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Outcome assessment after hip fracture

IS EQ-5D THE ANSWER?

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Objectives

To study the measurement properties of a joint specific patient reported outcome measure, a measure of capability and a general health-related quality of life (HRQOL) tool in a large cohort of patients with a hip fracture.

Methods

Responsiveness and associations between the Oxford Hip Score (a hip specific measure: OHS), ICEpop CAPability (a measure of capability in older people: ICECAP-O) and EuroQol EQ-5D (general health-related quality of life measure: EQ-5D) were assessed using data available from two large prospective studies. The three outcome measures were assessed concurrently at a number of fixed follow-up time-points in a consecutive sequence of patients, allowing direct assessment of change from baseline, inter-measure associations and validity using a range of statistical methods.

Results

ICECAP-O was not responsive to change. EQ-5D was responsive to change from baseline, with an estimated standardised effect size for the two datasets of 0.676 and 0.644 at six weeks and four weeks respectively; this was almost as responsive to change as OHS (1.14 at four weeks). EQ-5D correlated strongly with OHS; Pearson correlation coefficients were 0.74, 0.77 and 0.70 at baseline, four weeks and four months. EQ-5D is a moderately good predictor of death at 12 months following hip fracture. Furthermore, EQ-5D reported by proxies (relatives and carers) behaves similarly to self-reported scores.

Conclusions

Our findings suggest that a general HRQOL tool such as EQ-5D could be used to measure outcome for patients recovering from hip fracture, including those with cognitive impairment.

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Article focus

- The measurement properties and association between the Oxford Hip Score, ICECAP-O and EuroQol EQ-5D in a large cohort of patients with a hip fracture

Key messages

- Our findings suggest that a general health-related quality of life tool such as EQ-5D has good measurement properties and could feasibly be used as an outcome measure for patients recovering from hip fracture

Strengths and limitations

- This is a large study that reports strong and highly significant associations between hip specific function and general quality of life outcome measures in patients after hip fracture
- The main limitation is the fact that all of the data were collected in a single trauma centre; further research is required to see whether EQ-5D is feasible and generalisable for other UK centres.

Introduction

Fragility fracture of the proximal femur (hip fracture) is one of the biggest healthcare challenges of the twenty-first century. In 1990 the global incidence of hip fractures was 1.31 million and was associated with 740 000 deaths.[1] With an ageing population, the morbidity, mortality and socioeconomic costs of hip fracture have increased substantially.[2]

Traditionally, outcome after hip fracture has been measured using characteristics such as mortality, the need for further surgery and length of patient stay in hospital. This focus on mortality and 'process' data is reflected in the outcomes reported in the UK National Hip Fracture Database (NHFD).[3] However, it is increasingly recognised and expected that healthcare evaluations should routinely include health domains that are important to patients; patient reported outcome measures (PROMs) aim to assess how patients function and feel about their condition and the success or otherwise of their treatment.[4,5]

For patients who have sustained a hip fracture, there is little consensus on the most appropriate PROM.[6,7] In many areas of healthcare, PROMs specific to a particular disease or area of the body are considered the most sensitive to changes in outcome. However, patients who suffer fragility fracture of the hip represent a highly heterogeneous population; ranging from extremely frail to fit and active patients, with and without serious comorbidities or cognitive impairment, sometimes with pre-existing deterioration in health-related quality of life (HRQOL). Therefore, it may be that we need to think unconventionally about appropriate outcome measures in this population.

We compared the measurement properties of a joint specific PROM – Oxford Hip Score (OHS),[8] a measure of capability in older people – ICEpop CAPability measure for older people (ICECAP-O)[9] and a general HRQOL tool – EuroQol EQ-5D (EQ-5D)[10] in a large cohort of patients with a hip fracture.

Methods

Data. Data were available from two distinct, but related, studies.

