Prospective Evaluation of Preferences and Quality of Life in Women with Hip Fractures

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ABSTRACT. ***Objective.*** Hip fractures are a major cause of morbidity for older women, which result in impaired health related quality of life (HRQOL). Few studies have prospectively evaluated the effect of hip fractures in women on HRQOL with different health state preference measures. We compared how 4 different preference measures change in women post-hip fracture and evaluated the responsiveness of the preference measures. We also compared HRQOL in women with recent hip fractures to a control sample at baseline and to normative Canadian data at followup.

Methods. Health status measures [the Medical Outcomes Study Short Form-36 (SF-36)] and preferences (direct and indirect) of women over age 50 years with hip fractures were measured at baseline and at 3 and 9 months. Baseline preferences [Health Utilities Index (HUI), Feeling Thermometer, Standard Gamble, and SF-36] were obtained from women without hip fractures for comparison. Independent sample t tests were used to compare baseline scores of fracture and nonfracture controls. Correlations between preference and health status measures were assessed and repeated measures ANOVA was used to assess change in health status and preferences over time.

Results. Health status and preference measures were lower in women with hip fractures in comparison to nonfracture controls. After 9 months, the SF-36, HUI, Feeling Thermometer, and SF-6D scores improved significantly. Values for the SF-36 remained lower than an age-matched normative sample. The HUI and SF-6D were sensitive to change over time, but the Standard Gamble was not.

Conclusion. HRQOL and preference measures improve over time in women with recent hip fractures, with the majority of the change occurring in the initial 3 months. Our results suggest that the HUI and SF-6D are valid measures to assess change over time post-hip fracture. (J Rheumatol 2005;32:2393–9)

Key Indexing Terms:
HEALTH RELATED QUALITY OF LIFE HIP FRACTURES OSTEOPOROSIS

Hip fractures are the dominant fracture in women over age 75 years and are associated with significant morbidity and mortality[1]. Over 20% of women who sustain a hip fracture require longterm care and over one-third of women are unable to return to their prior functional status. The mortality rate after a hip fracture is as high as 20% within the first year[2]. In Canada the economic burden of osteoporotic fractures is estimated at $1.3 billion dollars, with hip fractures constituting the majority of the cost[3]. The age-adjusted rates of hip fracture were 479/100,000 in women and 187/100,000 in men in 1993-94, and the number of hip fractures is anticipated to rise exponentially over the next 4 decades[4]. Hip fractures have been shown to have an adverse impact on health related quality of life (HRQOL), although few studies have prospectively evaluated the change in HRQOL after a hip fracture[5-10]. HRQOL has been evaluated prospectively, using health status measures such as the Medical Outcomes Study 36-item Short Form survey (SF-36)[11,12] and the disease-specific Osteoporosis Assessment Questionnaire (OPAQ2) in women who have sustained hip fractures[5]. Randell, *et al* assessed 32 patients with hip fractures and compared them to 29 sex-matched nonfracture controls in a prospective case-control study[5]. Subjects were interviewed one week and 12 to 15 weeks post-fracture. Controls had stable SF-36 scores, while hip fracture patients had a lower baseline HRQOL and experienced a significant deterioration in the HRQOL based on results using the OPAQ2 and SF-36. Similar results were noted by Boonen, *et al*[9]. Peterson, *et al*[7] conducted a prospective study of a cohort of 38 hip fracture patients over 65 years using as outcomes the SF-36 and the Cummings Hip Scale. They found that recovery was almost complete by 6 months, except for the role-physical domain of the SF-36[7].

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Due to limited healthcare resources, there has been an increased need for proof of the cost-utility of new osteoporosis therapies. The influence of hip fractures on HRQOL needs to be incorporated into cost-effectiveness analyses of therapies[13,14]. Preference measures both direct or indirect can be used to determine quality-adjusted life years (QALY), which can then be used in cost-utility analyses[15]. A systematic review of health state values found only 5 studies that evaluated the effect of osteoporotic-related conditions on health state valuations. Brazier, *et al* found marked variation in estimates for the valuations for hip fracture (range 0.28 to 0.72), which depended on the health state description, characteristics of the population evaluated, and the valuation technique used[16]. This review showed that patients give higher estimates for health state values than non-fracture patients. Few studies have compared alternative measures of health state preferences[17].

