IMPROVED FATIGUE AND PHYSICAL FUNCTION ARE CORRELATED WITH HEALTH-RELATED QUALITY OF LIFE IN PSORIATIC ARTHRITIS SUBJECTS TREATED WITH APRIMLAST: RESULTS FROM A PHASE 2, RANDOMIZED, CONTROLLED STUDY

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OBJECTIVES: Psoriatic arthritis (PsA) is an inflammatory arthritis with deleterious effects on health-related quality of life (HRQoL). We evaluated the effect of apremi- last (APR) on patient reported outcomes (PROs) in PsA subjects and the correlation between the 36-Item Short-Form Health Survey (SF-36) domains and disease-specific measures of physical function and fatigue. METHODS: A phase II, multicentre, double-blind, placebo-controlled study randomised 204 subjects with active PsA (duration >6 months; ≥3 swollen joints; ≥3 tender joints) 1:1 to oral APR 30mg BiD (APR20), 40mg QD (APR40), or placebo for 12 weeks. PROs included Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F), Health Assessment Questionnaire–Disability Index (HAQ-DI), pain visual analogue scale (VAS), and SF-36 domain scores. Correlations between the HAQ-DI, pain VAS, and FACIT-F and the SF-36 Physical Function (PF), Bodily Pain (BP) and Vitality (VT) domains were described with statistical significance. RESULTS: At week 12, mean change in PF, BP, and VT was –2.1, 2.7, and 3.1 with placebo; 6.2 (P=0.012 versus placebo), 11.5 (P=0.001 versus placebo), and 6.6 (P=0.005 versus placebo) with APR20; and 3.8, 7.9 (P<0.001 versus placebo), and 5.7 with APR40, respectively. Mean change in HAQ-DI was –0.1, –0.2, and –0.2 with placebo, APR20, and APR40. Mean change in FACIT-F was 0.54, –4.1 (P=0.005), and –4.3 with placebo, APR20, and APR40. Mean percent change in pain VAS was 7.4%, 14.5%, and –15.1% with placebo, APR20, and APR40. Moderate (≥0.3) and statistically significant (P<0.001) correlations were ev- ident in the mean pain VAS and HAQ-DI (r=0.43) and FACIT-F and VT (r=0.55). High (≥0.60), statistically significant (P<0.001) correlations were observed for FACIT-F versus VT (r=0.66) with APR20 and HAQ-DI versus VT (r= –0.73) with APR40. CONCLUSIONS: Treatment of PsA with APR20 was associated with statistically significant improvement versus placebo in FACIT-F and HAQ-DI. Moderate to high correlations were evident among PROs.

NEW DEVELOPMENTS IN THE ANKYLOSING SPONDYLITIS QUALITY OF LIFE SCALE (ASQOL) SCALE

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OBJECTIVES: The PsAQoL is a measure of quality of life (QoL) specific to psoriatic arthritis (PsA) patients published in 2003. Conceptual design of the PsAQoL was derived from qualitative interviews conducted with UK PsA patients. New language versions have since been developed for several European countries, the US, Canada, Argentina and Brazil. Interest in the PsAQoL has increased lately due to the need to determine changes in QoL associated with new biological treatments. In recent years there has been a move towards conducting clinical trials in developing countries. This has increased interest in adapting patient-reported outcome measures developed in Europe and the United States for use in new regions of the World. An important question remains to be answered, can such measures provide valid assessment of QoL in these regions? METHODS: New adaptations are currently being produced for Eastern Europe (4), the Middle East (2), Central and South America (2) and Asia (5). The measures are being translated (using the two panel methodol- ogy required for needs-based measures) and tested with local patients by patients themselves. RESULTS: To date cognitive debriefing interviews have confirmed the adapted measures’ acceptability to patients who found it easy to understand and complete. The adaptations also have good internal consistence (alphas >0.85) and reproducibility (test-retest reliability coefficients: >0.85). The adaptations also exhibited construct validity by their ability to distin- guish groups of PsA patients that varied by perceived disease severity and general health and by correlating as expected (moderately) with the Nottingham Health Profile. CONCLUSIONS: It is intended to use Item Response Theory analyses to determine whether respondents in the developing countries answer the PsAQoL in the same way as those in Western countries. This will show whether the scales work validly in the developing countries.

