■ TRAUMA

Patient-reported outcome measures in hip fracture patients

DATA ON 35,206 PATIENTS FROM THE NORWEGIAN HIP FRACTURE REGISTER, 2014 TO 2018

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Aims
The aims of this study were to assess quality of life after hip fractures, to characterize respondents to patient-reported outcome measures (PROMs), and to describe the recovery trajectory of hip fracture patients.

Methods
Data on 35,206 hip fractures (2014 to 2018; 67.2% female) in the Norwegian Hip Fracture Register were linked to data from the Norwegian Patient Registry and Statistics Norway. PROMs data were collected using the EuroQol five-dimension three-level questionnaire (EQ-5D-3L) scoring instrument and living patients were invited to respond at four, 12, and 36 months post fracture. Multiple imputation procedures were performed as a model to substitute missing PROM data. Differences in response rates between categories of covariates were analyzed using chi-squared test statistics. The association between patient and socioeconomic characteristics and the reported EQ-5D-3L scores was analyzed using linear regression.

Results
The median age was 83 years (interquartile range 76 to 90), and 3,561 (10%) lived in a healthcare facility. Observed mean pre-fracture EQ-5D-3L index score was 0.81 (95% confidence interval 0.803 to 0.810), which decreased to 0.66 at four months, to 0.70 at 12 months, and to 0.73 at 36 months. In the imputed datasets, the reduction from pre-fracture was similar (0.15 points) but an improvement up to 36 months was modest (0.01 to 0.03 points). Patients with higher age, male sex, severe comorbidity, cognitive impairment, lower income, lower education, and those in residential care facilities had a lower proportion of respondents, and systematically reported a lower health-related quality of life (HRQoL). The response pattern of patients influenced scores significantly, and the highest scores are found in patients reporting scores at all observation times.

Conclusion
Hip fracture leads to a persistent reduction in measured HRQoL, up to 36 months. The patients' health and socioeconomic status were associated with the proportion of patients returning PROM data for analysis, and affected the results reported. Observed EQ-5D-3L scores are affected by attrition and selection bias mechanisms and motivate the use of statistical modelling for adjustment.

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Introduction
Hip fractures represent a substantial public health concern. Most patients affected are elderly with associated high rates of post-treatment morbidity, increased mortality, and deteriorating functional outcomes.[1,2] Assessment of outcomes of care for hip fracture patients has largely focused on clinical endpoints such as morbidity, mortality rates, and the need for reoperation. Patient-reported outcome measures (PROMs) have emerged as additional tools to evaluate the impact of treatment on patient health and functional status.[3-7]

However, measurement and interpretation of PROMs in a geriatric population are challenging; there are many outcome measures in widespread use, patients are lost to follow-up due to high

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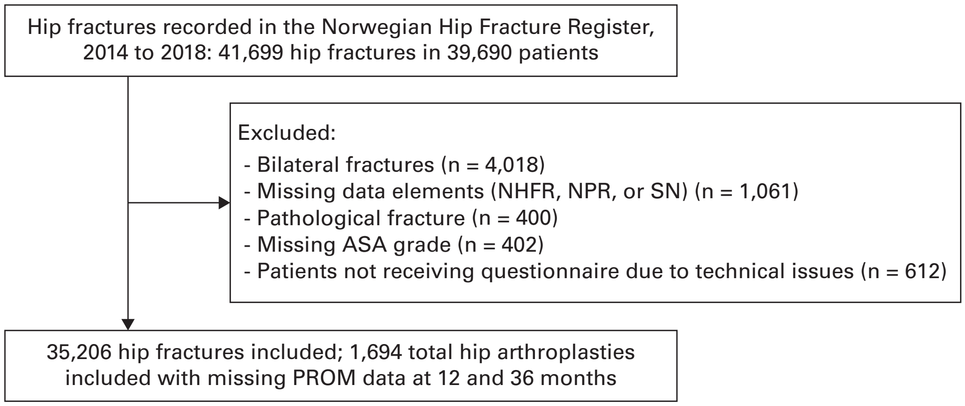