We compared 4 different preference measures, in both their absolute values and their sensitivity to change over time, in women after hip fracture. Secondary objectives included comparing hip fracture patients to controls at baseline (all outcomes) and to an age-matched normative sample (SF-36 only) at followup.

MATERIALS AND METHODS

Research design. Postmenopausal women over the age of 50 years with a hip fracture were identified within one month of their hip fracture. Women were recruited through the Ottawa Hospital, Civic Site, through the orthopedic and geriatric wards from 1999 to 2001. Women were excluded if they were cognitively impaired, deaf, legally blind, unwilling to consent, severely depressed, did not speak English, or had a pathological fracture. The research assistant recruited a convenience sample of controls of a similar age through local service organizations. For both groups, 40 respondents were included. Ethics approval was obtained from the Ottawa Hospital Research Ethics Board.

For all respondents, background demographics including age, level of education, use of hormone replacement therapy or other osteoporosis medications, and comorbidity were recorded[18]. For women with hip fractures, study interviews were performed at baseline and at 3 and 9 months. For the controls, only baseline interviews were obtained.

SF-36. Health status was measured at baseline for the control sample and at baseline and 3 and 9 months post-hip fracture using the SF-36 generic health survey. The SF-36 is a 36-item questionnaire that produces 8 domains, including physical function (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social function (SF), role emotional (RE), and mental health (MH), detailing health related quality of life[19]. Scores range from 0 to 100, 100 representing optimal HRQOL. About 80%–85% of the reliable variance in the 8 health concepts is explained by 2 constructs, which resulted in the construction of 2 summary measures: the Physical Component Summary (PCS) and the Mental Health Component Summary (MCS)[12]. The SF-36 is widely used and has been shown to be valid and reliable, and Canadian normative data are available for it[20].

Preference elicitation. Preferences were elicited using 2 direct measures (Feeling Thermometer, Standard Gamble) and 2 indirect measures [Health Utilities Index II (HUI) and the SF-6D][21-23]. The standard gamble method was selected since it is based on axioms of utility theory that incorporate the strength of preference and attitude toward risk, whereas other preference measures like the time tradeoff are not based on utility theory. The feeling thermometer does not present the subject with a decision, but is efficient to administer and has interval properties[21].

Feeling thermometer. The feeling thermometer is a derived psychological scale consisting of a horizontal or vertical scale anchored by defined endpoints: death (zero, worst imaginable state) at one end and perfect health (100) at the other[21]. Patients were requested to rate the desirability of the different health states and their own health state along an interval scale with the anchors "perfect health" at the top and "death" at the bottom.

Standard gamble. This standard gamble was administered using a probability wheel as a visual aid to facilitate understanding[21]. Each woman was offered a choice between remaining in their current health and a gamble, with chance p to obtain perfect health and a chance 1 – p of death. Chance p was systematically varied using the ping-pong approach.

Health Utilities Index. The HUI Mark II multiattribute classification system is an indirect measure of preference elicitation. Two steps are involved; first, an individual's health status is elicited along several dimensions using a 15-item questionnaire. Then a preference for the health state is derived, based on values obtained from previous community populations. This multi-attribute health status measure consists of 7 attributes including sensation, mobility, emotion, cognition, self-care, pain, and fertility[22].

SF-6D. The SF-6D is a preference-based measure derived from the SF-36 that reduces all the outcomes to a single summary measure scored on a 0.20 to 1.00 scale, with 1.00 indicating full health[23]. The SF-6D scores were calculated using an algorithm designed to map responses from 6 dimensions of the SF-36 scores (physical functioning, role limitations, social functioning, pain, mental health, and vitality).

Analyses. The analysis was designed to address each of the 2 objectives outlined above. All analyses were conducted using SPSS version 11.0 for Windows.

Independent samples t tests were used to compare the baseline scores of fracture patients and controls. Comparisons of preference measures were conducted through paired t tests for each assessment point to assess differences in absolute values, and through Spearman's rho correlation to assess correlation in rankings. The mean scores for the SF-36 were compared to age-adjusted normative data for Canadian women[20]. Significance testing was not done, as the large sample for the normative data results in significant findings even for small differences; the analysis focused on determining whether differences were clinically important, defined as greater than a 5 point difference.

