

## Effectiveness of treatment with Rituximab depends on autoantibody status – results from 2 years of experience in the German biologics register RABBIT

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**Purpose:** To investigate the effectiveness of treatment with Rituximab (RTX) over the first six to twelve months in daily rheumatologic care.

**Methods:** The German biologics register RABBIT is a prospective cohort study observing all licensed biologic agents. Since 2006, patients with a first or repeat treatment cycle of RTX have been enrolled. They will be followed up for at least 5 years. Regular assessments include clinical status as well as therapy.

**Results:** Of a total of 661 patients enrolled at start of RTX therapy, 424 patients (78% female) were observed for at least six months. Their median disease duration was 11 years. 16.3% of the patients achieved a EULAR good response, 44.7% a moderate response and 39.0% no response after six months. There was no difference in the proportion of moderate or good responses between patients who received RTX for the first time or a repeat cycle or between patients who received RTX in combination with methotrexate and those on RTX monotherapy.

	Treatment RTX		Rheumat. factor		anti-CCP	
	+ MTX	Monoth.	Neg.	Positive	Neg.	Positive
n	229	120	75	348	82	342
DAS28 month 0	5.5	5.7	5.3	5.6	5.2	5.6
DAS28 month 6	4.5	4.3	4.7	4.3	4.4	4.4
% EULAR response <sup>#</sup>	56.8	64.2	45.3	64.4	54.9	62.6
OR EULAR response <sup>*</sup>	Refer.	1.38	Refer.	2.01	Refer.	1.26
CI 95% of OR		[0.86; 2.21]		[1.2; 3.4]		[0.76; 2.07]

\* odds ratio adjusted for baseline status of DAS28, <sup>#</sup> DAS28 good or moderate response

Rheumatoid factor (RF) positive patients had a significantly better response than seronegative ones (p=0.003). Taking the baseline status into account this difference corresponds to an adjusted odds ratio of 2.0 (95%CI: 1.2 - 3.4). A similar, albeit insignificant, difference was observed for anti-CCP antibodies. Among 265 patients observed for at least 12 months, 180 (68%) had a second cycle of RTX after a mean duration of 8.7 months. After six months, 9% of the patients had already received their second cycle.

**Conclusion:** The data show effectiveness of RTX in a majority of unselected real-life RA patients. The higher improvement in rheumatoid factor and/or anti-CCP antibody positive patients might indicate that B-cell depletions is more effective in autoantibody positive patients.