College of Rheumatology criteria for 20% improvement (ACR20 criteria). Data was obtained from a comprehensive literature review using PubMed, Medline, and Cochrane library. Efficacy values were obtained from published randomized clinical trials. A decision tree analyses was conducted followed by one-way and two-way sensitivity analyses. Efficacy and efficacy values associated with therapeutic options were varied in the sensitivity analyses. RESULTS: The probability of achieving ACR20 response for ETAN+MTX, ADA+MTX, INF+MTX, and MTX were 85.5%, 65.95%, 61.26%, and 39.94%, respectively. The probability of an adverse drug event occurring for ETAN+MTX, ADA+MTX, INF+MTX, and MTX were 14.0%, 6.5%, 7.9%, and 9.5%, respectively. The analysis revealed that ETAN+MTX option was the most cost-effective, with an annual cost of $52,369 to the patient. The annual cost savings with ETAN+MTX combination use would be $19,318. Annual costs of ADA+MTX, INF+MTX, and MTX monotherapy were $79,058, $68,932, and $67,071 respectively. Results were robust to both one-way and two-way analysis. CONCLUSIONS: Etanercept plus Methotrexate combination therapy was a better option based on the ACR 20 outcome measure considered. An analysis using real world data and/or a prospective head-to-head comparison study could provide better conclusive evidence for decision-makers.

PM254
LOWER HIP FRACTURE RATES IN THE FIRST YEAR OF THERAPY TRANSLATE INTO FAVORABLE COST-EFFECTIVENESS FOR RISEDRONATE VS. GENERIC ALENDRONATE AMONG HIGH RISK PATIENTS
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OBJECTIVES: An observational study comparing risedronate to alendronate (REAL) in a managed care group of non-vertebral osteoporosis (NVO) women with prior fractures demonstrated that treatment with risedronate reduced the incidence of hip fracture by 66% in the first year of treatment (Delmas, 2008). The object of this analysis was to determine the cost-effectiveness of risedronate compared to alendronate at generic pricing using these effectiveness data in a high risk PMO population in the U.S. METHODS: A validated Markov model of osteoporosis (Tosteson, 2001) was used to estimate the impact of therapy on hip fractures, costs, and quality-adjusted life years (QALYs). The model simulated a cohort of 10,000 women ages 65+ with BMD T-score -2.5 and a previous vertebral fracture, treated with risedronate or alendronate for one year. Associated costs and QALYs were tracked for an additional two years in each arm. Hip fracture incidence and mortality rates, as well as drug (generic alendronate 93.5% lower than risedronate) and hip fracture costs were extracted from published studies. RESULTS: In a cohort of high risk women treated with risedronate versus alendronate, the model predicted 25 fewer hip fractures and 8.41 additional QALYs, resulting in a cost savings of $330,378. Extrapolating to a population of PMO women with a prior vertebral fracture in the U.S. suggests that risedronate prevents over 114,000 fractures in roughly 4.6 million women at cost savings of over $1,515 million. A sensitivity analysis assuming treatment for 2 years and parity efficacy in year 2 resulted in a cost per QALY gained for earlier fracture protection of $9925 (cost per fracture averted: $3419) when treating with risedronate versus alendronate in the population 65+. Risedronate remains cost-saving in the 80+ population, CONCLUSIONS: Risedronate therapy is both cost and resource sparing “real world” data this analysis suggests risedronate’s early fracture protection results in favorable cost-effectiveness versus generic alendronate despite its higher drug cost.

