**Patients treated with biologics in daily practice differ in treatment response according to their eligibility for the major RCTs**

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**Objective.** To compare the effectiveness of anti-TNF therapy in routine rheumatologic practice with efficacy results found in randomized controlled clinical trials (RCTs) for etanercept (Moreland LW et al. Intern Med 1999; 130:478-486), infliximab (Maini R et al. Lancet 1999; 354:1932-1939), and adalimumab (Weinblatt ME et al. Arthritis Rheum 2003; 48:35-45).

**Methods**. RA patients starting anti-TNF therapy were enrolled into the German biologics register RABBIT between 2001 and December 2004. Baseline characteristics of patients beginning treatment with etanercept, infliximab, or adalimumab were used to stratify these patients according the fulfilment of the inclusion criteria for the corresponding trial. We investigated treatment effectiveness (ACR20/50 responses) after 6 months of treatment.

**Results.** Table 1 shows the characteristics of patients according to their eligibility for the major trials.

| | Eligible | ETA (criteria of Moreland 1999) | INF (criteria of Maini 1999) | ADA (criteria of Weinblatt 2003) |
|---|---|---|---|---|
| n of cases | yes | 149 (23.0%) | 122 (32.8%) | 119 (27.1%) |
| | no | 498 | 250 | 320 |
| Age in years (mean) | yes | 52.2 | 53.8 | 53.9 |
| | no | 53.6 | 52.6 | 54.7 |
| DAS28* (mean) | yes | 6.4 | 6.6 | 6.1 |
| | no | 5.8 | 5.8 | 5.7 |
| Function** (0-100), mean | yes | 62.0 | 57.8 | 64.2 |
| | no | 53.2 | 52.7 | 52.3 |
| n of previous DMARDs | yes | 2.9 | 3.6 | 3.0 |
| | no | 4.0 | 3.8 | 4.2 |

* Disease activity score 28 joints; ** Funktionsfragebogen Hannover, increasing values indicate better function

Less than one third of the patients fulfilled the inclusion criteria of the respective trials. Eligible patients had more active disease, a significantly better functional status and less previous DMARD failures than non-eligible pts.

ACR50 response rates after 6 months were comparable to the respective trials for eligible but lower for non-eligible patients (eligible pts.: ETA 37%, INF 28%, ADA 39%;non-eligible pts.: ETA 25%, INF 22%, ADA 20%).

ACR20 response rates were also higher in eligible pts.: ETA 65%, INF 52%, ADA 60% compared to the non-eligible pts.: ETA 56%, INF 44%, ADA 47%.

**Conclusion.** We found treatment responses comparable to the major trials for eligible and lower responses for non-eligible patients. Non-eligible patients had lower baseline disease activity, more previous DMARD failures, a higher percentage of patients with poor functional status and more severe co-morbidity and therefore a lower a-priori chance of relative improvement. These severely ill patients play an important part in real practice. Even if the expected benefit may be lower than in patients eligible for trials they show considerable improvement and should be offered adequate treatment.

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