prospectively. An independent Gastrointestinal Events Committee (GEC) reviewed all data in a blinded fashion. Events were categorised as UGI ulcer complications (perforations, gastric outlet obstruction, bleeding) or symptomatic UGI ulcerations (pre-defined as in CLASS). A total of 144 cases were reviewed and adjudicated by the GEC.

Results See Table 1.

Abstract THU0182 Table 1

	Celecoxib N = 8800	NSAIDs N = 4934	Odds Ratio	95% CI
Exposure (pt-yr)	1721.2	857.9		
Ulcer Complications (annualised rate)	2/1721.2 (0.1%)	7/857.9 (0.8%)*	7.02	1.46-33.80
Ulcer Complications + Symptomatic Ulcers (annualised rate)	18/1721.2 (1.0%)	21/857.9 (2.1%)*	2.01	1.04-3.86

*p < 0.05 vs celecoxib.

Conclusion These data confirm CLASS results that celecoxib is associated with significantly fewer ulcer complications and symptomatic UGI ulcerations than conventional NSAIDs. The differences in event rates between SUCCESS and CLASS may relate to regional differences in surveillance or clinical practice.

Sponsored by Pharmacia Corporation and Pfizer, Inc.

THU0183 SIGNIFICANTLY IMPROVED UPPER GASTROINTESTINAL (UGI) TOLERABILITY WITH CELECOXIB, A COX-2 SPECIFIC INHIBITOR, COMPARED WITH CONVENTIONAL NSAIDS. THE SUCCESS I TRIAL

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Background The Celecoxib Long-term Arthritis Safety Study (CLASS), a prospective outcomes study conducted in North America, demonstrated a significant reduction in UGI ulcer complications and improved tolerability.

Objectives To extend our understanding of the UGI safety advantages of celecoxib over conventional nonsteroidal anti-inflammatory drugs (NSAIDs), in day-to-day practice, a naturalistic study was conducted worldwide.

Methods SUCCESS I, a large, 12-week, multinational, double-blind, randomised trial in 13,274 osteoarthritis patients, was conducted in 39 countries. There were 6547 patients from Europe/Africa, 2756 from North America, 2889 from Latin America, and 1082 from Asia/Pacific. Celecoxib 200 mg/d (n = 4421) and 400 mg/d (n = 4429) was compared with naproxen 1000 mg/d (n = 914) and diclofenac 100 mg/d (n = 3510) with regard to GI tolerability.

Results The frequency of all reported GI adverse events (AEs), the three most frequently reported UGI AEs, and withdrawals due to GI AEs are shown in the Table 1.

Abstract THU0183 Table 1

NSAIDs (N = 4394)	Celecoxib (N = 8800)	% Reduction	p Value
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All GI AEs	21.0%	16.7%	20.4%	<0.001
UGI AEs	15.6%	11.9%	23.7%	<0.001
Abdominal pain	6.2%	4.8%	22.5%	<0.001
Dyspepsia	5.9%	4.8%	18.6%	<0.008
Nausea	3.4%	2.4%	29.4%	<0.001
Withdrawals due to GI AE	6.8%	5.2%	23.5%	<0.001

Conclusion UGI symptoms, more commonly associated with NSAID use, were consistently and significantly lower with celecoxib. The percent reduction ranged from 18.6% to 29.4%. These data confirm the superior GI tolerability of celecoxib vs conventional NSAIDs and establish that this difference is clinically meaningful in terms of discontinuation of therapy for such symptoms. Sponsored by Pharmacia Corporation and Pfizer, Inc.

THU0184 POLYMORPHONUCLEAR CELL COUNTS (PMN) EFFECTIVELY PREDICT MORTALITY IN RHEUMATOID ARTHRITIS (RA) PATIENTS FOLLOWED FOR UP TO 20 YEARS

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Background Mortality is increased in rheumatoid arthritis (RA), and this increase is related to disease severity markers, disease activity and psychosocial factors. It has been previously reported that white cell counts (WBC) predict total joint replacement in RA,¹ and WBC levels are associated with cardiovascular mortality in non-RA populations.² The effect of WBC, especially PMN, on mortality has not been studied in RA, but might be clinically important.

Objectives To investigate the relation between PMN and mortality in RA.

Methods During a 20-year period ending in 2000, 1500 consecutive RA patients had 21,581 clinic visits at which 18,850 WBC tests were performed. 544 patients died. The predictability for mortality of PMN and other variables obtained 1) during the first 2 years of follow-up and 2) over the entire course of RA was examined using Cox regression models (Cox). To assess the impact of covariates on the predictability of PMN, we controlled for RF, ESR, age, disease duration, sex, HAQ, and prednisone use in multivariate Cox models. Generalised estimating equations (GEE) were used to describe the relation of PMN to other variables.