The correlations between preference measures and HRQOL measurements were assessed using Spearman's rho correlation. Results were considered significant at $p < 0.05$.

A repeated-measure ANOVA was used to test the pattern of change in preference measures and SF-36 scores over the 3 timepoints. Sensitivity to change relates to whether the estimation technique is able to detect the smallest clinically important improvement. Sensitivity to change over a 9 month period was evaluated with the standardized response mean (SRM) or efficiency index, which is a ratio of the observed change for preference measurements, and the standard deviation reflecting the variability of the change scores[24]. The SRM is regarded as large (> 0.8), moderate (0.5), or small (< 0.2). An advantage of this method is that it removes the dependence on the sample size.

RESULTS

Study sample. In total 78 women with hip fractures were approached to participate in the study. Fourteen were not eligible due to pathological fracture or age < 50 years, or due to visual, hearing, or cognitive impairment (Figure 1). Of the 64 eligible women, 24 were not willing to participate and 40 agreed to participate. Thirty-five women completed all 3 assessments (3 women died, one dropped out after the baseline assessment, and one dropped out after the second

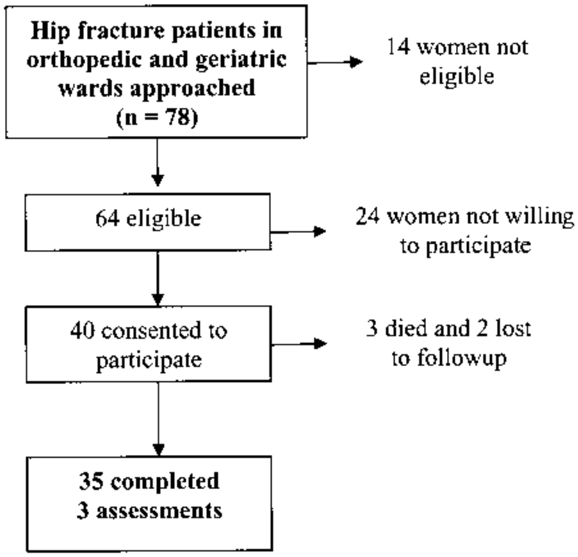

Figure 1. Identification of the population with hip fracture.

visit). Forty women without a history of fractures living in the community were identified as controls. The mean age of controls was 72 years compared to 80 years for hip fracture patients ($p < 0.001$). Seven out of 40 (17.5%) women with hip fractures changed from independent living to assisted living after their hip fracture. Twenty percent of controls were taking an osteoporosis medication as compared to 25% of the hip fracture patients. The mean pain score derived from a visual analog scale was 19 (SD 23) for controls and 51 (SD 23) for hip fracture patients ($p < 0.001$). Table 1 presents characteristics of the 2 samples.

Comparison between controls and hip fracture patients. SF-36 values were significantly lower for the hip fracture patients in comparison to controls at baseline, except for the MCS (Table 2, Figure 2). The most striking differences between hip fracture patients and controls were for the SF-36 physical function and the role physical domains ($p < 0.001$). Hip fracture patients scored well below the age-adjusted normative data for all 8 domain scores of the SF-36 and for the PCS (Figure 2), with lowest scores in the physical-related functioning domains. The controls scored higher

Table 1. Baseline demographics.

	Controls, n = 40	Hip Fracture Patients, n = 40	p
Mean age, yrs	72	80	< 0.001
Comorbidity score, %			
0	55	52.5	
1	27.5	37.5	
2	17.5	10.0	0.483
Education level > grade 13, %	75	50	0.004
Taking osteoporosis medication, %	20	25	NS

NS: nonsignificant.

Table 2. Baseline mean HRQOL scores (SD) for dontrols and hip fracture patients.

