

## **Prospective evaluation of quality of life and function after surgical management of femoral neck fractures in elderly patients.**

### **Abstract**

**Background:** The surgical management of femoral neck fractures is primarily done using internal fixation (IF), hemiarthroplasty (HA) or total hip replacement (THR). These surgical procedures effectively improve health-related quality of life (HRQOL) and function in these patients. The present study was conducted to determine quality of life (QOL) and function in elderly patients following operative treatment of fracture of the neck of the femur using known indicators.

**Materials and Methods:** This was a prospective, longitudinal study conducted on 60 consecutive patients treated surgically for the fracture with either of the procedures IF, HA and THR. The telephonic interview was conducted at 1, 3 and, 6 months post-operative to evaluate the quality of life using patient-rated outcome measure namely short form – 12 (SF - 12) Health Survey and Health-related quality of life (HRQOL -14 “Healthy Days Measure”.

**Results:** The mean age of the study participants was  $75.8 \pm 7.1$  years. In this study the physical ( $p=0.001$ ), mental component ( $p=0.003$ ) and, q value ( $p=0.001$ ) of SF-12 scores were significantly improved at 3 and 6 months postoperative as compared to 1 month postoperative. Further, there was significant improvement of HRQOL-14 outcome scores 3 and 6 months postoperative as compared to 1 month postoperative.

**Conclusion:** The present study concludes with compelling evidence that patients with femoral neck fractures experienced a significant deterioration in health-related quality of life one-month post-surgery and there was marked improvement in the subsequent follow up months.

**Keywords:** Femoral neck fracture, total hip replacement, quality of life, SF -12, HRQOL-14

**Comment [VS1]:** Femoral neck

## Introduction

Hip fracture is one of the complicated osteoporotic conditions with substantial morbidity and health issues. It is perhaps the most dramatic consequence of osteoporosis in the elderly. (1) Due to worldwide aging, increase in the incidence of hip fractures are on rise. Higher proportion of cases relative to age are noticed especially from the fifth to the eighth decade of life. (2)(3) Each year hip fractures are responsible for the loss of at least 2.35 million disability adjusted life years (DALY). Globally, estimated burden of hip fracture by year 2025 and 2050 is 2.6 and 4.5 million respectively. Thirty seven percent of these hip fractures will be in Asia by 2025 which may further increase to 45% in the year 2050. (4) The population of elderly patients with such fractures comprises several subpopulations, ranging from the lucid, healthy, active and independent patient with a substantial life expectancy, to the institutionalised, cognitively impaired and bedridden patient. (1)(5) Fracture of femur-neck is the most prevalent and common condition in hip fractures.

**Comment [VS2]:** Worst complication of osteoporosis than dramatic consequence

Treatment of femur-neck fracture considers age, functional needs, comorbidities and individual's risk profile. Despite of various factors, surgical intervention is the most commonly selected modality to treat hip fractures. Evidence is suggestive that delayed or no surgical treatment in observational studies are suggestive of mortality, post-operative complications, longer length of hospital stay, and delay in resuming post-fracture life-status. (6) Research has highlighted treatment and clinical outcomes measures, however, quality of life (QOL) impact on life participation, assessment of effectiveness on achieving pre-fracture level of functioning seems to be inadequately studied. In low middle class income countries, very few studies have addressed these. (7)(8) A high morbidity of this condition results in long-term hospitalization and lengthy rehabilitation which affects QOL. QOL is a multidimensional variable, reflecting physical, social and psychological wellbeing.

**Comment [VS3]:** Femoral neck more scientific term

**Comment [VS4]:** Need to use the correct grammatical adjective

**Comment [VS5]:** Risk profile would mean comorbidities – avoid redundant language

**Comment [VS6]:** Redundant non scientific language to be avoided

**Comment [VS7]:** Literature is not scant and in fact has been published in JBJS British as well as American and needs to be cited how this is compared

**Comment [VS8]:** Do we mean developing countries? This classification of countries not used to stratify the QUAL Index

**Comment [VS9]:** Studies prove that High morbidity is a result of long term immobilization including hospitalization and not the other way around as described by the authors!

Fracture in elderly has a substantial impact on medium to long term abilities, functions and overall QOL. There are different ways to access QOL in literature. (9) Health related QOL based on self-assessment seems to be powerful predictors in short and long-term adverse outcomes among elderly. (10) Community short-form survey (SF-12), and Health Related QOL (HRQOL) based on patient-rated outcome measure have **proven effective to** narrate the patient conditions about psychological well-being. SF-12 is a shorter version of SF-36 which along with HRQOL-14 is widely used for monitoring health, disease burden and prediction. (11)(12) Very few studies have assessed the changes in patient conditions on a longitudinal scale. Cross-sectional research studies highlighting QOL of elderly patients with hip fracture were mainly from the high-income countries (HICs). (8) Considering this research gap, we decided to study the QOL of elderly patients following operative treatment of fracture of the femur-neck. **This study aims to longitudinal** assessment of QOL and function in elderly patients after surgery of the neck fracture of femur bone.

