to test the robustness of the incremental effectiveness in economical analysis carried out in patients with schizophrenia or bipolar disorders.

PMH84

THE CORNELL-BROWN SCALE FOR QUALITY OF LIFE IN DEMENTIA: SPANISH ADAPTATION AND VALIDATION

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OBJECTIVES: The objective of this study was to culturally adapt and validate the Cornell-Brown Scale (CBS) for Quality of Life (QoL) in Dementia into Spanish. **METHODS:** The original CBS was translated into Spanish by mean of a conceptual equivalence approach, including forward and backward translations in duplicate. Subjects with mild-to-moderate dementia were recruited and interviewed by a psychologist who was trained in administering questionnaires to obtain sociodemographic information, health perceptions, depressive symptoms (GDS-15), functional ability (Barthel Index), dementia severity (MMSE), specific QoL (CBS) and generic QoL (WHOQOL-BREF). Participants were included if they had a diagnosis of dementia according to DSM-IV criteria, a MMSE scoring $\geq$ 9, were living at home, and had a known and stable caregiver with whom were living or had daily contact. Acceptability, reliability, and validity were assessed using standard psychometric methods. Exploratory factor analysis (EFA) was applied to analyze the dimensional structure of the scale for the first time. **RESULTS:** A total of 100 persons with dementia (66% female; 79.18 years) were recruited: 61% Alzheimer's disease; 17% vascular dementia; 14% mixed dementia; and 8% other dementia. Internal consistency reliability was good (Cronbach's α= 0.87). A priori hypotheses about the relationship between CBS and the WHOQOL-BREF psychological domain and GDS-15 were confirmed, indicating good criteria validity; Pearson's r= 0.570 and -0.537, respectively. Discriminant validity was confirmed by the ability of the scale to significantly differentiate between healthy and unhealthy and depressed and non-depressed participants; but not between mild and moderate dementia. The EFA showed a five-factor solution which accounted for 63.9% of the total variance of CBS. **CONCLUSIONS:** The Spanish version of CBS showed good psychometric properties of validity and reliability to explore QoL in patients with mild-to-moderate dementia in Spain. The factor structure of the CBS is reported for the first time.

Muscular-Skeletal Disorders – Clinical Outcomes Studies

PMS1

TUMOR NECROSIS FACTOR ALPHA INHIBITORS FOR THE TREATMENT OF ACTIVE ANKYLOSING SPONDYLITIS

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OBJECTIVES: To compare the efficacy and safety of tumour necrosis factor alpha (TNF) inhibitors in the treatment of active ankylosing spondylitis (AS), in adult patients naïve to biologic therapy. **METHODS:** A literature search was performed, first focused on identifying health technology assessment reports (HTAR), meta-analysis and systematic reviews. The databases searched were MEDLINE, EMBASE, CRD, and the Cochrane Library. An exhaustive search of randomized controlled trials (RCTs) that compared directly the TNF-inhibitors was also carried out in MEDLINE and EMBASE. Both searches covered until November 2010. Two authors independently selected the studies, assessed the quality, and performed the data extraction, with disagreements resolved by a third reviewer until consensus was obtained. In addition, an analysis of adjusted indirect comparisons (AIC) against a common comparator was done using the method of Bucher et al. and the software from the Canadian Agency for Drugs and Technologies in Health version 1.0. **RESULTS:** A HTAR was included, it compared the clinical efficacy of infliximab, etanercept and adalimumab associated with conventional treatment versus conventional treatment and it also compared TNF-inhibitors between them. Five RCTs were included to update the report. One study directly compared infliximab and etanercept and the other four RCTs evaluated each of the TNF-inhibitors (infliximab, etanercept, adalimumab and golimumab) versus placebo. In the AIC analysis performed considering all the evidence available, no statistically significant differences in the ASAS20 response between infliximab, etanercept, adalimumab and golimumab were found. Also, there were no statistically significant differences between the TNF-inhibitors in the rate of serious infections or withdrawals due to adverse events. **CONCLUSIONS:** Only one RCT directly compares two TNF inhibitors. Therefore, in the absence of such trials, AIC are considered. No clinically relevant differences are observed in the efficacy and safety between infliximab, etanercept, adalimumab and golimumab in the treatment of adult patients with AS.