Fig. 1

Flow chart of patient selection. ASA, American Society of Anesthesiologists; NHFR, Norwegian Hip Fracture Register; NPR, Norwegian Patient Register; PROM, patient-reported outcome measure; SN, Statistics Norway.

post-treatment death rates, and a substantial proportion of surviving patients with cognitive impairment limits response rates.[6,8] Consequently, the sample of responders may affect the validity and reliability of the reported PROMs, complicating the interpretation of the results and comparisons between studies.[4] It is important to acquire knowledge on how and to what extent the patient population changes with time, and to document factors that may influence the PROMs response rate and describe how the sample of respondents may affect the understanding and interpretation of PROMs data.

The aim of this study was therefore to assess generic health-related quality of life (HRQoL) after hip fractures, particularly the recovery trajectory, to describe the characteristics of respondents to PROMs questionnaires, and finally to explore the effects of potential bias on observed PROMs data and interpretation of PROMs.

Methods

This is a national retrospective analysis of prospectively collected data in Norway (population 5.5 million inhabitants in 2024),[9] based on linked data from the Norwegian Hip Fracture Register (NHFR), the Norwegian Patient Registry (NPR), and Statistics Norway (SN). Data from the three registries were coupled using each patient's unique national identification number.

The Norwegian Hip Fracture Register. The NHFR has collected data on all hip fracture patients (International Classification of Diseases-10 codes S72.0-S72.2)[10] operated on in Norwegian hospitals since 2005.[11] Total hip arthroplasty (THA) as primary treatment for hip fractures is recorded in the Norwegian Arthroplasty Register and subsequently imported to the NHFR. Data from the NHFR were used to identify patients and retrieve baseline information (sex, age, American Society of Anesthesiologists (ASA) grade,[12] and presence of cognitive impairment). Age was categorized in six groups: < 65 years, 65 to 74 years, 75 to 79 years, 80 to 84 years, 85 to 89 years, and > 90 years.

PROMs forms were sent from the NHFR to all living patients at four, 12, and 36 months postoperatively. No reminders were sent to non-responders. The cover letter encouraged support by a proxy respondent, and information on who filled in the form was collected. Information was dichotomized to patient or a proxy respondent. The questionnaires included a validated Norwegian translation of the EuroQol five-dimension three-level questionnaire (EQ-5D-3L). Information on pre-fracture EQ-5D-3L data was collected as part of the four-month questionnaire. Patients treated with THA (n = 1,694) only received the four-month PROMs questionnaire.

The EQ-5D-3L covers five dimensions of HRQoL: mobility, self-care, usual activities, pain/discomfort, and symptoms of anxiety and depression.[13] There are three response categories for each dimension, ranging from level 1 (indicating no problems or best state) to level 3 (indicating severe problems or worst state).[13]

The reference scores (EQ-5D-3L index scores) were generated from a large European population,[14] ranging from a score of 1 (indicating the best possible state of health) to a score of -0.217 (indicating a state of health worse than death), while 0 indicates a state of health equal to death.

Completeness of reporting of hip fractures to the NHFR is evaluated regularly and was 88.2% for osteosynthesis, 94.5% for hemiarthroplasties, and 87.8% for THAs in 2015 to 2016.[15] Date of death was retrieved from the Norwegian National Population Register.

The Norwegian Patient Registry. Administrative data from all hospitals and other specialist healthcare providers are reported to the NPR monthly and data were obtained on all in- and outpatient visits, including ICD-10 diagnoses, from 1 January 2013 to 31 December 2019 (i.e. at least one year before and one year after the index event). ICD-10 codes in the NPR were used to estimate comorbidity using the Charlson Comorbidity Index (CCI)[16] with the Quan modification,[17] validated for use in Norway.[18] Based on CCI, comorbidity was categorized into no comorbidity (0 points), mild comorbidity (1 to 2 points), moderate comorbidity (3 to 4 points), and severe comorbidity (≥ 5 points).