**Comment [VS10]:** ? Indicate

## Methods

We performed this **prospective observational longitudinal** study at an institutional setup in Mumbai.

**Study hospital** comprises **a multispecialty** setup in Mumbai. Among sixty consecutive elderly patients of either gender who were treated surgically for the fracture with either of the procedures mentioned namely internal fixation (IF), hemiarthroplasty and total hip replacement (THR). **Data** accessed at three different point of time post-surgical intervention. **This study was performed during the period starting from September 1<sup>st</sup>, 2017 to February 28<sup>th</sup> 2019. Patients of age more than or equal to sixty years, having inter-trochanteric of femur neck fracture were included. Those individuals with fractures of acetabulum and pelvis, open fracture and treated without surgical intervention were excluded from the consideration of this study.**

**Comment [VS11]:** Set up in scientific studies are expected to compare the outcomes by establishing uniform platform of care in treating Fractures of NOF

Patients who agreed to participate in study were enrolled after **valid written consent**. **Their** demographics and other details like age, gender, **educational attainment**, socioeconomic status,

**Comment [VS12]:** INCLUSION AND EXCLUSION CRITERIA FOR STUDY NEED TO BE DEFINED PRIOR

**Comment [VS13]:** IRB documentation and declaration important

BMI, type of family, type and site of surgery and other required clinical details were accessed from the Hospital Information System. For remaining details periodic assessment was done for Quality of life (QOL) with the follow-up questionnaire at three fixed intervals. For follow-up assessment, patients were contacted by the telephonic interview at one, three and six months of the surgical management of the fracture. At selected intervals each individual assessed with the help of a structured preoperative interview questionnaire.

We assessed the quality of life using patient-rated outcome measures namely short form twelve item questionnaire (SF-12) and health related 14 points questionnaires for QOL (HRQOL-14). Both of these instruments are validated to assess mental health, life participation, negative/positive affect, pain and quality of life. Patient reported scores calculated from standard treatment were compared over three different points of time. Within themselves and across patient demographics details data were compared. Primary variable of interest was overall QOL of patient at three different time points.

Data was collected and tabulated in a pre-designed excel spreadsheet. Analysis was done using Statistical Package for Social Sciences Version 25 (SPSS-25, IBM Inc., NY US)(13). Qualitative variables were presented using frequency and percentages of the groups. Quantitative variables like age, SF-12 and HRQOL-14, scores were presented by means (standard deviation (SD)) or median (inter-quartile-deviation (IQD)). We performed a data normality test using the Shapiro Wilk Test. Normally distributed variables were analysed using parametric one-way ANOVA test. Non-normally distributed variables were analysed using non-parametric Friedman test. P value below five percent was considered to be statistically significant. Study was approved by the institutional ethics committee of the hospital.

**Comment [VS14]:** Why was the preoperative interview questionnaire validated to use in the postop phase and how was the errors avoided in final readings

## Results

### Participants

Total 60 elderly patients were interviewed to assess the QOL after the surgical intervention of the femoral neck fractures. The majority of patients were female (62%). Half of the patients were from the age group 70-79 years. The mean age of the patients was  $75.75 \pm 7.11$  years (Range 60-91 years). Mean duration period from admission up to surgery time was 03 days. Out of 60, six patients in the first month after the surgery and 1 patient during the second stage lost follow-up due to mortality or some other reason. They were excluded from the further analysis of QOL assessment.

**Comment [VS15]:** Mortality in the first 6 months following the fracture neck of femur in developing countries crucial valid point in these studies?

### Descriptive data

Thirty-one patients (51.67%) had the neck of femur (NOF) fracture whereas 29 patients (48.33%) sustained an Intertrochanteric (IT) fracture. Only nine females (15%) were having the history of previous fracture. Five out of six participants were having either normal BMI or pre-obese obesity status. 85 percent of the patients reported that they have any form of comorbidity. (Table 1)

**Comment [VS16]:** Preobese obesity is not scientific classification of obesity according to WHO

**Table 1: Patient Characteristics**

Narration	Female n (r%)	Male n (r%)	Total n (c%)
Overall	37 (62%)	23 (38%)	60
Age group			
60-69	8 (57%)	6 (43%)	14 (23%)
70-79	17 (57%)	13 (43%)	30 (50%)
>=80	12 (75%)	4 (25%)	16 (27%)
Obesity Status			
Normal	8 (50%)	8 (50%)	16 (27%)
Pre-Obese	21 (62%)	13 (38%)	34 (57%)
Obese	8 (80%)	2 (20%)	10 (17%)
Location of Injury			
Home	33 (67%)	16 (33%)	49 (82%)
Outside	4 (36%)	7 (64%)	11 (18%)
Living with			
Extended Family	34 (65%)	18 (35%)	52 (87%)
Alone / With Spouse	3 (37%)	5 (63%)	8 (13%)
History of Previous Fracture			
Yes	9 (100%)	(0%)	9 (15%)
No	28 (56%)	23 (46%)	50 (83%)