Measure	Controls, n = 40	Hip Fracture Patients, n = 40
SF-36 Scores		
Physical function	76 (22)	10 (19)***
Role physical	70 (40)	0***
Bodily pain	70 (24)	26 (19)***
General health	76 (17)	65 (20)*
Vitality	70 (16)	44 (20)***
Social function	88 (20)	36 (24)***
Role emotional	90 (28)	70 (43)*
Mental health	83 (16)	73 (18)*
Physical component summary	46 (9)	21 (6)***
Mental component summary	56 (8)	53 (10)
Preference Scores		
Feeling thermometer	0.85 (0.10)	0.61 (0.17)**
Health Utilities Index	0.85 (0.10)	0.51 (0.18)***
Standard gamble	0.95 (0.10)	0.84 (0.22)**
SF-6D	0.81 (0.13)	0.50 (0.08)**

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Significance tests are based on independent samples t tests comparing baseline scores for hip fracture patients and controls.

than age-matched controls, which attained clinical relevance in the physical function, vitality, and role emotional domains (Figure 2). Preference scores for the HUI, standard gamble, SF-6D, and feeling thermometer were significantly lower ($p < 0.01$) in fracture patients (0.50–0.84) than in controls (0.81–0.95) at baseline (Table 2).

Comparisons between preference measures. The feeling thermometer results correlated significantly with the HUI results ($r = 0.46$), as did the standard gamble results ($r = 0.42$) and SF-6D ($r = 0.48$). The feeling thermometer and standard gamble did not correlate significantly with each other or with the SF-6D.

For the SF-6D and the HUI, the differences in scores between baseline and 3 months and baseline to 9 months were significant (Table 3). The differences in scores for the standard gamble and feeling thermometer were not significant for baseline to 3 months. None of the differences between the preference measures were significant at 3 and 9 months.

Correlation between preference scores and the SF-36. There were significant correlations between the HUI and all domains of the SF-36 ($r = 0.33$ to 0.59) except for social function ($r = 0.11$). There were also significant correlations between the feeling thermometer and 2 SF-36 domains, general health (0.48) and mental health (0.41), as well as for the MCS. The results were similar for correlations between the standard gamble and the general health, role emotional, and mental health domains as well as the MCS. There were significant correlations between the SF-6D and the SF-36 bodily pain and vitality domains, as well as the PCS. The changes in the HUI correlated with changes in 6 domains of the SF-36 and changes in the PCS.

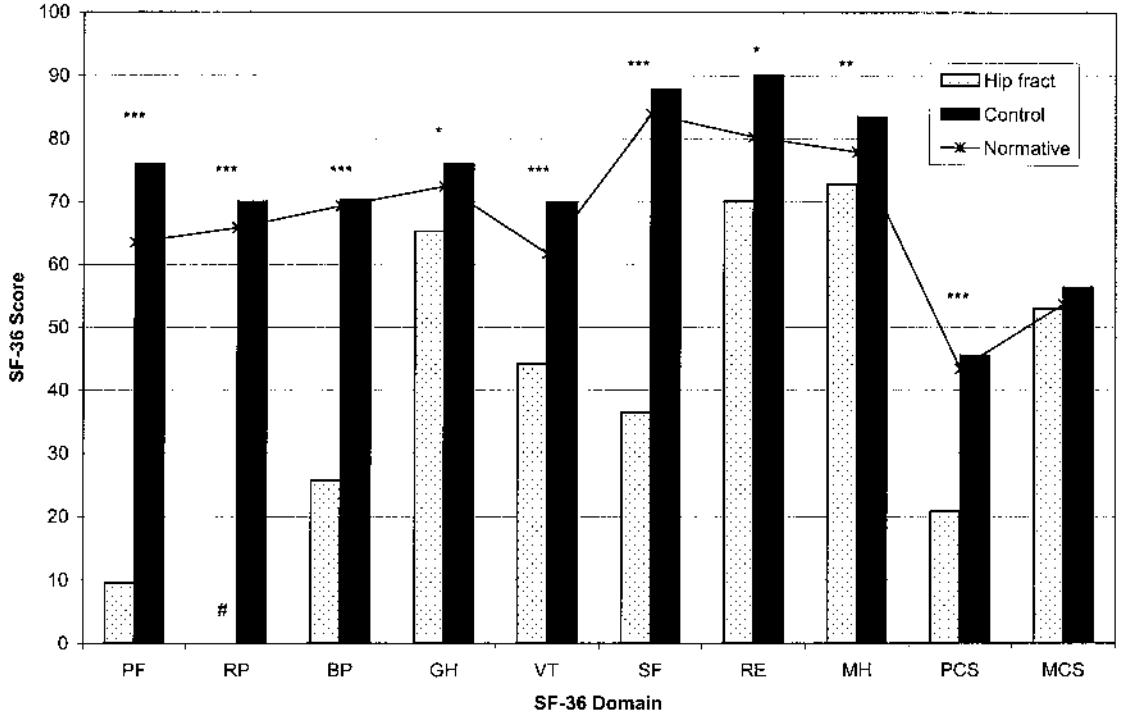

Figure 2. Baseline SF-36 scores for hip fracture patients and non-fracture controls. For definitions see Materials and Methods, SF-36.
Mean value = 0.

