

**Methods:** This was a 24-week, randomized, double-blind, placebo-controlled, Phase III study conducted in Korea that compared adalimumab + MTX vs. placebo + MTX. The primary efficacy endpoint was ACR20 response at Week 24. Secondary endpoints included ACR50/70 and individual components of ACR response criteria. Beginning at Week 18, non-responders [ $<20\%$  reduction in swollen joint count (SJC) and tender joint count (TJC)] were allowed to switch to open-label rescue and receive adalimumab 40 mg sc eow. Rescue-treatment patients were considered non-responders at all subsequent visits for ACR response analyses.

**Results:** A total of 128 RA patients enrolled at six Korean sites. Fifty-one of 65 (78.5%) patients randomized to adalimumab + MTX and 40 of 63 (63.5%) patients randomized to placebo + MTX completed the double-blind treatment period. Eight of 65 (12.3%) adalimumab patients and 19 of 63 (30.2%) placebo patients completed the double-blind period on rescue treatment. Baseline disease characteristics were comparable between groups and representative of moderate-to-severe RA. The ACR response rate at Week 24 was significantly higher in adalimumab patients than in placebo patients: ACR20 (61.5% vs. 36.5%;  $p < 0.01$ ), ACR50 (43.1% vs. 14.3%;  $p < 0.001$ ) and ACR70 (21.5% vs. 7.9%;  $p < 0.05$ ). Significant improvement was also observed in SJC ( $-9.4$  vs.  $-5.2$ ;  $p \leq 0.001$ ), Physician's Global Assessment ( $-33.9$  vs.  $-21.8$ ;  $p < 0.05$ ), Disability Index of the KHAQ ( $-0.6$  vs.  $-0.3$ ;  $p < 0.05$ ), and CRP concentrations ( $-1.5$  vs.  $-0.5$ ;  $p < 0.05$ ). Greater adalimumab patient improvements were seen at Week 24 vs. placebo in all ACR components (last-observation carried forward) ( $p < 0.05$ ). Adalimumab patients reported a higher rate of no morning stiffness vs. placebo (38.5% vs. 17.5%,  $p < 0.05$ ). Adalimumab was generally well-tolerated, and there were no relevant clinical differences between the two groups in incidences of adverse events (AEs), including severe AEs and related AEs (as judged by the investigator).

**Conclusions:** Adalimumab with concomitant methotrexate showed consistent efficacy in reducing the signs and symptoms of RA in Korean patients vs. placebo + MTX. Adalimumab was generally well-tolerated for up to 24 weeks. Treatment of Korean RA patients with adalimumab has a favorable benefit-risk ratio.

Abstract Number: P393

## Thyroid dysfunction in rheumatoid arthritis (RA) patients in south of Iran

Mohammad S. SARAI, Karim MOWLA

*Internal Medicine, Ahwaz University of Medical Sciences, Iran*

**Objective:** This study about thyroid dysfunction and rheumatoid arthritis (RA) activity. According to this matter that RA influence multi-system of body, we decided to study (consider) relationship between thyroid dysfunction and rheumatoid arthritis patients.

**Material and methods:** This study is accomplished by method of cross sectional retrospective in 350 RA patients. Patients were between 20–70 years. From 350 patients, 35 cases (10 percent) had thyroid dysfunction which 4.3 percent were hyperthyroidism, 3.7 percent were hypothyroid and 0.9 percent were subclinical hypothyroidism and 1.1 percent hyperthyroidism.

**Results:** From 35 patients who had thyroid dysfunction, 74.3 percent were in active phase of RA which 68 percent of them had positive RF. Also 98.3 percent of these patients were female and others were male.

There was meaningful relationship between thyroid dysfunction and RA activity ( $p > 0.050$ ). There was not meaningful relationship between just polyarthritis problem and thyroid dysfunction ( $p > 0.895$ ).

Also there was meaningful relationship between increasing RF and thyroid dysfunction ( $p < 0.05$ ).

**Conclusions:** In this study there was relation between thyroid dysfunction and RA activity. Thyroid dysfunction is more in female than in male. It is better to request thyroid function tests for all RA patients especially in active phase.