Statistics Norway. We obtained individual socioeconomic data (household income, highest completed education level,

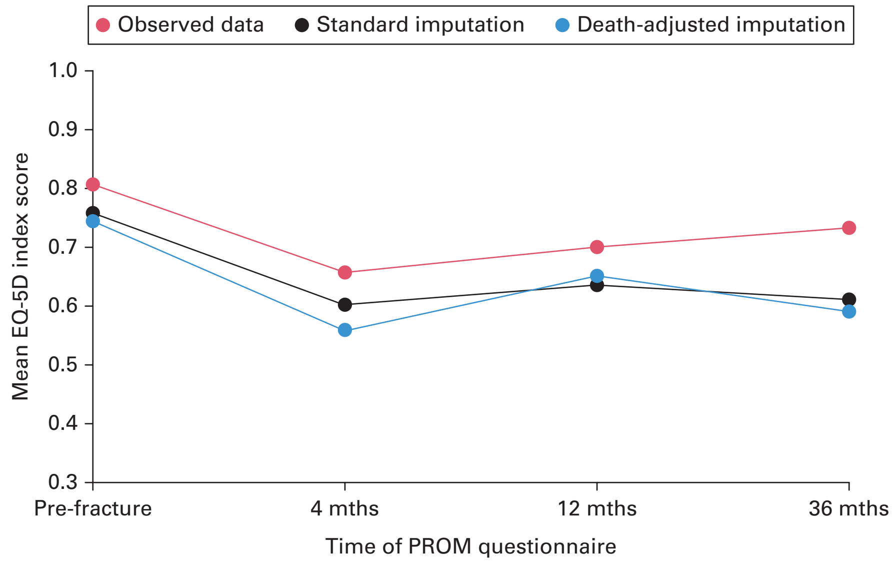


Fig. 2

EuroQol five-dimension three-level questionnaire (EQ-5D-3L) index score at follow-ups (observed and modelled data). PROM, patient-reported outcome measure.

Table I. EuroQol five-dimension three-level questionnaire index score measured in three different models: observed (unadjusted) data, standard imputed data (all missing values imputed), and death-adjusted imputed data (deceased patients' value set to 0, the remaining imputed).

Time of follow-up	Mean (95% CI)
Observed data	
Pre-fracture	0.810 (0.803 to 0.810)
4 months	0.658 (0.654 to 0.662)
12 months	0.700 (0.696 to 0.705)
36 months	0.733 (0.728 to 0.739)
Standard multiple imputation model	
Pre-fracture	0.758 (0.758 to 0.758)
4 months	0.602 (0.602 to 0.602)
12 months	0.636 (0.635 to 0.636)
36 months	0.612 (0.612 to 0.613)
Death-adjusted multiple imputation model	
Pre-fracture	0.745 (0.743 to 0.746)
4 months	0.559 (0.558 to 0.561)
12 months	0.651 (0.649 to 0.654)
36 months	0.591 (0.589 to 0.594)

CI, confidence interval.

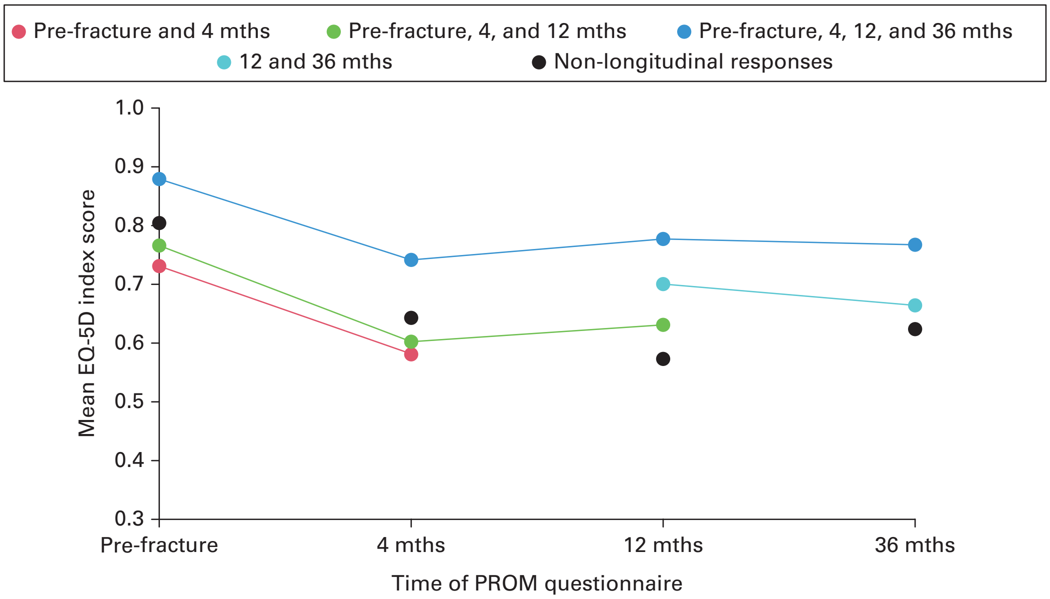
and living status) from SN. Living status was dichotomized into living independently (alone or with others) or living in a health-care facility at the time of fracture. Household income, defined as income in the year prior to injury, was categorized into quartiles of income. Educational status was grouped into three levels according to the International Standard of Classification of Education:[19] low (lower secondary education), medium (upper secondary to short-cycle tertiary education), and high (Bachelor's level and beyond).

