Burden of Illness, Costs and Outcomes of Rheumatoid Arthritis in Hungary

Póter S\textsuperscript{1}, Kobsa G\textsuperscript{2}, Szeleczek Z\textsuperscript{2}, Poóró G\textsuperscript{1}, Czirják L\textsuperscript{1}, Rojkovivi B\textsuperscript{1}, Genti G\textsuperscript{1}, Polgár A\textsuperscript{1}, Kiss CG\textsuperscript{1}, Lepp-Gazdag A\textsuperscript{3}, Brodzsky V\textsuperscript{1}, Mäjer I\textsuperscript{3}, Guláš L\textsuperscript{3}

\textsuperscript{1}Flóri Ferenc County Hospital, Kistarcsa, Hungary; \textsuperscript{2}European Health Economics, Speracedes, France; \textsuperscript{3}University of Debrecen Medical and Health Sciences Center, Debrecen, Hungary; \textsuperscript{4}National Institute of Rheumatology and Physiotherapy, Budapest, Hungary; \textsuperscript{5}Hungarian Brothers of St. John of God and University of Pécs, Pécs, Hungary; \textsuperscript{6}Policlinic of the Hospital Brothers of St. John of God, Budapest, Hungary; \textsuperscript{7}National Medical Center, Budapest, Hungary; \textsuperscript{8}Corvinus University of Budapest, Budapest, Hungary

Several cost-effectiveness studies have shown that the innovative highly effective, but costly new biological therapies are within acceptable ranges in rheumatoid arthritis (RA). The transferability of international results is limited. Country-specific data, standardised methodologies are needed to study the adaptability of cost-effectiveness models and to obtain comparable economic evaluations. OBJECTIVES: The aim of our study was to assess the burden and costs of the Hungarian RA population for the purpose of further cost-effectiveness studies and modeling of biological therapies. METHODS: A cross sectional questionnaire survey was performed in 2004 in 6 rheumatology centres focusing on clinical characteristics, resource utilisation, EQ-5D and HAQ were also used. A systematic search was performed in the National Health Insurance Found database. RESULTS: A total of 255 consecutive RA out-patients involved, mean age 55.3 years, females 86%, disease duration 9.12 years, HAQ 1.38, DAS28 5.09, EQ-5D 0.46, DMARD therapy 87.9%, steroids 48%. Progression in HAQ correlates with utility (EQ-5D: 0.78–0.19). Costs: 55% indirect costs (early retirement: 49%), direct medical costs 28% (hospital admissions 11%); direct medical costs 17% (informal care givers 15%). In 2000, 117,336 out-patient visits occurred with RA diagnosis. A total of 5089 patients were hospitalized because of RA (63,528 bed-days, mean duration 12.4 days), leading to about €1,340,000 consumption of reimbursement. CONCLUSIONS: Our study investigated Hungarian RA patients’ characteristics, health-care consumption and burden of illness. The questionnaire survey included patients with characteristics of target patients for biological therapy. Health status utility decrease and costs increase consistently with functional disability progression, early retirement and informal care have major impact. Biological therapies are not reimbursed yet in Hungary though arthritis centres network and guidelines has been established. Our study offers standardized data for economic analysis focusing on the adaptability of international cost-effectiveness studies and models of biological therapies in the Hungarian context.

Criteria-Based Interpretation of SF-36

Improvements from Adalimumab Plus Methotrexate (MTX) Combination Therapy vs. MTX Alone in Early Rheumatoid Arthritis (RA)

Cifaldi M\textsuperscript{1}, Sterz R\textsuperscript{2}, Dietz B\textsuperscript{2}, Chmiele J\textsuperscript{1}, Spencer-Green GT\textsuperscript{3}

\textsuperscript{1}Abbott Laboratories, Abbott Park, IL, USA; \textsuperscript{2}Abbott GmbH and Co KG, Ludwigshafen, Germany; \textsuperscript{3}Abbott Laboratories, Parsippany, NJ, USA

OBJECTIVES: To assess the ability of adalimumab + MTX to improve health-related quality of life (HRQOL) in early RA and interpret the results. METHODS: PREMIER was a 2-year study of MTX-naive, adult patients with early RA (<3 years) who...
Mean baseline PCS for the adalimumab + MTX monotherapy group at Week 12 had a difference of 0.18 for HUI3, and 8.54 for FACIT-F (both p < 0.0001). Based on criteria-based interpretation of the SF-36, differences in PCS scores between the 2 groups indicate patients on MTX alone had an increased likelihood of using more health resources and not being able to work. CONCLUSIONS: Adalimumab + MTX were superior to MTX alone in providing significant and clinically meaningful improvements in HRQOL in early RA. Significantly lower PCS at 2 years in the MTX group may mean patients on MTX alone have greater health care utilization and substantially greater job loss than patients on combination therapy.