PM255
COST-EFFECTIVENESS IN OSTEOARTHRITIS PAIN RELIEF TREATMENT WITH NSAIDS – A DETERMINATION AND ESTIMATION OF KEY DRIVERS
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OBJECTIVES: To determine and quantify the key drivers of cost-effectiveness in OA treatment with traditional NSAIDs and COX-2 selective pharmaceuticals. METHODS: Cost effectiveness analysis (CEA) in OA treatment with traditional NSAIDs and COX-2 selective pharmaceuticals focus on side effects given the non-significant differences in efficacy (pain relief) among treatments. The most frequently included side-effects and complications in OA CEA analysis are gastrointestinal (GI) complications and myocardial infarction (MI). Given the concern about broader cardiovascular (CV) risks associated with NSAID treatment, the scope of a recently published Markov model (five-year horizon, three-month cycles, health care perspective was extended to include four additional CV events (stroke, coronary insufficiency, venous thromboembolism and angina). Two treatments priced at 1) the average of celecoxib and etoricoxib, and 2) ibuprofen were evaluated. The model was populated with UK data. Absolute and relative GI risks were derived from a recent NICE HTA report whereas absolute CV risks were assumed to equal the normal population risk and relative CV risks were taken from the literature. The model was used to determine the most important drivers of cost-effectiveness in OA treatment. This was done by evaluating the responsiveness of the ICER to a 1% change in the input variable of interest, controlling for changes in all other variables. RESULTS: The five most influential variables were (% impact on ICER resulting from 1% change in the variable): Quality of life in arthritis (2.5%), relative risk of CV events (1.5%), relative risk of mild GI events (1.3%), price of the COX-2 pharmaceutical (1.3%) and quality of life in dyspepsia (0.7%). CONCLUSIONS: While the most important cost-effectiveness driver in OA treatment is overall quality of life changes, the analysis indicate that there might be higher economic benefits associated with decreasing CV risks rather than decreasing aspects of GI risk.

PM256
CHARACTERISTICS AND HEALTH CARE UTILIZATION RESULTING FROM INJECTION SITE REACTIONS WITH ANTI-TNF TREATMENTS FOR RHEUMATOID ARTHRITIS: A PROSPECTIVE ANALYSIS OF CASES AT THE URBAN TEACHING HOSPITAL
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OBJECTIVES: Injection site reactions (ISR) are the most common type of adverse event associated with the subcutaneous use of the tumor necrosis factor inhibitor (Anti-TNF) agents, etanercept (Enbrel) and adalimumab (Humira). The purpose of this study was to 1) investigate the incidence and characteristics of ISR, and 2) capture the change in economic consequences of ISR in patients who received etanercept and/or adalimumab for rheumatoid arthritis (RA). METHODS: RA patients were identified through a query of outpatient claims with an ICD-9 code for RA and practice code for Jefferson Rheumatology Associates, Philadelphia, PA. Patients who met inclusion criteria of 218 years old and having received etanercept or adalimumab in the past 3 years were administered a one-time observational survey developed by the investigators. RESULTS: The study included thirty patients, five of which had used both adalimumab and etanercept. The overall prevalence of ISR was 56.3% (9 patients, n = 16) for adalimumab and 84.2% (16 patients, n = 20) for etanercept. Clinical characteristics of ISR included erythema (44.4%-68.8%), pruritus (44.4%-68.8%), and swelling (33.3%-56.3%). Only one patient (3.3%) in the cohort was pre-medicated for ISR. Three patients in the adalimumab (n = 9, 33.3%) and one patient in the etanercept group (n = 16, 6.25%) called their physician when experiencing a time-outcome RR. The median time to ISR was 30 days (IQR: 15-60) and 7 days (IQR: 3-14) respectively. CONCLUSIONS: ISR occurred in over half of the patient cases studied, and was largely characterized by erythema, pruritus, and swelling. Patient counseling about ISR is essential since self-treatment is common and discontinuation may result.

