracture in the literature, was defined as a fracture located within 3 cm of the radiocarpal joint.

In the 2-year inclusion period, 324 patients with fragility wrist fractures were treated at the hospital, and 249 of these patients were clinically examined at the Osteoporosis Center (30 patients were excluded, and 45 declined BMD assessment). Of the 249 patients with wrist fractures examined at the Osteoporosis Center, 181 met the inclusion criteria and were willing to enroll in this study (21 patients were excluded, and 47 were unwilling to participate), yielding a response rate of 66%. At 1-year follow-up, data were available for 160 patients (21 dropped out) and 169 controls [9] and at 2-year follow-up for 152 patients (17 dropped out) and 164 controls.

Four hundred fifty-six patients with fragility hip fracture were treated at the hospital. Among them, 307 patients were clinically examined at the Osteoporosis Center (137 patients were excluded, and 12 declined BMD assessment). Of the 307 patients with hip fractures examined at the Osteoporosis Center, 97 met the inclusion criteria and were willing to enroll in this prospective study (134 patients were excluded, and 76 were unwilling to participate), yielding a response rate of 52%. Among the hip fracture patients, 72 patients had 1-year data (5 died and 20 dropped out) and 61 patients had 2-year data (5 died, and 6 dropped out) [15]. The 61 patients with a hip fracture who were still in the study at 2-year follow-up were age and sex matched with 61 of the controls (±5 years) who had valid measures at baseline and at 1- and 2-year follow-up [15].

At baseline, the patients were asked to report their status prior to fracture and the controls were asked to report their status at the time prior to inclusion. With regard to the 15D questionnaire, the patients were asked to report their HRQOL at the time before fracture and the controls at the time before inclusion, and for SF-36 the 4 weeks before fracture for patients and the 4 weeks before inclusion for the controls. The same data collection performed at baseline was repeated after 1 and 2 years.

The collected data included demographical and clinical data, exercise (more than 30 minutes three times a week), smoking habits, medication, previous fragility fractures after the age of 50 years, number of falls the year before the fracture, and comorbidity (heart diseases, pulmonary diseases, neurological disorders, urogenital disorders, gastrointestinal disorders, endocrine disorders, inflammatory joint disorders and connective tissue disorders, cancer, mental disorders) as listed in Table 1. For comorbidity, we also computed a sum score of the number of diseases for each patient.

BMD was measured at femoral neck, total hip, and lumbar spine (L2–4) by using the same dual-energy X-ray absorptiometry equipment (General Electric, Lunar Prodigy) previously described in detail [9]. Osteoporosis was defined as a *T* score of ≤ -2.5 SD, osteopenia as a *T* score of > -2.5 and < -1.0, and normal BMD as a *T* score of > -1.0, according to the World Health Organization definition for osteoporosis [18].

The Utility Measures 15D and SF-6D

The 15D questionnaire is a generic, multidimensional, standardized evaluation tool of HRQOL that can be primarily used as a single index measure but also as a profile utility measure. It describes the health status, assessing the following 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity [19]. Each dimension comprises one question with five response categories. A single utility index score is obtained by incorporating population-based preference weights into the dimensions. The algorithm has been developed on the basis of multiattribute utility theory, and the 15D weights are based on a Finnish study from 2001 [19]. The algorithm has also been used in Norwegian studies [20,21]. The utility scores fall between 0.0 (being dead) and 1.00 (no problems on any dimension). Regression analyses were performed to impute missing values. The questionnaire has been thoroughly tested for psychometric properties in other studies within several countries [19–21].

The SF-6D is a utility instrument in which SF-36 or SF-12 scores can be translated into this utility score by means of an algorithm based on a standard gamble technique [10]. The SF-6D is based on 11 questions from the SF-36 and includes six dimensions, each with four to six levels. The SF-6D utility scores range from 0.29 to 1.00, with 1.00 indicating "full health." The Norwegian standard SF-36 v. 1.00 was used to derive the SF-6D. The different health states are assigned values derived from valuations of SF-6D health status using standard gamble in a representative sample of the UK population. Regression analyses were performed to impute missing values. The questionnaire has been tested for psychometric properties in other studies in several countries [10].

Statistical Analysis

Statistical analyses were carried out by using the Statistical Package for Social Sciences for Windows (version 18.0). Chi-square tests and *t* tests were used to compare differences between subgroups. Paired samples *t* tests were used to compare changes in 15D and SF-6D scores between baseline and 1-year follow-up, and between baseline and 2-year follow-up, within each patient group and within controls. General linear model (repeated multivariate analysis of variance) was also applied to examine differences in the repeated HRQOL measures within the groups [12,22]. Mean 15D and SF-6D change scores (SD) over the 2-year period were calculated within the groups. Independent sample *t* tests were used to compare differences in 15D and SF-6D scores between patients and controls at baseline and at 1- and 2-year follow-up. Pearson correlation coefficients between 15D and SF-6D 2-year change scores were calculated.

To examine the internal responsiveness of the instruments, the observed change and effect size (ES) related to the change in the 15D and SF-6D scores were calculated within patients and within controls. ESs were calculated by subtracting the mean 15D and SF-6D scores at inclusion from the mean scores of the 1- and 2-year follow-up and then dividing by each group's SD at inclusion [23]. We applied Cohen standards for ESs as follows: small effect, 0.2; medium effect, 0.5; and large effect, 0.8 [22].

Multiple linear regression analysis (procedure general linear model in the Statistical Package for Social Sciences) was used to examine the impact of a fragility wrist or hip fracture on 2-year changes in the 15D and SF-6D scores. Independent variables in the multiple regression analyses were the demographic variables of age, gender, and marital status (cohabiting/living alone) and the clinical variables of BMD (normal BMD/osteopenia/osteoporosis) and patients/controls. These variables showed correlations with the patients/controls dichotomy at baseline and have been shown to be covariates of HRQOL in earlier studies [12]. The regression analyses were adjusted for 15D or SF-6D scores at baseline. To test whether the effects of independent variables in the regression models (potential predictors of change) on our dependent variables were significantly different for patients and controls, interaction terms involving the patient/control