Results The mean (SD) of WBC and PMN was 8.0 (2.8) and 6.0 (2.5), respectively. Total PMN but not lymphocyte counts predicted mortality (p < 0.05 and p = 0.522, respectively). The mean PMN values in its quartiles were 3.5, 4.9, 6.2 and 9.0. Over the entire course of RA the hazard ratios (HR) for mortality compared with Q1 were Q2 1.5 (1.1,1.9), Q3 1.9 (1.4,2.5) and Q4 2.8 (2.2,3.7). By contrast, the HR for rheumatoid factor positivity (RF) was 1.6 (1.3, 2.1). HR for PMN during the 1st 2 years of follow-up were Q2 1.5 (1.1,1.9), Q3 2.0 (1.6, 2.6) and Q4 2.4 (1.8, 3.1). For those in Q1-Q4 during the 1st 2 years, the predicted 25% time to death was 11.7, 8.8, 7.2 and 4.6 years, respectively. To assess the effect of covariates on the predictive ability of PMN, covariates that included RF, ESR, age, disease duration, sex, HAQ, and prednisone use were added to the 2-year and lifetime PH models. PMN remained significant in the multivariate Cox models, and was a stronger predictor of

mortality than RF or ESR. In GEE analyses, the strongest predictor of PMN was, by far, the use of prednisone, with users having 1.8 (1.6, 2.0) thousand cells increase compared to non-users. Weaker predictors of PMN included sex, HAQ, ESR, RF, disease duration, but not age.

Conclusion Total PMN predicts mortality in RA as effectively as RF, and the predictability is robust to duration of disease as well as to fixed and time-dependent disease severity covariates. This simple test appears to have been overlooked, but adds significantly to our ability to predict mortality in RA. Corticosteroids are the strongest influence on PMN among RA patients, and might be an important factor in mortality increase in RA. Treatment related PMN reduction that occurs in clinical trials of biologic agents may be a marker for increased survival, and is a candidate variable for measurement of pharmaco-economic benefit.

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THU0185 RELIABILITY OF RA MRI SCORING

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Background At OMERACT5 recommendations were developed for acquisitions/scoring of MRI synovitis/bone destruction of hand/wrist in RA: OM5 RA MRI Score (Om5 RAMRIS).¹ These were based on results of a multicentre inter-reader agreement studies of two earlier MRI scoring methods, developed at EULAR 1999 and ACR 1999.²

Objectives Determine whether reader calibration, standardisation of imaging protocols and more precise definitions of lesions improved inter-reader agreement of MRI scoring.

Methods MRIs (1.5T, cor and axial T1& T2, FS, iv Gd) of wrist (8)& 2[5 MCPJ(10) scored by experienced readers in 5 centres. Synovitis determined by Gd enhancement in synovial compartment by 2 methods: global score (0[3)(wrist 3 sites, MCPJ 4 sites) and direct measure (mm) of maximal thickness of enhancing tissue (wrist 4 sites, MCPJ 2 sites). Bone erosion (wrist 15 sites, MCPJ 8 sites) was a bone defect with sharp margins, with a cortical break. Bone defect and bone oedema also defined. All measured 0[10 by volume of defect as proportion of assessed bone volume by 10% increments judged on all images.

Results Reliability for most sites for all lesions was good. Poor intraclass correlation coefficients for bone defect (but excellent agreement) were due to predominance of zero scores. Table 1 shows results of summated scores). Om5 RAMRIS performed better than our previous scoring methods.

Abstract THU0185 Table 1

	MCPJ ICC	MCPJ % agree 1 interval	Wrist ICC	Wrist % agree 1 interval
Synovitis Glob	0.77	59	0.71	34
Synovitis mm	0.58	23	0.56	55
BE	0.46	37	0.68	11

BD	0.12	90	0.13	70
BO	0.60	22	0.84	25

Reliability of inter-reader MRI scores.

Conclusion We found Om5 RAMRIS has acceptable inter-reader reliability. Whether it can be further improved and degree to which it's sensitive to change will need to be determined by its performance in longitudinal/intervention studies.

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THU0186 THE EVALUATION OF THE RISK FACTORS FOR GENERALISED OSTEOPOROSIS IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background In patients with rheumatoid arthritis (RA), the frequency of generalised osteoporosis is increased. The factors related to the disease like duration, functional capacity, medical treatment (corticosteroid, nonsteroidal drugs, methotrexate) and disease activation (C-reactive protein, erythrocyte sedimentation rate) are present among the probable factors which increase the risk of generalised osteoporosis such as the general factors like sex, age and menopausal status.

Objectives The effects of the general risk factors and the risk factors related to the disease on the formation of osteoporosis were assessed statistically with the ordinal logistic regression test.

Methods The bone mass of 36 patients with RA (between the ages of 25 – 75 and duration of disease 0,25 – 43 years ? 32 female, 4 male) were evaluated with calcaneal ultrasound.

Results It was estimated that the risk of osteoporosis is increased 7.44 times in patients using nonsteroidal anti-inflammatory drugs (NSAID) compared with those who received no NSAID treatment. (P = 0.05, Odds Ratio = 7.44, 95% Confidence interval = 1 – 55.46)

Conclusion This data has shown us the importance of NSAID treatment in increasing the risk of generalised osteoporosis in RA patients.

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THU0187 QUALITY OF LIFE IN RHEUMATOID ARTHRITIS: ADAPTATION OF RAQOL FOR USE IN TURKEY

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