PM257
COSTS OF PSORIATIC ARTHRITIS IN HUNGARY: RESULTS FROM A CROSS-SECTIONAL SURVEY
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OBJECTIVES: Psoriatic arthritis (PsA) is an inflammatory arthritis occurring in about 10–30% of the patients with psoriasis. Registration of highly effective but costly biological drugs for the treatment of PsA gave an extra impulse to economic evaluations in rheumatology. There are no data on cost-of-illness of PsA neither from Hungary nor from countries with similar income levels (i.e. Poland, Romania, and Czech Republic). The main goal of present study was to collect data on disease burden and costs of patients with PsA in Hungary. METHODS: A cross sectional questionnaire survey of consecutive patients aged ≥18 years with diagnosis of PsA was conducted in 8 hospital based rheumatology outpatient centres in Hungary in 2008. Data were collected by rheumatologists during routine outpatient visits. Observed variables were demographic data, disease duration, disease activity score (DAS28), psoriasis area severity index (PASI), drug use, the use of aids and devices, imaging, gastroscopy, outpatient visit, admissions to hospital, orthopaedic surgery, spa, physiotherapy, home care, transportation, non-reimbursed health care services, home remodelling and infor mal care. Data on PsA related reduction of working hours, sick leave and disability pension were collected also. RESULTS: A total of 183 patients were enrolled, of these, 104 (57%) were women. The mean age of the sample was 50.3 (SD 12.9) years and the mean disease duration was 9.2 (9.2) years. The annual average direct, indirect and total costs were 2 670, 2 904 and 5 574 euros/patient/year in PsA, respectively. The main cost domains were the productivity losses due to work disability (49%) and the costs of biologic therapies (18%), with 2 742 (SD 4 920) and 1 098 (SD 4 134) euros/patient/year, respectively. CONCLUSIONS: Our study showed that the economic burden of PsA is considerable in Hungary and provided a baseline to evaluate the economic effect of treatments in PsA.
Annual direct costs were calculated (by third-party payer perspective) for privately-insured (n = 4,764) and Medicare (n = 48,742; medical costs only) beneficiaries. Indirect costs were calculated for privately-insured employees with disability data (n = 1148). Costs were reported in 2006 dollars. RESULTS: In Medicare, mean medical costs per non-vertebral, non-hi fracture patient were $7,463 in excess of controls ($13,720 vs. $6,258; p < 0.01). The most expensive patients had fractures of the hip, multiple sites, and femur (excess costs of $25,125; $20,049; $19,213, respectively). Aggregate annual excess medical costs of these NVNH patients (n = 35,933) were $268 million versus $200.9 million for hip fracture patients (n = 7,997) (excludes patients with hip and NVNH on index date). In the privately-insured population, excess mean direct costs per NVNH fracture patient were $5,381 ($11,090 vs. $5,709; p < 0.01). The most expensive patients had fractures of the hip, multiple sites, and pelvis (excess costs of $15,801; $9,642; and $8,164, respectively). Aggregate annual excess direct costs of these NVNH patients (n = 4478) were $241.1 million versus $3.5 million for hip fracture patients (n = 255). Mean excess indirect costs per NV employee were $1936 ($4,349 vs. $219; p < 0.01). CONCLUSIONS: Excess direct and indirect costs of NV osteoporotic fracture patients to payers are substantial. While hip fracture patients are more costly per patient, NVNH fracture patients are associated with a larger percentage of fractures and aggregate excess costs for both these privately-insured and Medicare samples.

GOLIMUBAL SIGNIFICANTLY REDUCES TIME LOST FROM WORK FOR PATIENTS WITH RHEUMATOID ARTHRITIS: POOLED DATA FROM THREE PHASE 3 STUDIES

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OBJECTIVES: To evaluate the effect of golimumab (GLM) on time lost from work in patients with rheumatoid arthritis (RA). METHODS: The effect of GLM on time lost from work (days) was prospectively evaluated in 3 multicenter, randomized, double-blind, placebo-controlled studies in patients with RA. Pooled data from patients receiving any injection of study agent (GLM or placebo) with or without methotrexate (MTX) in 3 RA studies (GO-BEFORE, GO-FORWARD, and GO-AFTER) were included. GLM SC injections of 50 or 100 mg were administered q8 weeks. Time lost from work for patients was collected through a questionnaire at baseline and qf weeks through week 24 and was summarized cumulatively through week 24. The number of associations between groups using the Mann-Whitney tests. The proportion of patients reporting no time lost from work in the GLM +/- MTX group was compared with the PBO +/- MTX group using the chi square test.

RESULTS: Through week 24, significant differences in time lost from work were observed between the GLM +/- MTX group and the PBO +/- MTX group. At week 24, the PBO +/- MTX group lost 9.9 ± 19.7 days compared with 5.0 ± 19.4 days for the combined GLM +/- MTX group. At week 24, the 75th percentile for the combined GLM +/- MTX group was 1,000 day (range 0-180) compared with 3,000 days (range 0-120) for the PBO +/- MTX group. A significantly higher proportion of patients in the combined GLM +/- MTX group reported no time lost from work compared with the PBO +/- MTX group (73.1% vs. 60.7%; p<0.002). CONCLUSIONS: GLM +/- MTX significantly reduced time lost from work for patients with RA compared with PBO +/- MTX.

