Significantly higher chance of 'functional remission' or physical independence in RA patients receiving biologics. Results from the German biologics register

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RABBIT

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Introduction

The German prospective cohort study RABBIT (German acronym for: **r**heumatoid **a**rthritis – o**b**servation of **bi**ologic **t**herapy) was established in May 2001 to investigate the long-term safety, effectiveness and costs of biologic therapies in comparison to conventional DMARD therapy in rheumatoid arthritis (RA).

Objective

To investigate how often significant improvements in function can be achieved.

We compared patients treated in routine care with either biologic or conventional DMARD therapy:

a) How many patients achieve a functional status above 'functional remission'?

b) How many patients of a subgroup that were very disabled at start of the therapy reach a status of physical independence?

Patients and Methods

- RA patients enrolled into the German biologics register RABBIT.
- New prescription of etanercept, adalimumab, infliximab, or anakinra at study entry.
- New prescription of a DMARD after at least two DMARD failures including MTX (control group).

A total of **1,083 patients** who were enrolled between May 2001 and December 2003, **fulfilled the inclusion criteria**. As expected, the patients in the biologics groups had significantly more active disease and more previous DMARD failures (see Tab. 1 at poster FRI0140).

Assessments at baseline, 3, 6 and 12 months

- 28 joint counts of tender (TJC) and swollen joints (SJC)
- CRP, ESR
- treatment (DMARD and/or biologic therapy, glucocorticoids)
- previous treatment failures and treatment terminations during follow up with recording of reasons for terminating
- functional capacity (Funktionsfragebogen Hannover, FFbH). The FFbH measures limitations in activities of daily living. Scores are given in percent of full function (range is 0 to 100) and can be transformed in HAQ values.

Endpoints

- Physical independence at 12 months (FFbH ≥ 67) according to Westhoff et al. (Arthr Care Res 2000; 13:11-21).
- Functional remission at 12 months (FFbH > 83). This cut-off point was derived from data of 12.303 patients recorded in the German rheumatologic database in 2003.

Statistical analysis

- Propensity score methods were applied to adjust for confounding by indication (please see details of variables used at poster FRI0140).
- Multivariate logistic regression was applied to calculate adjusted odds ratios (OR) of functional remission and physical independence.

Functional remission

% of patients with...	Biologics	Controls
... functional status > 83% at baseline	11.6 *	19.9
... functional status > 83% at 12 months	26.7	30.1
... functional status > 83% at 12 months when baseline function was < 67%	13.2	8.3

Tab.1: Improvement of functional status; * difference significant with p<0.001

Characteristics of patients treated with biologics (BIOL) differed significantly from those receiving conventional DMARDs with respect to important predictors of functional improvement e.g. DMARD failures, disease activity, and propensity scores.

Adjusted for these baseline differences we found an **adjusted OR of 2.18** [95% CI: 1.71-8.79] for the achievement of functional remission in BIOL patients compared to the control group.

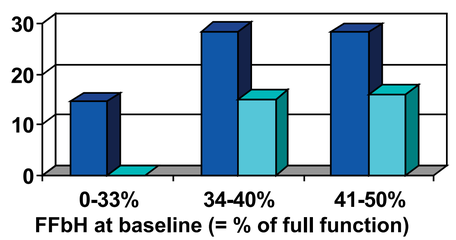
Maintainance of the achieved functional status

The chance to maintain the improved functional status was higher than the chance to maintain clinical remission: most of the severely disabled patients (85.4%) who achieved an FFbH ≥ 67 at 6 months maintained this status as well at 12 months.

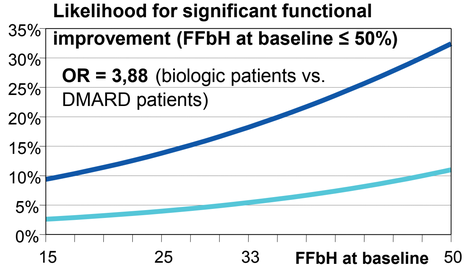
77.2% of the patients who were in functional remission at 6 months achieved this status also at 12 months.

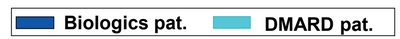
The chance of achieving physical independence for patients severely disabled at baseline is nearly four times higher in patients receiving biologicals (OR = 3,88 [95% CI: 1.71-8.79]):

Percentage of patients achieving physical independence (FFbH ≥ 67) after 12 months grouped by FFbH at baseline:



Likelihood for significant functional improvement (FFbH at baseline ≤ 50%)





At baseline 46% of the biologics patients (n=818) and 33% of the DMARD patients (n=265) were severely disabled.

Conclusion

Anti-TNF agents increase the chance to achieve a status of functional remission or at least physical independence in RA patients treated in routine care.

Especially severely disabled patients who are frequently excluded from randomized controlled trials benefit from treatment with biologics in routine care. We found that in those patients with long-standing disease biologic agents lead to significant improvements mainly regarding the ability to live an independent life.

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