Changes in SF-36 scores over time. There was a progressive increase in most of the mean SF-36 domains over the 9 month period for the hip fracture patients (Figure 3). There was a significant increase between the baseline and 9 month values for hip fracture patients for 4 SF-36 domains (role physical, bodily pain, physical function, and social function) as well as the PCS. These findings are supported by the repeated-measures ANOVA, which examined the 3 month data in addition to the 9 month data. When the results are compared to the normative data, the 9 month values were still considerably lower than the age-adjusted norms, with 6 domains still showing a difference in excess of 5 points. Exceptions included the role emotional and mental health domains. There were also striking differences between the PCS scores of the 2 groups (31.2 for the hip fracture vs 41.9 for the normative sample), but the mean MCS scores were similar (53 vs 54.1).

Change in preference scores over time. For all preference scores, the mean values improved by 9 months (Table 3, Figure 4). However, scores remained lower than for controls, especially for the HUI (0.73) and feeling thermometer (0.71). There was a significant increase in the SF-6D, HUI, and feeling thermometer results from baseline to 9 months for the hip fracture patients analyzed using a repeated-measures ANOVA ($p < 0.001$; Table 3). The change in the standard gamble results from baseline to 9 months was not significant, however. The changes in HUI were significantly correlated with changes in the feeling thermometer ($p < 0.05$).

Table 3. Change in preference scores over time.

Measure	Baseline	3 mo	9 mo
HUI	0.51 (0.18)	0.63 (0.20)**	0.73 (0.19)***
Standard gamble	0.84 (0.22)	0.86 (0.21)	0.91 (0.14)
Feeling thermometer	0.61 (0.17)	0.68 (0.20)	0.71 (0.19)*
SF-6D	0.50 (0.08)	0.63 (0.14)**	0.64 (0.14)*

*** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. HUI: Health Utilities Index; SF-6D: derived from the SF-36.

Responsiveness to change. Table 4 presents the results of the SRM using the change at 9 months. The SRM was large for the SF-6D, moderate for the HUI and feeling thermometer, but low for the standard gamble.

We calculated the minimally important difference as described by Walters and Brazier[25], using results of the mean change on the SF-6D for patients who reported change on question 2 (health now as compared to a year ago) of the SF-36 survey, and obtained a value of 0.048 (standard error 0.03).

DISCUSSION

In this sample of women with recent hip fractures, health related quality of life and health state preference values were assessed prospectively. The results may therefore represent a more realistic estimate of the decrement in health status. Although a number of studies have evaluated HRQOL in osteoporosis, few studies have collected both direct and indirect preference values, prospectively, in hip