SENSITIVITY OF PRO’S TO DETECT CHANGES IN QUALITY OF LIFE IN PATIENTS TREATED WITH A BILOGIC AGENT

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OBJECTIVES: To investigate whether patient reported outcomes in patients who had been prescribed etanercept, an anti-TNF inhibitor, by their specialist could demonstrate changes in quality of life over time. A longitudinal evaluation was designed to compare patients with their disease activity and current medications and in a quality of life experience. METHODS: The evaluation was conducted throughout the UK using a web-based system supplemented by telephone reporting PROBE (patient reported outcomes based evaluation). Outcome measures included demographic data, the condition, treatment and healthcare and quality of life. RESULTS: A total of 344 people participated in the evaluation at baseline, 290 online and 54 by telephone with a mean age of 53 years and 62% female. 191 of these patients had Rheumatoid Arthritis, 44 Psoriatic Arthritis, 43 Ankylosing Spondylitis, 35 psoriasis and 31 oth- er/missing data. Patients were severely affected by their condition as noted on their quality of life measure at baseline. Treatment had a marked beneficial effect for patients as recorded by all measurement tools. All scores given in order. Baseline measures (mean (SD)) clinical global impression best/worst 1.7 (1.09) to 4.31 (1.50); p<0.001. EQ SD Questionnaire 0.0 worsen health 1.0 best health 0.39 (0.34) to 0.64 (0.27); p<0.001. DLQI 30 worst effect 0.0 on effect on life 14.57 (7.64) to 3.69 (6.14) p<0.001. HAQ 0 no difficulty 3 unable to perform activity 1.77 (0.63) to 1.25 (0.73) p<0.001. CONCLUSIONS: This evaluation shows that patients have significant improvement of their condition before coming to a PROBE agent across a range of conditions. Treatment with the biologic agent showed a sustained improvement in their quality of life up to 6 months. The PROBE methodology (web-based system supplemented by telephone reporting) successfully captured changes in patient reported quality of life measures.

QUALITY OF LIFE FOR THAI HIP FRACTURE PATIENTS: ASSESSMENTS WITH MEDICAL OUTCOMES STUDY, A 36-ITEM SHORT FORM SURVEY (MOS SF-36) AND ONE-YEAR HEALTH CARE RESOURCE UTILIZATION IN A PUBLIC HOSPITAL

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OBJECTIVES: Hip fracture is a major health burden in Thailand. We determined the health-related quality of life for patients living with hip fracture, correlated factors and relationships with one-year health care resource utilization. METHODS: A self-administered Medical Outcomes Study 36-item Short Form Survey (MOS SF-36) questionnaire was mailed to patients after discharge from the hospital. A cross-sectional analysis of MOS SF-36 was carried out among 119 hip fracture patients of Chiangrai Hospital. Healthcare resource utilization was follow-up for one year taken from hospital database. RESULTS: Response rate was 67% and a mor- tality rate of one year was 10.6%. The QoL domains are separated into physical and mental health. CONCLUSIONS: Health-related quality of life assessments with MOS SF-36 for Thai hip fracture patients are reliable. Thai hip fracture patients reflect poorer physical health functions than mental functions. Presence of co-morbidity is a factor well correlated with poorer health-related quality of life. There is no significant corre- lation between one-year health care resource utilization and health-related quality of life for Thai hip fracture patients.

