difference in both groups according to age, presence of rheumatoid factor, values of erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), bacteriuria, presence of erosions in hand and weight. It was found, that patients with proven amyloidosis in AFAB had longer duration of RA (15 years) than patients without amyloidosis (4,5 years). The patients without amyloidosis were more intensively treated with disease-modifying anti-rheumatic drugs (DMARDs) than patients with amyloidosis what was especially distinct in patients with duration of RA at least ten years; simultaneously time of corticosteroid treatment was longer in patients with amyloidosis.

Conclusion The observed frequency of amyloidosis was very high when compared with results from other countries. In our opinion the reason probably lies in fact that RA patients were treated only with corticosteroids instead of intensive use of DMARDs. In addition AFAB gives a possibility to find the early phase of amyloidosis before occurrence of overt clinical symptoms like proteinuria or renal insufficiency.

THU0175 THE CELECOXIB LONG-TERM ARTHRITIS SAFETY STUDY (CLASS): CELECOXIB IS ASSOCIATED WITH LESS RENAL TOXICITY COMPARED TO CONVENTIONAL NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

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Background

Objectives Conventional NSAIDs, which nonselectively inhibit cyclooxygenase (COX)-1 and COX-2, are associated with deleterious effects on renal function such as reductions in glomerular filtration rate and sodium retention. Celecoxib specifically inhibits COX-2. Such specific inhibition raises the possibility that the incidence of renal toxicity vs conventional NSAIDs may be reduced.

Methods In a randomised, double-blind trial with exposures of up to 15 months, 7968 patients with osteoarthritis (OA) (n = 5746) or rheumatoid arthritis (RA) (n = 2183) were randomised to receive supratherapeutic doses of celecoxib (400 mg BID; n = 3,987) vs ordinary therapeutic doses of conventional NSAIDs: ibuprofen (800 mg TID; n = 1996) or diclofenac (75 mg BID; n = 1985).

Results Fewer celecoxib-treated patients experienced renal toxicity compared to patients treated with NSAIDs (see Table 1; *p < 0.05 vs celecoxib, **serum creatinine levels above 2 mg/dL and/or BUN values above 40 mg/dL).

Abstract THU0175 Table 1

	Celecoxib (n = 3987)	Incidence (% of patients) Diclofenac (n = 1985)	Ibuprofen (n = 1986)
Peripheral oedema	3.7	3.5	5.2*
Generalised oedema	0.5	0.6	1.0*
Hypertension (HTN)	2.0	2.0	3.1*
Aggravated HTN	0.8	0.6	1.2
Creatinine and/or BUN elevation**	1.3	2.1*	1.4

Conclusion Celecoxib at supratherapeutic doses was associated with a lower incidence of renal toxicity compared to conventional NSAIDs at ordinary therapeutic doses.

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THU0176 CELECOXIB IS ASSOCIATED WITH SIGNIFICANT ACR50/70 RESPONSES IN RHEUMATOID ARTHRITIS (RA)

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Background

Objectives Celecoxib, a specific cyclooxygenase (COX)-2 inhibitor, has been shown to improve the signs and symptoms of RA. Because of the safety and tolerability of this agent, celecoxib administration is more sustainable, potentially producing long-term decreases in disease activity.

Methods The ability of celecoxib to induce responses at the ACR20, ACR50, and ACR70 levels was determined in a pooled analysis of two placebo- and active-comparator controlled trials. In addition, radiographic data from a long-term open label safety trial were analysed for the effect of celecoxib on radiographic evidence of disease progression using the Sharp score and Sharp count. Dose titration was allowed during this trial.

Results Celecoxib induced significant improvement compared to placebo at the ACR20, ACR50, and ACR70 levels at 12 weeks during the controlled trials (see Table 1 for % of responders, *p < 0.05 vs placebo). Prior to entry to the long-term open label trial, the average changes in the Sharp score and count were 2.76 (95% confidence interval [CI] 0.68–4.84) units/year and 1.15 (95% CI 0.10–2.19) units/year. After entry, the average changes in the Sharp score and count were 1.72 (95% CI 1.04–2.39) units/year and 0.63 (0.40–0.87) units/year, with an average duration of follow-up of approximately 1 year.

Abstract THU0176 Table 1

	Placebo	Celecoxib 100 mg BID	Celecoxib 200 mg BID	Naproxen 500 mg BID
Response Level				
ACR20	26%	34%*	41%*	38%*
ACR50	5%	7%	12%*	11%*
ACR70	1%	1%	3%*	1%

Conclusion Combined with the safety and tolerability data derived from recent studies, these data suggest that celecoxib has the potential to modify disease activity in RA with long-term use in addition to providing symptomatic benefits over shorter durations.

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