The Warwick Hip Trauma (WHiT) study[11] was a single centre, parallel group randomised controlled trial. Between September 2009 and April 2011, 225 participants aged 65 years and over with an intracapsular fracture of the hip were recruited. All participants were followed-up at six weeks, 12 weeks and one year post-operatively and completed the EQ-5D at each time-point. In addition, basic demographic data were recorded on admission (baseline), and trial participants were asked retrospectively to report score data to assess function and quality of life before the fracture. Full details of the study and treatment effects are described in detail elsewhere.[12]

The Warwick Hip Trauma Evaluation (WHiTE) study[13] is a prospective cohort study performed at the same trauma centre, in an analogous manner and as an immediate extension of the WHiT study. Recruitment began in January 2012, and is on-going, with data currently available from 249 participants, all aged 60 years and above with all types of hip fractures. Following consent, all participants report their pre-operative hip function (OHS), quality of life (EQ-5D) and capability (ICECAP-O) retrospectively assessed through questionnaires. This is followed by telephone questionnaires at four weeks, four months and 12 months post-operatively. For those participants with cognitive impairment (defined as an abbreviated mental test (AMT) score less than 8),[14] this assessment is limited to the EQ-5D, which is reported by an appropriate proxy.

Outcomes. EQ-5D is a validated, generalised and standardised instrument comprising a visual analogue scale (VAS) measuring self-rated health and a health status instrument, consisting of a three-level response (no problems, some problems and extreme problems) for five domains related to daily activities[10]; (i) mobility, (ii) self-care, (iii) usual activities, (iv) pain and discomfort and (v) anxiety and depression. Responses to the health status classification system are converted into an overall score using a published utility algorithm for the UK population.[15] A respondent's EQ-VAS gives self-rated health on a scale where the endpoints are labelled 'best imaginable health state' (100) and 'worst imaginable health state' (0).

OHS was introduced in 1996 and uses 12 multiple choice questions to quantify disability secondary to hip osteoarthrosis.[8] It has good evidence supporting its validity[8,16,17] and is entirely patient-reported, thus can be administered by post or telephone as well as in the clinical setting, without the need for an assessment by a clinician. Each of the 12 items comprising the OHS is assessed on a scale from zero to four, where zero represents, for instance, no pain or difficulty in undertaking the task in question. The scores for the 12 items are summed for each patient to give an overall score that quantifies hip function on a scale from 0 to 48, where 0 indicates excellent hip function and 48 indicates very poor hip function.

ICECAP-O is a measure of capability in older people.[9] It comprises five attributes that are important to older people in the UK; (i) attachment (love and friendship), (ii) security (thinking about the future without concern), (iii) role (doing things that make you feel valued), (iv) enjoyment (enjoyment and pleasure) and (v) control (independence). Each attribute is assessed using four ordered levels from the lowest capability (level 1) to the highest capability (level 4), and scaled using UK index values[18] to ensure overall ICECAP-O values were constrained between zero (no capacity) and one (full capacity).

Statistical analysis. Descriptive data summaries (mean, standard deviation [SD], median and range) were calculated at each occasion to assess overall population changes and variability. Standardised effect sizes, calculated as the difference in means between the index occasion and the

Table I. Baseline characteristics of WHiT study participants (n = 225)

Characteristic	Measure	
	Mean	**SD**
Age in years	83.1	(7.94)
Time to theatre in hours	31.3	(28.3)
	F:M*	**%†**
	160:65	(71%:29%)
	N:Y‡	**%†**
Smoker	210:15	(93%:7%)
Diabetic	198:27	(88%:12%)
Chronic renal failure	215:10	(96%:4%)
Osteoporosis	182:43	(81%:19%)
Steroids	210:15	(93%:7%)
Dementia	153:72	(68%:32%)
Displaced fracture	48:177	(21%:78%)
Platelet drugs	160:64	(71%:29%)
NSAID§	217:8	(96%:4%)

*F:M, Female:Male
†Percentages interpreted based on full population
‡N:Y, No:Yes
§NSAID, Non-steroidal anti-inflammatory drug