By 31 December 2019, the NHFR had compiled data on 41,699 fractures, admitted from 1 January 2014 to 31 December 2018. Bilateral fractures during follow-up were excluded (n = 4,018 in 2,009 patients). Patients with missing information in the coupled datasets (NHFR, NPR, and SN) (n = 1,061), with pathological fractures (n = 400), with missing information on ASA grade (n = 402), and 612 living patients who did not receive any questionnaires due to technical issues at the register were excluded, leaving 35,206 fractures for analyses (Figure 1).

Statistical analysis. Categorical variables are presented as absolute numbers and percentages. Level of significance was set at 5% in all analyses. Pearson's chi-squared test was used to evaluate the significance of differences in categories for each covariate and proportion of returned questionnaires.

The dataset contains an arbitrary pattern of missing data in the continuous EQ-5D-3L index score variable at all follow-up times. The challenges with missing data (death and selection bias) were addressed applying a multiple imputation procedure in which each missing value was substituted with an estimated plausible value. The imputation method of choice depends on the patterns of missingness in the data and the type of imputed variable. The fully conditional specification (FCS) method in the SAS/STAT for Windows software was deemed suitable for large mixed datasets with both continuous and categorical variables and an arbitrary pattern of missing data as in the present dataset.[20]

The dataset was analyzed using two alternative approaches: in the first, deceased patients' missing responses were imputed by the described procedure (standard dataset); the second was a death-adjusted imputation where EQ-5D-3L scores of all deceased patients were set to 0. We performed 100 imputation iterations for both models. The multiple imputed data sets were then analyzed using standard procedures for complete data. The measures from these separate analyses were then combined. The means and 95% confidence intervals (CIs) of EQ-5D-3L index score based on the observed and imputed data are presented at pre-fracture and at four, 12, and 36 months.



Responses to questionnaires (n)

	Pre-fracture	4 mths	12 mths	36 mths
● (Pre-fracture and 4 mths)	4,740	4,740	-	-
● (Pre-fracture, 4, and 12 mths)	4,281	4,281	4,281	-
● (Pre-fracture, 4, 12, and 36 mths)	7,432	7,432	7,432	7,432
● (12 and 36 mths)	-	-	1,058	1,058
● (Non-longitudinal responses)	822	822	2,116	1,556

Fig. 3

EuroQol five-dimension three-level index score in different response patterns. EQ-5D, EuroQol five-dimension questionnaire; PROM, patient-reported outcome measure.

Multiple linear regression models were used to assess the magnitude of a possible association between the covariates and the EQ-5D-3L index score at pre-fracture and at four, 12, and 36 months.

