USE OF TNF-INHIBITORS IN THE UNITED STATES: UTILIZATION PATTERNS AND DOSE-ESCALATION FROM A REPRESENTATIVE UNITED STATES RA POPULATION

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OBJECTIVES: TNF-inhibitors were the first biological therapies approved for RA treatment and five are approved by the US FDA: etanercept (ETN), adalimumab (ADA), infliximab (IFX), certolizumab pegol (CZP) and golimumab (GOL). The study objective was to understand “real-life” dosing patterns, including dose-escalation, which may impact costs/outcomes of TNF-inhibitor therapy. METHODS: We used a longitudinal claims database (3 Pharmaka Informatics) to assess RA patients receiving ETN, ADA, or IFX. Due to product launch date, CZP and GOL were excluded. Patients having a TNF-inhibitor claim, RA diagnosis (ICD-9: 714.0), at least 6 months pre-biologic eligibility and 24-months enrollment post-claim from January 2007–March 2009 were included. Dose-escalation was defined as an increase in bi-weekly dosing from 40 to 80mg for ADA, an increase in weekly dosing from 25 to 50/100mg for ETN, and the addition of 1 vial to the subsequent 8-week maintenance treatment dose, or a reduction in weeks between IFX treatments. RESULTS: A total of 59,928 patients filled a TNF-inhibitor prescription and 3448 were eligible for inclusion in this analysis. Dose-escalation rates were 13% for ADA, 3% for ETN, and 39% for IFX. Additionally, 6% of patients initiated on 25mg ETN experienced dose-escalation versus baseline. Switching to another biologic occurred in 14% (ETN), 16% (ADA) and 17% (IFX). CONCLUSIONS: These “real-life” data confirm dose-escalation occurs in clinical practice. Further analyses including all anti-TNF approvals should be performed to further elucidate the clinical and cost implications for physicians and payers. A limitation of this study is lack of standardized methodology for calculating anti-TNF doses from claims data. Previous studies used standardized dose-escalation rates for ETN (1-17%), ADA (0-12%) and IFX (30-53%). In this study, cut-points were based on current standards of care correlated with frequency distributions within a closed system, ensuring resulting dose-escalation rates are clinically representative.

HEALTH CARE UTILIZATION AND PATIENT FINANCIAL BURDEN ANALYSIS OF NEWLY DIAGNOSED FIBROMYALGIA (FMS) PATIENTS

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OBJECTIVES: FMS is a chronic disease characterized by widespread pain and can impose substantial economic burden. This study estimates the annualized differences in healthcare costs associated with improvement in FM severity among pregabalin-treated patients. METHODS: Data from 3 similarly designed, 3-month placebo-controlled, clinical trials of pregabalin in FM patients were modeled. Expiration of efficacy results was based on a 1-year open-label study. Mean annual costs (direct and indirect) were assigned based on FM severity levels (mild: $10,219; moderate: $26,217; severe: $42,456) and were derived from the US Fibromyalgia Burden of Illness Study. FM severity levels were defined using established classification criteria. Mean annualized direct costs at endpoint were estimated for all patients within each cohort and the mean differences in costs were compared between cohorts using a regression model. RESULTS: Relative to placebo, the proportion of mild subjects at endpoint was significantly lower; 83% with high pregabalin 450mg and significantly lower for severe subjects: Mean total costs were lower with pregabalin (300mg, $25,721; 450mg, $24,103) than placebo ($26,162). Relative to placebo, the difference in mean annual costs was $2059 lower for pregabalin 450mg (P=0.003) and $441 lower for pregabalin 300mg (P=0.029). Costs were higher with pregabalin (300mg, $41,913; 450mg, $4820) than placebo ($4,364). Relative to placebo, the difference in mean annual direct costs for pregabalin 450mg was significantly lower by $2,429 (P=0.001), and for pregabalin 300mg was lower by $951 (P=0.012). CONCLUSIONS: Improvements in FM severity are associated with overall reductions in costs that may offset the costs of treatment with pregabalin.

BURST OF RHEUMATOID ARTHRITIS DISEASE FLARES

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OBJECTIVES: To assess the impact of disease flares of clinical outcomes, health status, and work productivity loss among patients with RA. METHODS: Data were collected from individuals aged ≥18 and reporting an RA diagnosis through a cross-sectional, self-administered, Internet-based questionnaire. Frequency of disease flares were categorized as: no flares (reference group), <1 per month, 1 per month, 1 per 2 months, 1 per 3 months, 1 per 4 months, and ≥1 per month. Patient demographics and comorbidities were adjusted using linear regression and negative binomial regression as appropriate. RESULTS: Of 2,135 patients, 47.4% (n=1,011) experienced a disease flare in the past six months and 52.7% (n=1,124) experienced no flares. Greater frequency of flares was significantly associated with greater functional disability (ADL), poorer health status (SF-36 physical component summary: b=−0.56, p<0.001), fatigue, and pain; poorer physical and mental health status; greater lost work productivity and activity impairment. Specifically, daily flares were associated with greater functional disability (ADL), greater severity of morning stiffness, fatigue, and pain; poorer physical and mental health status; greater lost work productivity and activity impairment. Daily flares were associated with greater functional disability (ADL), greater severity of morning stiffness, fatigue, and pain; poorer physical and mental health status; greater lost work productivity and activity impairment.