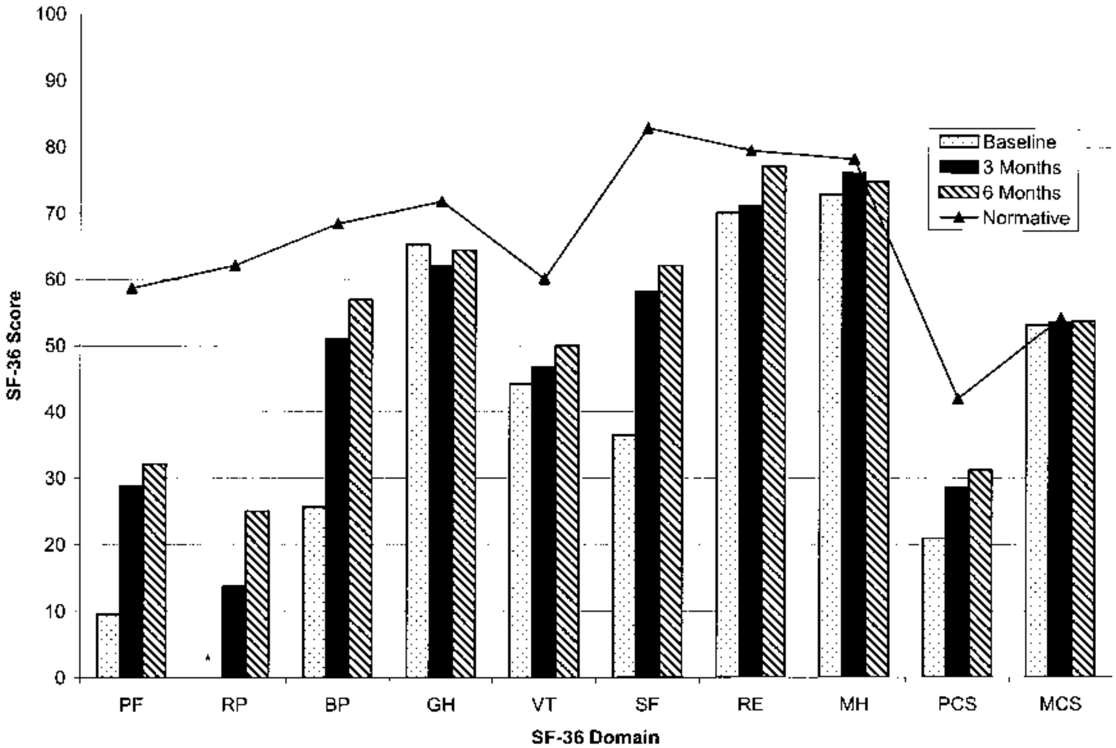

Figure 3. SF-36 scores for hip fracture patients at baseline and at 3 and 9 months. For definitions see Materials and Methods, SF-36.
* Mean value = 0.

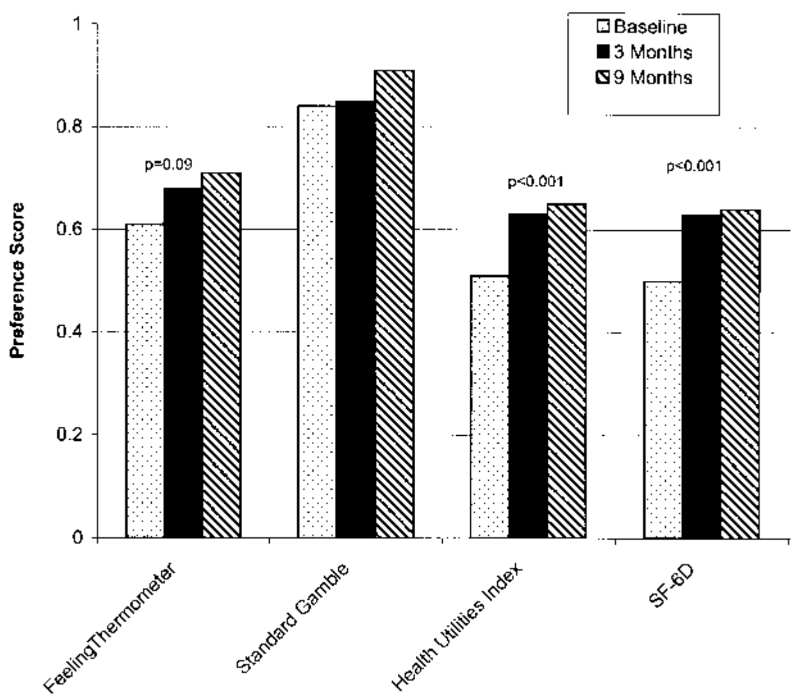

Figure 4. Preference scores for hip fracture patients at baseline and at 3 and 9 months.

Table 4. Sensitivity to change for preference measures.

Measure	Standardized Response Mean
Feeling thermometer	0.45
HUI	0.64
Standard gamble	0.25
SF-6D	0.81

fracture patients[16]. In a cross-sectional valuation study, Gabriel, *et al* evaluated utility measures in individuals who had experienced a fracture in the last 5 years, using the HUI II, Time-Tradeoff, and Rating Scale[26].