Table II. Summary of EQ-5D and EQ-VAS outcome data for WHiT at baseline (Base), and six weeks (6w), 12 weeks (12w) and 52 weeks (52w) post-operation

	Base	6w	12w	52w
EQ-5D				
n	151	125	121	107
Range	(-0.48 to 1)	(-0.32 to 1)	(-0.35 to 1)	(-0.24 to 1)
Median	0.73	0.52	0.69	0.69
Mean	0.66	0.44	0.56	0.57
SD	0.32	0.32	0.31	0.34
Effect Size*	-	0.68	0.32	0.27
t-test†	-	< 0.001	< 0.001	< 0.001
EQ-VAS				
n	93	63	65	47
Range	(10 to 100)	(28 to 100)	(1 to 100)	(1 to 100)
Median	70.0	70.0	70.0	80.0
Mean	67.6	66.2	66.9	74.7
SD	19.3	18.7	21.4	20.8
Effect Size*	-	0.07	0.03	-0.37
t-test†	-	0.712	0.882	0.368

* Effect size, change in mean from baseline/baseline standard deviation (SD)
† Paired *t*-test, comparison with baseline data

baseline assessment divided by the baseline standard deviation, were estimated in order to assess responsiveness for all of the available outcome measures. Paired *t*-tests were also calculated to assess the significance of changes in mean outcome measures from baseline. For WHiT, receiver operator characteristic (ROC) curves were constructed for six weeks of EQ-5D using the defined gold-standard outcomes of subsequent revision and death within 12 months. Areas under the curves, and 95% bootstrapped confidence intervals, were calculated to assess the predictive power of post-operative EQ-5D. Scatterplots were used to assess ceiling and floor effects visually. Construct validity was also assessed by scatterplot and by pairwise correlations between outcome measures, which were quantified using Pearson's correlation coefficient. This was further explored for OHS and EQ-5D data, available from WHiTE, by calculation of item-to-item Spearman correlation coefficients; that is correlations between all pairs of individual questionnaire items. Responsiveness was quantified for proxy and patient scored EQ-5D for WHiTE by calculating appropriate statistics for demented and non-demented groups. EQ-5D and ICECAP-O data for this population were compared with previously reported normative values for the UK population. Statistical significance was set at the 5% level and all analyses were undertaken using the statistical software package R.[19]

Results

Characteristics of the sample. Baseline characteristics for WHiT participants are shown in Table I and summaries of

Table III. Baseline characteristics of WHiTE participants

Characteristic*	Total† (n = 249)		Demented (n = 103)		Non-demented (n = 139)	
Age in years (mean and SD)	83.6 (7.77)		85.6 (6.37)		82.0 (8.28)	
Sex (F:M)	180:60	(75%:25%)	78:21	(79%:21%)	100:39	(72%:28%)
Smoker (N:Y)	215:32	(87%:13%)	91:11	(89%:11%)	119:20	(86%:14%)
Diabetic (N:Y)	213:30	(88%:12%)	93:8	(92%:8%)	115:22	(84%:16%)
Chronic renal failure (N:Y)	233:8	(97%:3%)	97:2	(98%:2%)	132:5	(96%:4%)

*SD, standard deviation; F:M, Female:Male; N:Y, No:Yes
† Percentages interpreted based on full population

Table IV. Summary of (a) OHS, (b) EQ-5D, (c) EQ-VAS and (d) ICECAP-O outcome data for WHiTE at baseline (Base), and four weeks (4w) and four months (4m)