Type of fracture			
LIT	6 (60%)	4 (40%)	10 (17%)
LNOF	12 (80%)	3 (20%)	15 (25%)
RIT	11 (58%)	8 (42%)	19 (32%)
RNOF	8 (53%)	7 (47%)	15 (25%)
NOF	(0%)	1 (100%)	1 (2%)
Co-morbidity status			
Yes	30 (59%)	21 (41%)	51 (85%)
No	7 (78%)	2 (22%)	9 (15%)
Family type			
Extended Family	34 (65%)	18 (35%)	52 (87%)
Living Alone	3 (50%)	5 (50%)	8 (13%)

**Comment [VS17]:** WHY IS ADDITIONAL NOF in addition to left and right ?

### Main results

The quality of life of a patient was measured by SF-12 questionnaire through physical health composite summary (PCS), mental health composite summary (MCS) and Q value. One way ANOVA was used to assess the QOL at four different time points. The PCS and Q-value scores are statistically different ( $p$  value  $< 0.001$ ). The mean score of PCS and Q-value is significantly low at one month after the surgery ( $27.87 \pm 8.78$  and  $0.62 \pm 0.08$  respectively), whereas means score for MCS is low at one month after surgery but it is not significant ( $p$ -value 0.215). (Table 2)

**Table 2: Quality of Life using SF-12 Score**

Descriptive	Pre-OP	1-Month	3-Month	6-Month	p-value
PCS	42.1 (10.74)	27.87 (8.78)	40.18 (9.7)	41.14 (9.83)	$<0.001$
MCS	44.24 (10.57)	40.62 (8.85)	44.11 (11.09)	43.75 (10.82)	0.215
Q-Value	0.78 (0.14)	0.62 (0.08)	0.76 (0.14)	0.77 (0.14)	$<0.001$

*Values represented as Mean (SD), PCS: Physical health composite summary, MCS: Mental health composite summary*

Health related quality of life (HRQOL-14) outcome measure is assessed using three major modules namely healthy days core module, activity limitation module, and healthy days symptom module.

To assess this health-related quality of life at four points, Friedman's test was used. The HRQOL-

14 score for all three domains (healthy days core module, activity limitation module and healthy days symptom module) are significantly low at one month after the surgery (p-value <0.05). The median score for all these three modules were 49, 8 and 81 respectively. (Table 3)

**Table 3: Comparison of quality of life using HRQOL-14**

	Pre-operative	Post-Operative			p-value
		1 Month	3 Months	6 Months	
<b>Healthy days core module</b>					
Unhealthy Days – Values: Median (IQD)	2 (0 - 19)	30 (20 - 30)	4 (0 - 20)	2 (0 - 17.5)	<0.001#
Frequent Mental Distress – Values: Freq (% Total Patient)	14 (23.33%)	29 (48.33%)	13 (21.67%)	10 (16.67%)	<0.001*
<b>Activity Limitations Module (Freq (% Total)) *</b>					
Limitation in the activities because of any impairment or health problem	28 (46.7%)	50 (94.3%)	31 (58.5%)	30 (56.6%)	<0.001
Need of personal care because of any impairment or health problem	22 (84.6%)	50 (98%)	24 (92.3%)	23 (92%)	0.044
Need in routine work because of any impairment or health problem	20 (76.9%)	48 (94.1%)	22 (84.6%)	21 (84%)	0.044
Major impairment or health problem that limits activities	25 (41.67%)	51 (85%)	26 (43.33%)	25 (41.67%)	<0.001
<b>Healthy Days Symptoms Module (Median, (IQR), n) #</b>					
Pain Days	15 (7.5 - 30), 18	30 (20 - 30), 51	20 (7.5 - 25), 23	15 (6 - 25), 22	<0.001
Sad Days	10 (2 - 27.5), 22	25 (20 - 30), 51	17.5 (5 - 23.75), 24	10 (2 - 23.75), 23	<0.001
Tense Days	15 (5 - 30), 21	30 (17.5 - 30), 51	20 (7.5 - 25), 24	10 (7.5 - 25), 23	0.001
No Sleep Days	17.5 (12.25 - 30), 17	25 (11.5 - 30), 43	20 (8 - 30), 17	15 (4.25 - 30), 14	0.061
Healthy / Energy Days	30 (30 - 30), 49	2 (2 - 4), 38	30 (20 - 30), 41	30 (30 - 30), 38	<0.001