CONCEPTUAL MODEL OF THE IMPACT OF HIP FRACTURE ON PATIENTS’ LIVES

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OBJECTIVES: Hip fractures are traumatic and debilitating events which are more frequent in the elderly, and are associated with loss of mobility and independence, mortality, and significantly increased health care resources. Our objectives were to evaluate the impact of hip fractures on patients’ lives and summarise the patient experience in a conceptual model. METHODS: Twenty-one adults aged ≥50 years who experienced a hip fracture in the previous 2-18 months were recruited to participate in in-depth semi-structured interviews exploring their experience of hip fracture and impacts on their life. Thematic qualitative analysis of interview transcripts was conducted using ATLAS.ti software to identify areas of impact (concepts) and explore the interrelationships between concepts. A conceptual model was developed based on this analysis. RESULTS: Participants were mostly elderly female (n=12) with mean age 75 years (range 53-87 yrs), and 5 participants had a hip fracture treated with partial or total hip replacement. Pain and limited mobility were commonly reported by participants and were associated with increased physical activity, social isolation, difficulties walking (distance, speed, up/down stairs), restricted or difficult lower limb movements, getting or standing up and driving. Restrictions to various activities (everyday, physical, leisure and social) were reported as well as wide-ranging impact on patients’ sleep, energy levels, daily routine, emotions, family and other relationships. Mental health and the impact of hip fracture on patients were also identified and incorporated into the conceptual model. CONCLUSIONS: The conceptual model summarises important experiences and related impacts of hip fracture from the patient’s perspective and demonstrates the wide-ranging effects in other areas of patients’ lives during their recovery.

DETERMINING THE TRUE IMPORT OF DUPYTNER’S DISEASE: A QUALITATIVE STUDY

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OBJECTIVES: To explore the impact of Dupuytren’s Disease (DD) on patients’ quality of life (QoL) and identify implications for clinical practice. A search of the literature was conducted to identify key areas and common themes in individuals’ personal experiences. RESULTS: Thirty-four DD patients (73.5% male; aged 41-90; mean (SD): 62.4 (12.5) years) were interviewed. The sample had a wide range of ages and durations of DD (6 months-12 years). A total of 9032 thematic statements were coded into 22 themes. A significant impact on the quality of life (QoL) and emotional reactions, activity limitations and QoL. In any trial designed to deter consequences of socio-demographic and clinical variables. Thus, treatment with Unhais da Serra shows up as an effective complementary treatment modality in selected patients with lumbar spondylarthrosis. It seems to be justified and useful to familiarize patients and their physicians with this modality of treatment because the socio-economic impact of the pathology.

Muscular-Skeletal Disorders – Health Care Use & Policy Studies

PM570 EVALUATION OF PRESCRIBED PAIN MEDICATIONS PRIOR TO THE INITIATION OF DULOXETINE THERAPY IN A COMMERCIALLY INSURED POPULATION

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OBJECTIVES: Duloxetine is approved for the treatment of major depressive disorder (MDD) and general anxiety disorder (GAD), and for the management of diabetic peripheral neuropathic pain (DPNP), fibromyalgia (FM), and chronic musculoskeletal pain, as studied in patients with osteoarthritis (OA) and chronic low back pain. This study assessed pain medication use prior to duloxetine initiation among patients with each of these medical conditions. METHOIDS: Duloxetine initiators aged 65+ with Medicare Supplemental Insurance in 2007, 2008 and during January 1, 2009-March 31, 2010 who had any of the 6 medical conditions mentioned above during the 12 months prior to duloxetine initiation (defined as no duloxetine pill coverage in the previous 90 days). Utilization of pain medications including antidepressants, anticonvulsants, opioids, non-steroidal anti-inflammatory drugs (NSAIDs), and muscle relaxants was assessed over the 3, 6 and 12 months prior to duloxetine initiation. RESULTS: The study identified 19,546, 5,764, 2,334, 15,362, 12,317, and 27,781 duloxetine initiators in the MDD, GAD, DPNP, FM, OA, and chronic low back pain (LBP) groups. Antidepressant use was highest across all conditions during the 12 months prior to initiation, especially among patients with MDD (84.4%) or GAD (79.9%). Anticonvulsant utilization was highest in DPNP (63.1%) and FM (51.9%), lowest in GAD (39.5%), and similar among other groups (range: 42.8%-48.3%). Opioid use varied greatly across groups (54.5%-81.6%), with the lowest use among GAD patients and the highest use among LBP patients. GAD patients had the lowest NSAID use (32.9%), while OA patients had the highest utilization (58.1%). The use of muscle relaxants ranged from 29.4% (DPNP) and 56.7% (LBP) at 12 months prior to duloxetine initiation. Pain medication use in the prior 6 months showed similar trends. CONCLUSIONS: Patients used several types of pain medications prior to initiating duloxetine across disease states. The trends in use were consistent 3, 6, and 12 months prior to duloxetine initiation.