	Base	4w	4m		Base	4w	4m
(a) OHS				(b) EQ-5D			
n	118	67	28	n	236	159	88
Range	(11 to 48)	(8 to 48)	(19 to 48)	Range	(-0.43 to 1)	(-0.59 to 1)	(-0.59 to 1)
Median	40.5	29.0	36.5	Median	0.62	0.27	0.52
Mean	38.8	29.1	35.5	Mean	0.55	0.32	0.44
SD	8.5	9.9	8.5	SD	0.34	0.37	0.39
Effect Size*	-	1.14	0.39	Effect Size*	-	0.64	0.30
t-test†	-	< 0.001	0.064	*t*-test†	-	< 0.001	0.012
(c) EQ VAS				(d) ICECAP-O			
n	226	146	76	n	113	59	29
Range	(0 to 100)	(5 to 100)	(10 to 100)	Range	(0.25 to 1)	(0.00 to 1)	(0.25 to 1)
Median	70.0	65.0	70.0	Median	0.82	0.76	0.88
Mean	65.2	62.6	65.4	Mean	0.79	0.73	0.83
SD	21.5	22.0	20.2	SD	0.16	0.22	0.17
Effect Size	-	0.12	-0.01	Effect Size†	-	0.39	-0.24
t-test	-	0.363	0.999	*t*-test‡	-	0.018	0.355

* Effect size, change in mean from baseline/baseline standard deviation
† Paired *t*-test, comparison with baseline data

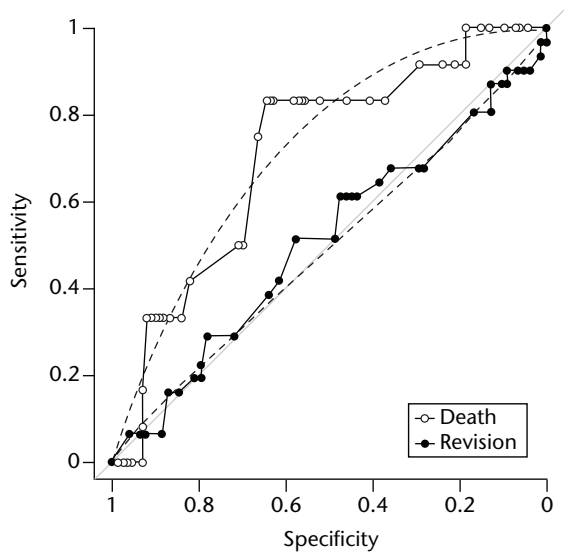

Fig. 1

Receiver operating characteristic (ROC) curves for WHiT EQ-5D at six weeks and subsequent death and revision within 12 months; data (solid) and smoothed curves (dashed)

outcome measures, EQ-5D and EQ VAS, in Table II. Table II shows estimates of the means, medians and standard deviations at baseline and each of the follow-up time points at six weeks, 12 weeks and 52 weeks. Baseline characteristics for WHiTE participants are shown in Table III and summaries of outcome measures, OHS, EQ-5D, EQ VAS and ICECAP-O, in Table IV. Table IV shows estimates of the means, medians and standard deviations at baseline and each of the follow-up time points at four weeks and four months. Also shown are effect sizes, which are used to assess responsiveness to change from baseline, and paired *t*-tests at four weeks and four months.

Longitudinal change in outcome scores. There was clear evidence from both WHiT and WHiTE of a smooth increase in EQ-5D scores in the post-operative period, as patients returned to comparatively normal function (Table II and Table IV); that is scores gradually returned to their pre-operative (baseline) level.

The estimated (standardised) effect size in the WHiT Study decreased from a medium to a small level during follow-up for EQ-5D (0.68 at six weeks, 0.32 at 12 weeks and 0.27 at 52 weeks), consistent with the change in mean scores. EQ-VAS proved to be unresponsive to change from baseline. ROC curves for six week EQ-5D based on estimated sensitivity and specificity for subsequent revision and death within 12 months are shown in Figure 1. The estimated area under the ROC curve (AUC)

Table V. Pair-wise Pearson correlation coefficients between outcome measures for WHiTE, with 95% confidence intervals from 1000 bootstrap replicates. 4 w, four weeks; 4 m, four months

Pair-wise terms*		Baseline	4 w	4 m
EQ-5D	OHS	0.74 (0.66 to 0.82)	0.77 (0.63 to 0.80)	0.70 (0.57 to 0.82)
EQ-5D	ICECAP-O	0.34 (0.19 to 0.49)	0.62 (0.43 to 0.75)	0.47 (-0.07 to 0.76)
ICECAP-O	OHS	0.38 (0.23 to 0.55)	0.54 (0.36 to 0.70)	0.37 (-0.17 to 0.76)