The analyses were performed using SAS/STAT for Windows v. 8.3 (SAS Institute, USA). The STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines were followed.[21]

Results

A total of 23,649 females (67.2%) and 11,557 males (32.8%), with a median age of 83 years (interquartile range 76 to 90), were included in the study. More than half of the patients (55.2%) were categorized as ASA grade III and 23.8% had cognitive impairment at time of injury. The majority (89.8%) lived at home. Most patients had a low or medium education level (86.4%), whereas 13.6% had higher education. Pre-fracture baseline patient characteristics and underlying descriptive data at four, 12, and 36 months after fracture are presented in Supplementary Table i. In total, 32% of the PROMs were filled out by a proxy. Among the cognitive impaired, 82% had responses by proxy.

Respondent characteristics. Supplementary Table i shows that younger and healthier female patients living at home with higher income and higher education were more likely to receive a questionnaire, irrespective of follow-up time. The proportion of males receiving the questionnaire at 36 months was lower than that of females (47% vs 54%; $p < 0.02$). Of ASA grade III patients, 45% received a form at 36 months, significantly lower than the 80% of those with ASA grade I ($p < 0.001$). Cognitive impairment led to a 33-percentage-point reduction in survival at 36 months compared to patients without cognitive impairment (60% vs 27%; $p < 0.001$).

Despite the fairly even overall response rate at all observation points (four months 58%; 12 months 59%; 36 months 55%), the distribution of response rates between categories of the variables varied significantly (Supplementary Table i). Patients with higher age and comorbidity, cognitive impairment, lower income and education, and those in residential healthcare facilities had lower response rates. We found significant differences ($p < 0.001$) in response rates between all variable categories, except sex, at all follow-up points (Supplementary Table i).

EQ-5D-3L trajectories after hip fractures. We observed a decrease of 0.15 points in the mean EQ-5D-3L index score from pre-fracture to four months after treatment (18.5% reduction). From four months onwards, the observed mean EQ-5D-3L index score increased 0.04 points up to 12 months and an additional 0.03 points up to 36 months follow-up (Table I; Supplementary Table i), i.e. a 0.08 point reduction compared to pre-fracture.

In the standard imputation dataset, we observed a similar consistent decrease from pre-fracture to four months (-0.15 points). Compared to the observed dataset, there were minimal changes in EQ-5D-3L at 12 months (+0.03 points) and 36 months (-0.01 points), resulting in a larger reduction from

Table II. Effects of covariates on EuroQol five-dimension three-level questionnaire (EQ-5D-3L) index score at the observation timepoints. Regression coefficient (β) reflects magnitude and direction of association covariates with EQ-5D-3L index score.

Covariate	Pre-fracture estimate, β (95% CI)	p-value	4-mth estimate, β (95% CI)	p-value	12-mth estimate, β (95% CI)	p-value	36-mth estimate, β (95% CI)	p-value
Male sex	0.007 (-0.001 to 0.014)	0.094	-0.004 (-0.012 to 0.005)	0.393	-0.007 (-0.017 to 0.002)	0.120	0.001 (-0.010 to 0.012)	0.900
Age	-0.006 (-0.008 to -0.003)	< 0.001	-0.017 (-0.020 to -0.014)	< 0.001	-0.011 (-0.014 to -0.008)	< 0.001	-0.020 (-0.024 to -0.016)	< 0.001
Cognitive impairment	-0.154 (-0.165 to -0.142)	< 0.001	-0.182 (-0.194 to -0.169)	< 0.001	-0.175 (-0.189 to -0.161)	< 0.001	-0.173 (-0.194 to -0.152)	< 0.001
ASA grade	-0.067 (-0.073 to -0.061)	< 0.001	-0.075 (-0.081 to -0.068)	< 0.001	-0.068 (-0.075 to -0.061)	< 0.001	-0.070 (-0.078 to -0.062)	< 0.001
CCI	-0.021 (-0.026 to -0.016)	< 0.001	-0.020 (-0.026 to -0.014)	< 0.001	-0.024 (-0.030 to -0.017)	< 0.001	-0.027 (-0.035 to -0.018)	< 0.001
Residental status	-0.096 (-0.104 to -0.087)	< 0.001	-0.074 (-0.083 to -0.064)	< 0.001	-0.071 (-0.081 to -0.060)	< 0.001	-0.078 (-0.095 to -0.061)	< 0.001
Educational level	0.019 (0.014 to 0.024)	< 0.001	0.017 (0.011 to 0.023)	< 0.001	0.020 (0.014 to 0.026)	< 0.001	0.024 (0.017 to 0.032)	< 0.001
Household income	0.013 (0.009 to 0.016)	< 0.001	0.010 (0.006 to 0.014)	< 0.001	0.010 (0.006 to 0.014)	< 0.001	0.011 (0.006 to 0.016)	< 0.001