HRQOL is significantly lower compared to non-fracture controls when measured with a generic health status measure and preference measures. At baseline, all the SF-36 domains were lower than controls in our study. These results reflect the physical limitations imposed on women with recent hip fractures. At the 9 month followup the SF-36 scores had increased significantly for physical function, role physical, body pain, and social function domains and the overall PCS. The majority of the improvement occurred by the 3 month period, similar to what has been found in the other studies[6]. Despite improvements other studies have noted, there is still a significant reduction in HRQOL at 3 months post-fracture when compared to controls[5,10]. In our study, the HRQOL remained lower at 9 months compared to the SF-36 results from age-matched Canadian normative data[20]. This suggests that older women who sustain hip fractures continue to suffer from impaired quality of life.

At baseline, the preference scores for the HUI, standard gamble, SF-6D, and feeling thermometer were significantly lower compared to controls. There was a significant increase in the feeling thermometer, HUI, and SF-6D scores from baseline to 9 months for the women with hip fractures, but not in the standard gamble. This could be explained by a ceiling effect, which is one potential limitation of using the standard gamble to assess health status. The results obtained for the HUI, feeling thermometer, and SF-6D scores were very similar. The health state valuations obtained in our study were similar to those reported in other studies of hip fracture patients. Tosteson, *et al* found a mean value of 0.63 (95% CI 0.52, 0.74) in women with hip fractures (n = 67) using the Time Tradeoff[6]. Gabriel, *et al* obtained a mean value of 0.72 (SD 0.16) with the rating scale (feeling thermometer), 0.70 (SD 0.41) with the Time Tradeoff, and 0.68 (SD 0.18) for the HUI II in women (n = 37) who had survived at least one year post-hip fracture[26], and these values are comparable to the values we obtained at 9 months in our study (Table 3).

Overall, correlations between the preference measures and the SF-36 domains were relatively low, with the majority falling between 0.4 and 0.6. The HUI correlated with the majority of the SF-36 domains, in contrast to the feeling thermometer and the standard gamble. The lack of correlation between the domains of the SF-36 and the feeling thermometer were unexpected, and differed from results of other studies. The standard gamble did not correlate with the feeling thermometer, which we noted in an earlier study[27], and this could be explained by the fact that the standard gamble includes an element of risk attitude. The 9 month values obtained for the HUI and feeling thermometer were similar.

The results of sensitivity to change indicate that the HUI and SF-6D have similar responsiveness to the SF-36, suggesting they could be used as measures to detect change in clinical trials of patients with hip fracture. Tidermark, *et al* observed a high responsiveness for the SF-36 when used in patients with hip fracture[8]. The standard gamble did not prove to be sensitive to change over time, which may have implications for its use in clinical trials[27].

Our results suggest that the HUI and SF-6D are valid methods of assessing preferences for current health in older women with hip fractures. Gabriel and colleagues have suggested that the HUI may be an efficient and less expensive alternative to using direct assessment of preferences[26].

There are several limitations with our study. The control subjects were younger than the patients with hip fracture, which may have influenced the HRQOL results. In addition, the control subjects were only interviewed at baseline, and the results would have been strengthened had we measured HRQOL at 3 and 9 months for controls. However, studies have shown stability of HRQOL assessments in control populations[5,9]. A disease-specific measure for patients with osteoporosis or hip fracture was not administered to patients in our study. Randell, *et al* found that the disease-specific osteoporosis measure, OPAQ, was more sensitive than the SF-36 for assessing social function[5]. Cognitively impaired women were not included in this study, so the results are not generalizable to this population. Unlike other studies, we did not have patients estimate their prefracture health status, since their health state valuations may be lower than healthy controls.

We conclude health related quality of life improves in older women with hip fractures, especially in the initial 3 months post-fracture, but even at 9 months both health status and preferences remain lower than in non-fracture controls. The SF-6D and HUI appear to be sensitive enough to detect change in women post-hip fracture, based on SRM results, but larger studies of direct and indirect preference measures are needed to confirm our findings. Thus, for economic analysis of treatments for osteoporosis, values based on either the SF-6D or HUI would be appropriate. Similarly, given the improvement in HRQOL over time, the disutility of hip fracture should be modeled over a period of time to determine the potential restoration to normal health status. Future research should also address the effect on HRQOL of different interventions targeted for the treatment of women with hip fractures.

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