* OHS, Oxford Hip Score; ICECAP-O, measure of capability in older people

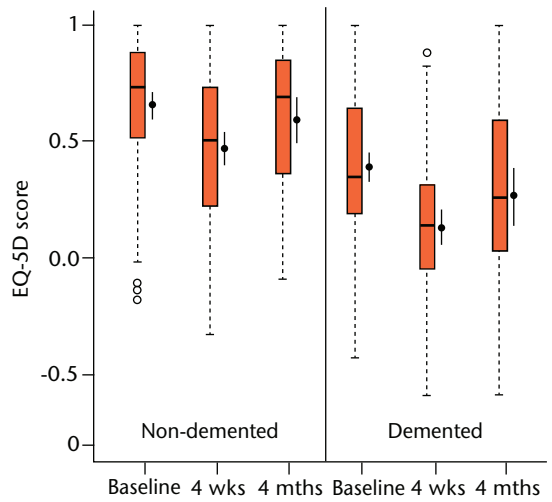

Fig. 2

Boxplots for WHiTE for EQ-5D at baseline, four weeks and four months for demented and non-demented patients; symbols (•) and bars show means and 95% confidence intervals

for death was 0.72 (95% CI; 0.57, 0.85 for 2000 bootstrap replicates) and the area under the ROC curve for revision was 0.49 (95% CI; 0.38, 0.62). The AUC measures discrimination, that is, the ability of EQ-5D to classify correctly those who will die or be revised within 12 months; a value of 0.5 indicates no predictive value. Therefore, EQ-5D is not predictive of revision, but is moderately good predictor of death within 12 months.

The estimated effect size in the WHiTE Study decreased from a medium to a small level during follow-up for EQ-5D, consistent with the change in mean scores. There was an analogous decrease in effect sizes, from large to small, from four weeks to four months for OHS. EQ-VAS proved to be unresponsive to change from baseline and ICECAP-O was moderately responsive at four weeks only.

Proxy reported EQ-5D. For those participants with cognitive impairment (nominally referred to here as 'demented') EQ-5D was reported by an appropriate proxy. Temporal trends in scores for demented and non-demented groups, shown in Figure 2, were similar with scores being lower overall for the latter than the former group. Estimated effect sizes at the four week assessment for the two groups were 0.85 and 0.58 and of approximately the same magnitude as those observed for the full population (Table IV).

Comparison between EQ-5D and other instruments. Pair-wise correlations for EQ-5D, OHS and ICECAP-O at baseline, four weeks and four months (Table V) showed that there were significant strong positive correlations, > 0.7, between EQ-5D and OHS at all occasions. Correlations between EQ-5D and ICECAP-O, and between ICECAP-O and OHS were also all significant, although smaller than between EQ-5D and OHS, at baseline and four weeks. The correlations between EQ-5D and ICECAP-O, and between ICECAP-O and OHS failed to reach significance due to the paucity of available data at this occasion. This is apparent in the scatter-plots between pairs of outcome measures at each occasion (Figure 3).

Item-to-item correlations between EQ-5D and OHS at four weeks showed a strong correlation (0.72; 95% bootstrapped CI 0.51 to 0.85) between the EQ-5D Self Care domain and OHS item 2 (Have you had any trouble washing and drying yourself because of your hip?). There were similar strong associations between the EQ-5D 'Mobility', 'Usual Activities' and 'Pain' domains and those aspects of the OHS that were relevant to these construct (e.g. walking or climbing stairs for 'Mobility'). There were generally many fewer significant associations between the EQ-5D 'Anxiety' domain and OHS questionnaire items, consistent with what one might expect for this construct that does not feature explicitly in the OHS.