ASA, American Society of Anesthesiologists; CCI, Charlson Comorbidity Index; CI, confidence interval.

pre-fracture to 36 months (-0.15 points). In the death-adjusted imputed dataset, the drop to four months' follow-up is 0.19 points, but the total difference at 36 months follow-up is comparable to the standard imputation model (-0.15 points) (Table I). Figure 2 depicts the mean EQ-5D-3L scores in the observed and modelled datasets (standard and death-adjusted imputation).

Figure 3 presents the mean observed EQ-5D-3L index scores pre-fracture and at four, 12, and 36 months related to response pattern, i.e. at which timepoints patients responded. Patients completing and returning the questionnaires at all observation points reported a higher mean EQ-5D-3L index score than other response pattern categories.

Effects of covariates on the observed EQ-5D-3L index score. At the pre-fracture measurement, we found that cognitive impairment (regression coefficient (RC) -0.154 (95% CI -0.165 to -0.142); $p < 0.001$) and living in a healthcare facility (RC -0.096 (95% CI -0.104 to -0.087); $p < 0.001$) versus living at home had the strongest negative impact on EQ-5D index score (based on magnitude of coefficient) (Table II). Higher level of education (RC 0.019 (95% CI 0.014 to 0.024); $p < 0.001$) and higher household income (RC 0.013 (95% CI 0.009 to 0.016); $p < 0.001$) increased the EQ-5D-3L index score significantly, while higher age, cognitive impairment, comorbidity at the time of fracture, and living in a healthcare facility were significantly associated with a lower EQ-5D-3L index score. Sex had no significant effect on EQ-5D-3L index score at any observation points. The effects of covariates on the EQ-5D-3L index score at four, 12, and 36 months were comparable to those of pre-fracture data and were consistent regarding directions and magnitude of effects.

Discussion

This study demonstrated a persistent clinically relevant reduction in HRQoL after hip fractures measured by EQ-5D-3L index scores in a large unselected national hip fracture population with an observation time of up to 36 months. Higher age, male sex, increased comorbidity, lower socioeconomic status, and living in a healthcare facility were shown to be associated with both a lower proportion of patients receiving and returning PROM data for analyses and a lower reported HRQoL. Such bias mechanisms lead to a risk of overevaluation of the HRQoL of hip fracture patients in observational studies. The findings of this study provide insight into the limitations and strengths of PROMs as a tool for evaluating patient outcomes following hip fractures.

Our pre-fracture EQ-5D-3L index score corresponds with that of Mangen et al[22] in a study on community-dwelling older people in the Netherlands. Gjertsen et al,[23] in a previous study from the NHFR, also showed a marked reduction in EQ-5D-3L index score after fracture, with a drop in all EQ-5D dimensions. Both Peeters et al[7] and Schraut et al,[24] in systematic reviews, documented a marked decrease in HRQoL after hip fractures, and found that recovery was lengthy if ever reached. In the present study, patients showed an 18.5% drop in EQ-5D-3L index score from their pre-fracture state to four months follow-up. In the observed data, we found an improvement after the initial fall of 0.07 points from four to 36 months. This contrasts with the imputed datasets where the improvement with time was minimal.

Minimal important difference (MID) is not clearly defined for EQ-5D-3L for hip fracture patients, but Jehu et al[25] defined a range from 0.03 to 0.06 for minor improvements in older adults with falls. Both the observed and modelled data document a reduction in HRQoL above the proposed MID.[25] Hip fracture leads to a clinically important impact on the patients' HRQoL.

