**HEALTH-RELATED QUALITY OF LIFE IN POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS AND AN INADEQUATE RESPONSE TO ANTI-OSTEOPOROSIS MEDICATION: BASELINE RESULTS OF THE FRENCH COHORT FROM THE OBSERVATIONAL STUDY OF SEVERE OSTEOPOROSIS (OSSO)**

Fardellone P1, Liu-Leage S2, Alfonsi A2, Tcherny-Lessenot S2

1CHRU Amiens, Amiens, France; 2Lilly France, Suresnes, France

**OBJECTIVES:** To evaluate changes in health-related quality of life (HRQoL). METHODS: The OSSO study is a 12-month, European, prospective, observational study of postmenopausal women with osteoporosis and an inadequate response to anti-osteoporosis therapy, defined as: 1) presence of a new fragility fracture despite prescription of any approved anti-osteoporosis therapy for at least 12 months before the fracture, and/or 2) discontinuation of any approved anti-osteoporosis therapy due to compliance problems and/or side effects. RESULTS: A total of 418 women enrolled in France were included in the baseline analysis: 196 (46.90%) had a new fragility fracture and 222 (53.10%) had compliance problems/ side effects, a less severe patient group based upon baseline patients’ characteristics. HRQoL was assessed using the osteoporosis disease-specific QUALLEFFO questionnaire. At baseline, the mean (SD) total QUALLEFFO score for the OSSO French population (n = 418) was 42.7 (18.8), and the mean (SD) scores for the five domains were: pain 46.2 (27.4), physical function 33.0 (23.0), social function 56.9 (25.9), general health 62.7 (20.7) and mental function 42.7 (18.8), and the mean (SD) scores for the five domains were significantly higher in the fracture group. The vertebral fracture worsens quality of life across multiple aspects of QoL most notably health, relationships and productivity. Contrary to physician beliefs, these impairments are still evident several years post injury for most patients. The short term impacts occur in the first 4-6 weeks post injury and include sleep disturbances and work loss. For patients who do not heal properly or develop infections, the severity of the impact on QoL midterm (6 weeks–3 months) is greater and impacts self image and feelings of helplessness. These patients are at greater risk for long-term consequences which include divorce and continued mental and physical health issues. The full conceptual model of the short, mid and long term QoL impacts, potential determinants and modifiers of the relationships along with the Fracture-QoL Measure will be presented. CONCLUSIONS: Improving the ability of orthopedic experts to recognize the significant QoL impacts will facilitate patient access to necessary support services and appropriate treatments. Discussion of these impacts with patients will help them to be better prepared for a realistic recovery.

**UNDERSTANDING AND ASSESSING TIBIA FRACTURE ON QUALITY OF LIFE; CONCEPTUAL MODEL AND NEW DISEASE SPECIFIC HR-QOL MEASURE**

Brod M1, Lammert M2, Rasmussen MH1

1The BROD GROUP, Mill Valley, CA, USA; 2Novo Nordisk, Bagsvaerd, Denmark

**OBJECTIVE:** Tibia fractures are the most common long bone fracture and are associated with significant morbidity ranging from infection and amputation to employment problems. Additionally, general health problems such as stiffness and ongoing pain are not uncommon. The purpose of this qualitative study was to examine QoL issues for tibia fracture, develop a conceptual model of the QoL impact of fractures and generate a preliminary version of the Fracture-QoL Measure. METHODS: Data were collected from the literature, orthopedic experts (N = 6) and patients, individually or in focus groups (N = 42), in 4 countries (US, Canada, UK, Germany) by interviews following a semi-structured interview guide. Transcripts were analyzed for common themes and the conceptual model and item generation was based on these themes. Items underwent cognitive debriefing. RESULTS: Tibia fractures have a significant negative impact across multiple aspects of QoL most notably health, relationship-