Recall of pre-fracture status. The mean baseline EQ-5D scores were 0.66 (95% CI; 0.61 to 0.71) and 0.55 (95% CI; 0.50 to 0.59) for the WHiT and WHiTE studies respectively. A more informative categorisation for the WHiTE study gave means of 0.39 (95% CI; 0.33 to 0.45) and 0.66 (95% CI; 0.60 to 0.71) for the demented and non-demented groups. The UK normative data[20,21] derived from face-to-face interviews with randomly selected individuals from England, Scotland and Wales, suggest a mean EQ-5D score of approximately 0.680 for the 80+ age group, based on tabulated data that consists of marginal proportional splits by level and EQ-5D category. This is close to our reported values for both WHiT and WHiTE, taking the non-demented group as a more realistic point of comparison for the latter group, and provides strong evidence for the veracity (reliability) of retrospective assessments of EQ-5D in this population.

Discussion

This study compared the measurement properties of three types of patient-reported outcome measure in

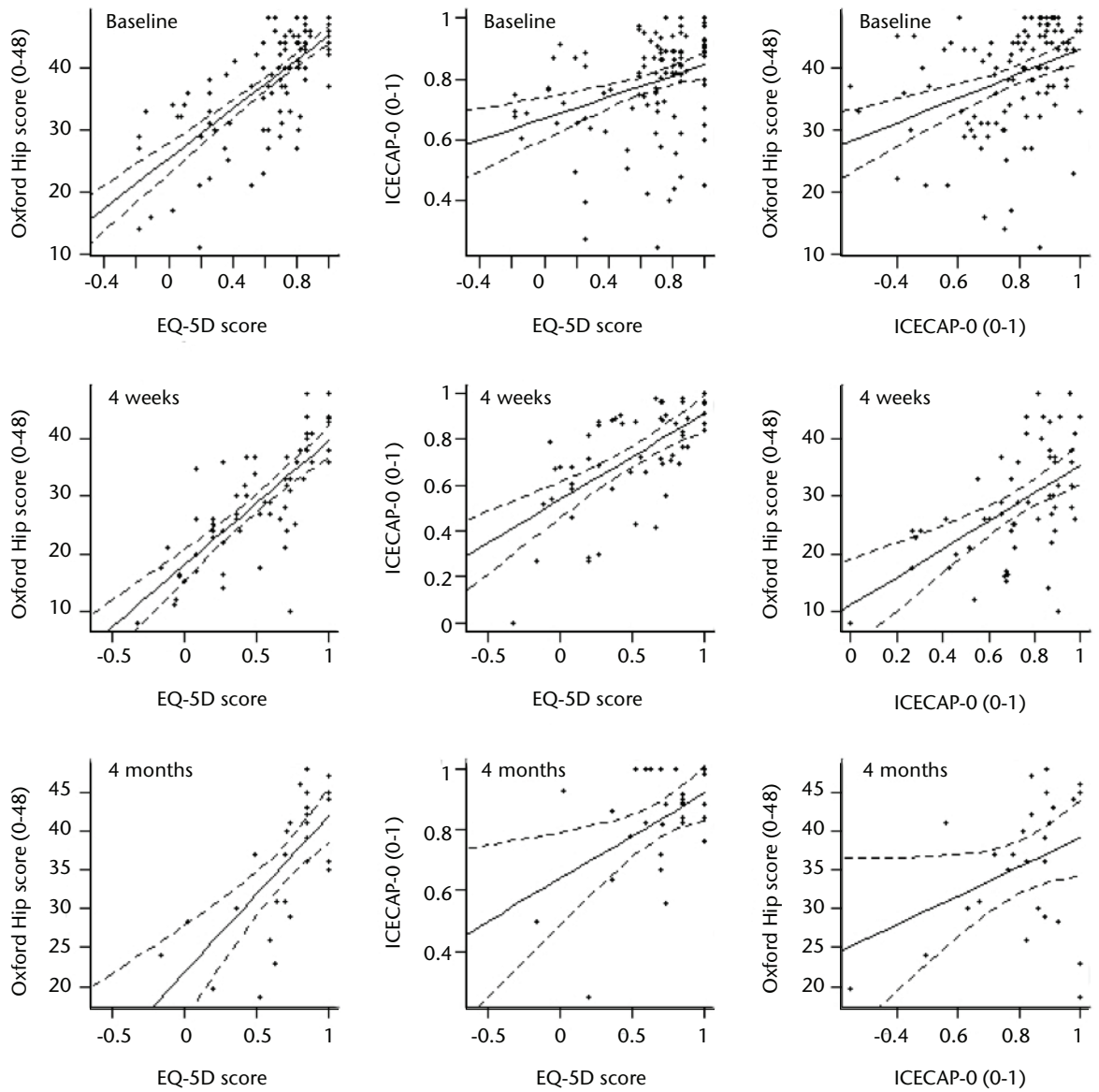

Fig. 3

Scatter-plots between pair-wise combinations of EQ-5D, Oxford Hip Score (OHS) and ICECAP-O from WHiTE at baseline (top row), four weeks (middle row) and four months (bottom row); solid lines show linear regression fit, with 95% prediction intervals shown as dashed lines

patients with a fragility fracture of the hip. We found that hip fracture has large effects on quality of life that can be detected using a general HRQOL measure.

Furthermore, the general measure (EQ-5D) correlates strongly with a hip specific PROM (OHS) and is almost as responsive to changes over time. The measure of capability in older people was not responsive to change in patients with hip fracture. EQ-5D is also a moderately good predictor of death at 12 months following hip fracture. Finally our data suggests that EQ-5D scores can reasonably be collected from proxies (relatives and carers) where participants are unable to complete the questions themselves.

EQ-5D is a global measure, and as such it is designed to capture the complex and multifactorial aspects of a patient's health status. It is not a PROM for hip fracture surgery specifically. However, it is not at all clear whether a PROM specific to hip fracture could be developed in this group of patients, who often have difficulty articulating which aspects of their health experience relate to the hip fracture and which relate to other conditions.