Abstract Number: P394

## The burden of informal caregivers for people with rheumatoid arthritis in Egypt and the Netherlands

Tarek M. EL-MANSOURY,<sup>1</sup> Erik TAAL,<sup>2</sup>  
Robert P. RIEMSMA,<sup>3</sup> Ahmed ABDEL NASSER,<sup>1</sup>  
Johannes J. RASKER<sup>2</sup>

*<sup>1</sup>Department of Rheumatology and Rehabilitation, El-Minia University Hospital, Egypt, <sup>2</sup>Faculty Behavioural Sciences, Department of Psychology and Health, University of Twente, The Netherlands*

**Objectives:** To study the burden as experienced by informal caregivers for people with Rheumatoid Arthritis (RA) in Egypt and the Netherlands and to determine which factors are related to this burden.

**Methods:** A total of 99 Dutch and 30 Egyptian females with RA and their caregivers participated in the study. Data were collected by means of questionnaires including the amount of help provided, mental health and subjective burden as experienced by the caregiver, patient demographic and health status, social support, self-efficacy expectations and caregiver characteristics.

Differences between Egypt and the Netherlands were analysed with ANCOVA, controlled for age and disease duration. Variables related to subjective burden and mental health were analyzed by multiple regression.

**Results:** The objective burden as measured in the hours spent on helping the patients was less in Egypt (24 hours) compared to the Netherlands (35 hours). But the number of ADL tasks performed by the caregiver was higher in Egypt (4.3 vs 2.4). Subjective burden of the Egyptian caregivers was higher (32.4 vs 14.2) and their mental health was worse (61.5 vs 78.6) than those of the Dutch caregivers.

In Egypt 34% of the subjective burden of caregivers could be explained by negative attitude towards help ( $\beta = -0.47$ ), worse affect ( $\beta = 0.31$ ), and the fact that the caregivers felt that the patients were heavily dependent upon them ( $\beta = 0.26$ ). Whereas, in the Netherlands 27% could be explained by negative attitude towards help ( $\beta = -0.45$ ), the fact that the caregivers felt that the patients were heavily dependant upon them ( $\beta = 0.30$ ), and higher patient income ( $\beta = 0.27$ ). Poor mental health among Egyptian caregivers could for 33% be explained by higher level of education ( $\beta = -0.47$ ), and more pain ( $\beta = -0.47$ ) of patients. Among the Dutch caregivers 45% could be explained by positive attitude towards help ( $\beta = -0.53$ ), less negative social support for patients ( $\beta = -0.34$ ), high self efficacy of caregivers for giving help ( $\beta = 0.27$ ), and good physical health of the caregivers ( $\beta = 0.19$ ).

**Conclusion:** Egyptian caregivers for RA patients have higher subjective burden than the Dutch and worse mental health. In both countries

negative attitude towards help and high caregiver estimation of dependency of their care-receivers were consistent variables for predicting subjective burden. In Egypt patient variables are the most important variables in predicting poor mental health of the caregivers whereas in the Netherlands caregiver variables are.

Abstract Number: P395

### Value of glucose-6-phosphate isomerase in the diagnosis of rheumatoid arthritis

Tiehan ZHANG,<sup>1</sup> Yongxin ZHAO,<sup>1</sup> Wei WANG,<sup>1</sup> Caiqing XU,<sup>2</sup> Dongxia WANG<sup>1</sup>

*Department of Clinical Laboratory in the Third Affiliated Hospital of Xinxiang Medical College, China*

**Objective:** To investigate glucose-6-phosphate Isomerase (GPI) in the diagnosis of rheumatoid arthritis (RA) and compare the relativity of GPI with anti-cyclic citrullinated peptide (CCP) antibody, anti-keratin antibody (AKA) and rheumatoid factor (RF).

**Methods:** Serum samples from 96 RA patients and 172 normal control subjects were tested by enzyme-linked immunosorbent assay (ELISA), indirect immunofluorescence and turbidimetry.

**Results:** The sensitivity and specificity of GPI in the 96 RA patients were 51.0% and 96.7% respectively, there was significant difference between test group and control group ( $P < 0.05$ ). The Cross positive rate of GPI with anti-CCP, AKA, RF were 95%, 35.2%, 43.4% respectively. It was demonstrated that there was a relativity between GPI and anti-CCP, AKA, RF.

**Conclusions:** GPI assay has high sensitivity and good specificity and might be used as a valuable index in the diagnosis of RA.