PMS2

RISK AND COST OF INFECTIONS IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH ANTI-TNF THERAPY IN ALBERTA, CANADA

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OBJECTIVES: To evaluate the risk of infection and associated healthcare costs in Rheumatoid Arthritis (RA) patients treated with anti-Tumor Necrosis Factor (anti-TNF) therapy in Alberta, Canada. **METHODS:** RA patients initiating anti-TNF therapy between January 2004 and March 2009 in Edmonton and Calgary were followed prospectively to identify treatment efficacy and adverse events. Clinical and self-reported data was linked with provincial healthcare administrative databases. Infections (any and severe) were identified by using ICD 9 and 10 diagnosis codes. We used Cox-regression to assess the risk of infection and linear regression to assess the associated costs. **RESULTS:** The cohort consists of 1,086 patients (70% female, mean age of 54 years) with a mean follow-up of 2.3 years. Seventy percent of patients (n=764) reported an infection during follow-up, while 4% (n=42) suffered a severe infection. Compared to patients on their first anti-TNF (n=731), patients who switched to another anti-TNF (n=212), patients on DMARD (n=75), and patients switched from DMARD to anti-TNF (n=68) had similar Hazard Ratios (HR) ($p>0.05$) for both any and severe infection. Pre-existing lung disease (HR=1.98, $p<0.001$) and heart disease (HR=1.42, $p=0.037$) increased, while male sex (HR 0.79, $p=0.005$) decreased the risk of any infection. The risk of a severe infection was increased by underlying anemia (HR=3.20, $p=0.018$) and in those with longer disease duration (HR=1.03, $p=0.032$), but was reduced in patients with university-level education (HR=0.34, $p=0.018$), and osteoarthritis (HR=0.37, $p=0.035$). In linear regression, Log(cost) was significantly associated with higher baseline HAQ score and longer disease duration and in patients who required a switch between anti-TNF agents for inefficacy or adverse events. **CONCLUSIONS:** The risk of any or severe infection did not differ significantly between treatment groups. Some pre-existing diseases increased while being male and having university education decreased the infection risk. Healthcare cost variations between the treatment groups were small.

PMS3

DIFFERENTIATION OF OSTEOPOROSIS TREATMENTS ACTION ON BONE REMODELING: PRINCIPAL COMPONENTS ANALYSIS OF BONE HISTOMORPHOMETRY PARAMETERS

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OBJECTIVES: Osteoporosis is a disease with accelerated bone loss associated with an increased risk of fractures. Histomorphometry of bone biopsy specimens from postmenopausal women with osteoporosis measures bone remodeling activities which include both bone formation and resorption. This study compared the effects of two osteoporosis treatments (20 μg/day teriparatide vs. 10 mg/day alendronate) on bone remodeling using the principal components analysis (PCA) of bone histomorphometry parameters. **METHODS:** Postmenopausal women with osteoporosis treated with either teriparatide or alendronate and completed iliac crest bone biopsy at either the sixth or eighteenth month in the randomized, double-blind Forteo Alendronate Comparator Trial were included in the analysis (teriparatide: N=12; alendronate: N=9). Eighteen histomorphometric parameters were grouped into either the formation (13) or resorption (5) category. Within each category, the first principal component was estimated through the PCA and defined as the principal formation component (PFC) and principal resorption component (PRC). The summation of PFC and PRC was calculated to represent the overall level of bone turnover. The difference between PFC and PRC was computed to determine the imbalance between formation and resorption. **RESULTS:** The PFC accounted for 61.8% of total variance in the 13 formation parameters, and the PRC accounted for 70.4% of total variance in the 5 resorption parameters. The PFC was significantly higher in the teriparatide group than in the alendronate group (0.68 vs. -0.95, $p<0.0001$), while the PRC was significantly lower in the alendronate group (-0.47 vs. 0.32, $p<0.05$). The difference between the PFC and PRC was positive in the teriparatide group and negative in the alendronate group. **CONCLUSIONS:** In postmenopausal women with osteoporosis, teriparatide treatment stimulates both bone formation and resorption, and formation dominates resorption. Treatment with alendronate suppresses both bone formation and resorption, and resorption dominates formation.

PMS4

EFFICACY AND EFFECTIVENESS OF COLLAGENASE CLOSTRIDIUM HISTOLYTICUM FOR DUPUYTREN'S CONTRACTURE

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OBJECTIVES: The objective was to determine if the effectiveness of collagenase clostridium histolyticum (XIAFLEX, CCH) in real-world settings is comparable to the efficacy demonstrated in the clinical trials. **METHODS:** A retrospective chart review was conducted at selected sites. Charts of each patient treated with CCH in 2010 were abstracted. Effectiveness results were compared to efficacy findings from the clinical registration trial (CORD-I)1 on 1) final contracture angle, 2) change in contracture, 3) final range of motion, and 4)change in range of motion, with means of 12°, 38°, 81°, and 37° respectively. The equivalence range was set at +/− 10°. **RESULTS:** 501 patient charts were abstracted from 10 sites. The average patient age was 65 years; 76% were male. The 95% confidence interval (C.I.) fell within the corresponding predefined equivalence range of +/− 10° for each of the 4 effectiveness measures (with means of 12°, 37°, 81°, and 37° respectively.) The effectiveness injections/joint rate was 1.08±0.32(n=629 joints) with a 95% C.I. of 1.05 to 1.11, This CI does not fall within the reported C.I. of 1.6 to 1.8 in published trials ($p<0.05$). The average number of (injection, manipulation, and follow-up) office visits/injection was 2.92±1.05 (n=620). **CONCLUSIONS:** CCH effectiveness findings were equivalent to those published for the CORD-I clinical trial, yet the effectiveness injections/joint rate was 36% lower than in the trial. Visits per injection cycle were also lower than in the published CORD-I trial. The number of CCH injections used in real-world settings may be lower because a) both patient/physician knew that active drug was administered; b) anesthesia was used at manipulation; c) patient focused treatment outcomes were used without the strict requirements of a clinical trial protocol.