Given that no specific measure exists and is unlikely to be developed, it is surprising that the evidence for available outcome measures in this elderly population is poor.[6] However, the measurement properties of EQ-5D have been widely studied more generally.[22-24] EQ-5D also facilitates the generation of health utility. Despite its general health status heritage, EQ-5D covers the domains of health which patients consider important in their

recovery following hip fracture: (i) mobility, (ii) self-care, (iii) usual activities, (iv) pain and discomfort and (v) anxiety and depression.[7]

The OHS has been shown previously to map accurately onto the EQ-5D utility index;[25] with a correlation and regression coefficient consistent with the analysis reported here. The good responsiveness properties of EQ-5D reported here confirms analyses reported elsewhere for elderly patients with hip fractures.[26] Up to 40% of patients with a hip fracture have permanent cognitive impairment.[3] When comparing patients without cognitive impairment, who provided their own EQ-5D score, and proxy scores for those with cognitive impairment, EQ-5D proved similarly responsive in both groups and supports evidence reported elsewhere for proxy completion of EQ-5D in patients with dementia.[27]

The main limitation of this study is the fact that all of the data were collected in one trauma centre. However, the baseline characteristics of the patients were very similar to those recorded in the NHFD report,[3] suggesting that the patients were representative of patients with hip fracture throughout the UK.

In contrast with other areas of healthcare, it seems that a general-HRQOL tool such as EQ-5D could be used to measure outcome for patients recovering from hip fracture; including those with cognitive impairment. Further research is required to see if it is feasible to collect EQ-5D scores in other centres around the country and, more importantly, whether the collection of patient-reported outcomes can be used to improve the design and delivery of healthcare for this vitally important group of patients.

Supplementary material

Three tables and six figures showing correlations and distributions at various time points are available alongside this article at www.bjr.boneandjoint.org.uk

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Author contributions:

- N. Parsons: Data analysis, Writing the paper
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- J. Achten: Critical review of the paper
- M. L. Costa: Conception of the study, Writing the paper

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- None declared