#: Friedman's test, \*: Cochran's Q test for dichotomous variable

Healthy days and Activity limitations modules, majority of patients responded to questions, hence 'n' values are not given

## Discussion

The present study documents the assessment of quality of life (QoL) followed by surgical treatment of neck of the femur fracture in the elderly. Study recorded significant drop in physical composite health score (PCS) one-month post-surgery, which improved over the period of three to six months. These changes in PCS shows the improvement due to surgical intervention which was evident longitudinally. Systematic review on long-term disability outcome following hip-fracture concluded the mixed results, with proportionate of people achieving pre-fracture levels of functioning and some may not able to achieve the same. (7) An institutional study among Singapore population have endorsed the surgical management of hip-fracture without drastic effect into patient's QoL.(14)

Comment [VS18]: Grammar check

Overall, in study population shows difficulty in different areas of HRQoL the first month after surgery and shows further improvement during subsequent period. In present study population for all domain compared to pre-operative level much better improvement was recorded at six-month operative. Study in Thai patients, shows below pre-operative improvement at the end of three months. However, subgroup of younger patients shows relative improvement therein. (15) Further, in activity limitations and personal care patient, patients improved was slightly poor pre-operative days at three-month and slightly better at six-month. In need of personal care and activity limitation some assistance needs to reported by the patients. Spanish hip-fracture surgery patients reported to have attained significant improvement in these domains. (16)

Comment [VS19]: Fatal grammar errors consistent

Baseline patient characteristics in study population stated that three out of four patients were elderly from age group of more than seventy years. Female (3:2) patients in the study groups slightly higher than males. Comparatively, baseline patient characteristics, age group, sex and the number of comorbidities have an effect in the change in QoL score. Similar kind of changing aspects in QoL score were recorded in one year follow-up study post-surgery of hip fracture in Japan. They concluded no influence of serum vitamin-D level, comorbidities, and level of admission of patients.

(15) Studies however, have reported improvement in QoL score of patients with the supplement of calcium and vitamin-D. Hence, it is combined into standard treatment regimen. (17)(18) As seen towards the effect of patient's characteristic, in present study, female patients have shown slightly less improvement in terms of HRQoL domain score compared to male. **Review have shown**

**negative association of females, and comorbid conditions** (19) While, correlation between age, depression, surgery intervention, reported in Spanish individuals. (16)

As seen **towards the patients' characteristics subjects** in this study sustained hip fractures due to falls, and reported commonest location being at home. Educating the elderly about precautions measures to avoid falls at familiar or surrounding places may serve up to some extent prevent fractures. Practice of fall precautions was more in the educated patients compared to those who were not educated. (17) In this study, the level of education did not **correlate to the waxing and**

**waning experience on the quality of life and practice of fall** precautions. (14) The use of patient-rated outcomes in this study namely SF- 12 and HRQOL -14 provides a holistic view of the effect post-surgical management of fracture neck of femur. With an excellent follow-up our results showed clearly the deterioration in the quality of life after hip fracture in the first month but improvement in subsequent period. **All the patients who were interviewed were coherent in their understanding of their owns expectations and health condition.**

Summarily, present study attempts to systematically look QoL aspects of patient going through surgical of femur neck fractures. There are some limitations of study, that it's a single institution and with the relatively small sample size. **Comparison between patients operated with THR and hemiarthroplasty in terms of functional outcome was not done.** Factors affecting to the quality of life and related confounding variables are not under the purview of the study. However, complete follow-up of subject longitudinal period of time and validated instruments of survey covers the research gap in the domain from Indian settings. Studies with larger sample size from multicentre settings in similar context will be effective. Present study draws the foundation for the same.

**Comment [VS20]:** No specific relevant discussion point in this scientific study, reduces the strength of the scientific message.

**Comment [VS21]:** Grammar ???

**Comment [VS22]:** Waxing/waning of QoL with ageing population pre and post falls is multifactorial and level of education in developing countries is least discussed

## Conclusion

Hip fractures can be treated surgically, and pre-operative levels or improved quality of life was recorded at six-months post-surgery. The present study provides compelling evidence that hip fracture patients experienced a significant deterioration in health-related quality of life with a substantial decrease in the activities of daily living across all domains after 1 month post hip fracture surgery on both the SF-12 and HRQOL-14 outcome scores improving subsequently over the next few months to achieve a near preoperative status at 6 months. There exists a need to pay attention to all these aspects of HRQOL by health care professional. Development and evaluation of post-operative intervention programs should be conducted to determine its usefulness in improving physical, mental function and other HRQOL aspects. Moreover, HRQOL should be part of a comprehensive assessment of fracture-associated morbidity.

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**Comment [VS23]:** Please refer to guidelines for authors for the correct reference and review citations.