Abstract Number: P396

### Primary and secondary endpoints of autoimmune diseases by treatment with step-down bridge combination of 4–5 immunosuppressants

Tran Thi Minh HOA, An Ngoc TRAN

*Rheumatology Department, Bachmai Hospital, Vietnam*

**Objective:** To assess the efficacy of treatment of lupus systemic erythematosus, rheumatoid arthritis and ankylosing spondylitis patients with long term treatment with combination of 4–5 immunosuppressants.

**Methods:** Ten systemic lupus erythematosus (SLE), 6 rheumatoid arthritis (RA) and 1 ankylosing spondylitis (AS) patients who were refractory to conventional therapy were treated with combination of 4–5 immunosuppressants at Rheumatology Department Bachmai Hospital, Hanoi, Vietnam from February 2004 to February 2006. The therapy were consisting of:

1. Methyl Prednisolon 125 mg IV daily for 3 days, then step down 50% dose in the first 2–4 weeks and tapered gradually 5–10 mg per every 2 weeks later.
2. Cyclophosphamid 50 mg per day.
3. Methotrexate 7.5 mg–10 mg per week.
4. Chloroquine 0.25 g per day.

A182

5. Mycophenolate Mofetil (Cellcept or Myfotic): 250–500 mg per day.
6. Salazopyrine 1–2 g per day.

The baseline and follow-up clinical and laboratory data were collected on the first day, at 1 month, and subsequently every 6 months.

**Results:** 1. All 10 SLE patients were female with the age of  $26.6 \pm 8.2$  years (range 22–43). The disease duration was  $2.2 \pm 1.2$  years (range 8 months to 3 years). To date, 7 cases have received 24 months duration of the treatment with 4–5 combination of immunosuppressants. Good response was observed in 7 patients whose SLEDAI, routine blood test, urine tests, and renal function were all improved. No significant side effect was found.

2. Six RA patient (5 female and 1 men) with the age of  $42.5 \pm 6.8$  years (range 36–53). The disease duration was  $3.5 \pm 2.4$  years (range 2 years to 5 years). All patients have received 5 combination of immunosuppressants in 24 months with achievement of ACR 20 in 75% and remission in 80% from baseline.

3. One AS patient with uveitis who has received 4 combination immunosuppressant in 20 months with excellent improved eyes vision and joints function.

**Conclusion:** The long term combination treatment of 4–5 immunosuppressants drugs have good response in SLE, RA and AS patients who were refractory to conventional therapy.

Abstract Number: P398

### Fingers and wrists osteoporosis in early rheumatoid arthritis

W. HONG, G. JIE-SHENG, L. FEN, T. JING, X. XI

*Department of Rheumatology, The Second Xiangya Hospital, Central South University, China*

**Objective:** To evaluate the clinical importance of metacarpophalangeal, proximal interphalangeal and wrists joints (MPIWJ) osteoporosis as a threshold for early diagnosing rheumatoid arthritis (RA).

**Methods:** 167 polyarthritis patients, of which 155 patients presented with MPIWJ osteoporosis proved by x-ray, were taken into the study. 110 patients, all of whom had MPIWJ osteoporosis, fulfilled the 1987 ACR criteria for RA and were given combination treatment with disease-modifying antirheumatic drugs (DMARDs), accompanied by calcitriol (group 1) or not (group 2). The rest 57 patients, who failed the ACR criteria for RA, were investigated by magnetic resonance image (MRI) for further diagnosis.

**Results:** 1. According to MRI detecting bone erosions and synovitis in MPIWJ areas, 47 of the 57 patients were further diagnosed as rheumatoid arthritis, including all of the 20 (100%) patients who had MPIWJ osteoporosis and elevated ESR and CRP level, 4 of the 12 (33.3%) patients who had no MPIWJ osteoporosis but elevated ESR and CRP level, and 11 of the 15 patients (73.3%) who had MPIWJ osteoporosis but no elevated ESR and CRP level. 2. Treatment with DMARDs combination and calcitriol showed significantly more benefits than that with DMARDs only.

**Conclusion:** Fingers and wrists osteoporosis (MPIWJ osteoporosis) proved to be a highly useful marker for early RA diagnosis, which was confirmed by MRI. It may also be a useful tool for identifying patients at high risk of developing progressive RA. Further studies are needed to evaluate the role of hand bone loss in RA as effective prognostic factor and outcome measure.