Response rates to PROMs in register-based studies vary and decrease over time (attrition bias).[21] The inherent characteristics of a hip fracture population have led the NHFR to encourage proxy respondents (family, friends, others) to support patients in reporting PROMs. NHFR also offers both paper and digital forms to improve response rates. Wang et al[8] has documented that a combination of paper and digital forms improves response rates. The substantial proportion of proxy respondents shows the importance of this option to improve response rates, especially for the cognitively impaired.

The response rates were not randomly distributed across variable categories, which introduces a selection bias increasing with time. The youngest, healthiest patients, with a good income and higher education, were better responders. Many studies examining PROMs in hip fracture patients are randomized controlled trials or smaller cohort studies where only responders are included,[7] introducing a selection bias.

To our knowledge, there are no previous studies assessing the factors affecting response rates in hip fracture patients. Such information helps us to better understand observed results and to plan statistical correction for missing data.

Mortality rate after hip fractures, which is affected by a variety of patient factors, is highest in the first months after injury and then declines gradually.[1,26] A longer observation period will therefore reduce the patient population in both numbers and the composition of variable categories. The Fragility Fracture Network Special Interest Group for Hip Fracture Audits questions the length of follow-up after a hip fracture, and does not recommend routine follow-up beyond 120 days (four months).[27]

The usefulness of PROM instruments depends not only on patient acceptance but also on consensus on the method of data collection (self, interview, or proxy completion), and the validity and reliability of the response data.[3] In this study, EQ-5D-3L was used as the HRQoL instrument. In a systematic review by Marten et al,[28] EQ-5D-3L used in an elderly population was considered feasible. A systematic review by Haywood et al[3] evaluating studies using a variety of QoL instruments came to a similar conclusion. However, in many of the high-quality studies published,[3,7] cognitively impaired patients were excluded, even though EQ-5D has been shown to be useful for assessing HRQoL in patients with cognitive impairment.[3]

In our study, we observed that patients returning all questionnaires (pre-fracture and at four, 12, and 36 months) had markedly higher mean EQ-5D index scores than responders with an incomplete response pattern (Figure 3). Thus, reporting of a single mean EQ-5D index score may conceal important differences between responders. To our knowledge, this has not previously been demonstrated.

This observational cohort study included 89% (35,206 of 39,690 patients) of the national hip fracture population in the inclusion period. Most studies reporting on HRQoL have limited numbers of patients, with only a few high-quality studies of more than 1,500 patients.[7] In addition, few studies report follow-up beyond one year, compared to 36 months in our study. The overall PROM response rate was 55%. No other hip fracture registers have routinely collected PROMs from the patients and thus there are no comparable population register data. We argue that the data presented here lead to reliable and reproducible conclusions, taking the described biases into account.

Selection, attrition, and low response rate, together with the effect of the covariates on the outcome measures, might lead to an overevaluation of HRQoL in observational data. We argue that a better description of populations and results may improve understanding of generic quality-of-life measurement in hip fracture patients.

Reporting of preoperative status at four months introduced a possible recall bias, which might have been particularly strong in patients with reduced cognitive function. Some of the most comorbid patients, especially those with cognitive impairment, have their forms filled out by a proxy respondent. This may add uncertainty to the data, and Haywood et al[3] encourage further research on proxy completion.

In summary, hip fracture patients had a significant and clinically important reduction in HRQoL after fracture treatment, which did not improve clinically even at 36 months' follow-up. Age, sex, comorbidity, socioeconomic status, and living status were shown to affect the proportion of patients receiving and returning PROM data for analyses through selection and attrition. The same factors also affected the scores, leading to a possible overevaluation of the HRQoL results based on observed data. Consequently, better reporting of HRQoL data focusing on the potential biases occurring in an elderly hip fracture population must be encouraged, and imputation models should be used for estimation of missing HRQoL scores.

Take home message

- Hip fracture leads to a persistent reduction in measured health-related quality of life up to 36 months.
- The patients' health and socioeconomic statuses were associated with the proportion of patients returning patient-reported outcome measures, and affected the results reported.
- Observed EuroQol five-dimension three-level questionnaire scores are affected by bias mechanisms, and motivate the use of statistical modelling for adjustment.

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