THE ECONOMIC CONSEQUENCES OF RHEUMATOID ARTHRITIS: ANALYSIS OF THE MEDICAL EXPENDITURE PANEL SURVEY (MEPS) 2005 AND 2006 DATA

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OBJECTIVES: Previous research reported the prevalence and health care and productivity cost of rheumatoid arthritis (RA) using Medical Expenditure Panel Survey (MEPS) 2004 data; this study replicates the analyses using 2005 and 2006 data. METHODS: MEPS, a comprehensive survey of approximately 35,000 individuals in the US, was used to identify non-institutionalized US persons with RA. Multiple linear and semi-log regressions were applied to estimate total annual health care expenditure and income (yearly wages) associated with RA. Covariates in the expenditure equations included demographic, comorbidities, and overall health status. Semi-log regression of income renders the distribution of income more symmetric. Covariates in the income equations included demographic, comorbidities, education, occupation, and health status. RESULTS: A total of 150 and 148 patients with RA were identified in 2005 and 2006 versus 136 in 2004; 75% (2005) and 80% (2006) were women versus 76% 2004); and 53% (2005) and 50% (2006) of RA patients were between the ages 41–64 years versus 56% in 2004. Linear regressions demonstrated that the incremental increase in health care cost associated with RA was $2902 ($0.0001) in 2005 and $1882 ($0.003) in 2006, versus $4422 (2004). Semi-log regression of income explained wages in 2005 and 2006 had adjusted R of 56% and 59%. RA significantly reduced wages by $2207 ($0.9237 log estimate) annually (p < 0.0001) in 2005 and $1,559 (0.5338 log estimate; p = 0.05) in 2006; wages of RA patients in 2004 were reduced by $3526 (1.0388 log estimate). CONCLUSIONS: The economic impact of RA is substantial to both income loss and health care costs. Replication and validation of outcomes research is important to establish the precision of statistical associations as well as changes across time. Further study will explore whether changes in the care of patients with RA affect changes in outcomes over time.

CLINICAL AND ECONOMIC CHARACTERISTICS OF PATIENTS WITH FIBROMYALGIA

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OBJECTIVES: Fibromyalgia syndrome (FMS) is a chronic disorder defined by widespread musculo-skeletal pain that is often associated with a number of comorbidities including fatigue, sleep disturbance, stiffness and functional limitation. In absence of a specific diagnostic test, FMS is typically difficult to identify, and there is limited knowledge about the economic burden of FMS. The objectives of this study were to estimate prevalence of comorbidities, health care resources utilization and costs associated with FMS. METHODS: A retrospective cohort study was conducted using data from the Quebec provincial health plan (RAMQ) for a random sample of patients with two or more recorded diagnoses of FMS and a control cohort without FMS, matched for age and gender, for a period spanning from June 2006 to July 2007. The prevalence of comorbidities was estimated using a chi-square test and a chronic disease claim index. Health care resources consumed by FMS and non-FMS patients included visits to physicians, their interventions, pain-related medications, non-pain-related medications and hospitalizations. RESULTS: A total of 16,010 FMS patients were identified with a matched number of control patients. The mean age of the study population was 58.8 years and most subjects were women (67.8%). The prevalence of most comorbidities and the chronic disease score were significantly greater in the FMS patients than in control group (3.8 vs. 2.8; p < 0.001). Health resources utilization during the study period was significantly greater among FMS patients than non-FMS patients; the annual number of physician visits and interventions was 23.1 for FMS vs. 14.8 for non-FMS patients. The amount paid by the RAMQ was significantly greater for patients with FMS ($4063) compared to patients without FMS ($2766, p < 0.001). CONCLUSIONS: This analysis of the RAMQ database indicated that comorbidities are highly prevalent in FMS patients, and suggested that the economic burden associated with FMS is substantial.