**EFFECTS OF LONG-TERM ADALIMUMAB THERAPY ON HEALTH UTILITY AND FATIGUE IN PATIENTS WITH LONG-STANDING, SEVERE RHEUMATOID ARTHRITIS (RA)—RESULTS FROM A 3-YEAR FOLLOW-UP STUDY**

Mittendorf T, Sterz R, Von der Schuleenburg J, Kupper H, Cifaldi M, Dietz B

1University of Hannover; Hannover, Germany; 2Abbott GmbH and Co KG, Ludwigshafen, Germany; 3Abbott Laboratories, Abbott Park, IL, USA

OBJECTIVES: To investigate the ability of adalimumab therapy to provide simultaneous, sustained long-term improvement in two important patient-reported outcomes (health utility and fatigue) in patients with severe RA who had failed at least one DMARD. METHODS: The Health Utilities Index Mark 3 (HUI3) and Fatigue (FACIT-F, validated in RA) were simultaneously measured in a health economics companion trial to an adalimumab pivotal study (DE011). For the first 26 weeks patients were followed under double-blind, randomized conditions before rolling over into a long-term, open-label extension (OLE) (n = 99). A subset of patients receiving adalimumab 40 mg every other week was evaluated for up to 170 weeks. The HUI3 scale is 0–1, with “1” denoting perfect health and “0” denoting death. FACIT-F scores range from 0–52, with higher scores indicating greater fatigue.

CONCLUSIONS: Adalimumab provided clinically important, simultaneous improvements in health utility and fatigue in patients with severe, active RA who had failed at least one DMARD. These improvements were sustained over the 3-year observation period.

**ASTHMA**

**COMPARISON OF TREATMENT WITH Budesonide/Formoterol (BUD/FM) plus BUD/FM PRN AS SINGLE INHALER TREATMENT VERSUS REGULAR BUD AND FM PLUS FM PRN AS MONOPRODUCTS IN PATIENTS WITH ASTHMA IN GREECE**

Papageorgiou M, Loukides S, Gaga M, Zervas L, Christodouloupolou A, Georgatou N

1AstraZeneca SA, Athens, Athens, Greece; 2401 Military Hospital, Athens, Athens, Greece; 3Sotira Hospital, Athens, Athens, Greece

OBJECTIVE: To compare the efficacy of regular treatment with BUD/FM plus BUD/FM prn versus regular treatment with budesonide (BUD) and formoterol (FM) plus FM prn in the treatment of asthmatic patients in Greece. METHODS: Moderate asthmatic (mean FEV1 76% pred.) patients were recruited from 14 centers in Greece to participate in an open-label, randomized prospective clinical trial. The duration of the study was seven months with four scheduled visits: baseline, first month, third month and seventh month. Patients were randomized in 3 groups: Group A: BUD/FM 160/4.5Î¼g bid plus BUD/FM prn and Group B: BUD 200Î¼g and FM 9Î¼g bid plus FM prn. Outcome measures included lung function, number of exacerbations and relief inhalations, symptom control using the Asthma Control Questionnaire (ACQ) and quality of life using the Asthma Quality of Life Questionnaire (AQLQ). In addition, the use of health services and side effects were recorded. RESULTS: A total of 133 patients were recruited, 68 in Group A, and 65 in Group B. Both groups showed a significant improvement in ACQ at the end of the study (p < 0.0001). Relief inhalations were significantly less in Group A (p < 0.0001) during the last study period, between 3rd and 7th month. No statistically significant differences were found in the other outcome measures. CONCLUSIONS: BUD/FM therapy plus BUD/FM as needed demonstrated similar effectiveness in asthma control and quality of life compared to treatment with BUD and FM plus FM as needed. Since fewer relief inhalations were recorded in Group A, BUD/FM plus BUD/FM prn treatment seems preferable for patients with asthma.