RA patients treated with Rituximab – routine care data of the German biologics register RABBIT

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Background

With the CD20 antibody rituximab (RTX) a new treatment option in patients with rheumatoid arthritis (RA) has been available in Germany since July 2006. RTX is approved in combination with methotrexate after failure of (at least) one TNF-α blocker.

The German biologics register RABBIT investigates the safety and efficacy of RTX in patients with RA in daily rheumatologic care.

Objective

To describe baseline characteristics and adverse events of RA patients who receive RTX in daily rheumatologic care in Germany.

Patients and Methods

RABBIT is a long-term observational prospective cohort study.
RA patients were enrolled
- since 01/2007
- with a new start of a RTX-cycle.

Once enrolled, patients are followed-up regularly at 3 months and thereafter every 6 months up to at least 5 years of observation. Patients stay in the register irrespectively of any other treatment starts, stops and changes.

More than 300 rheumatologists all over Germany participate in the register.

Results

At the time of the analysis n=482 patients were enrolled with RTX. Their mean observation time was 5.2 (SD = 4.0) months. Median disease duration was 14 years (IQR= 6-18). 78.3% of the patients had erosions on hands or feet.
RTX was administered for the first time in 78% of patients.

	N = 482
Female	78.4%
Mean age (SD)	57.0 (11.7)
CRP , median (IQR)	11 (4 – 30)
RF positive	82.9%
Swollen joint count, mean (SD)	7.9 (5.7)
Tender joint count, mean (SD)	11.0 (7.5)
FFbH, % of full function, mean (SD)	50.5 (22.3)
DAS28, mean (SD)	5.6 (1.2)
Morning stiffness in minutes, mean (SD)	106.0 (95.3)

Table 1. Baseline characteristics of patients receiving RTX

Indication of RTX

In most of the cases RTX was prescribed after 2 treatment failures with biologic agents (SD = 1.3). Median time between stop of last DMARD and start with RTX was 5 months (IQR: 3-5).

Reasons to switch to RTX were high disease activity in 84% of the patients and inefficacy of the biologic therapy in 64% of the patients.
As further reasons adverse events under previous therapy (23%) and a quick radiographic progression (..%) were reported.

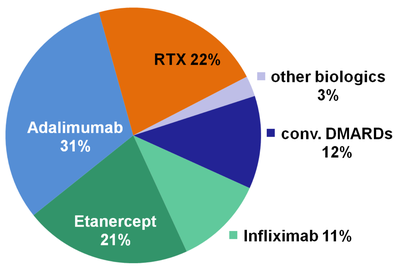

Figure 1.
Last therapy before start of RTX.

Concomitant therapies during RTX treatment

5% (n=24) of patients did not receive any premedication with glucocorticoids. Although RTX is approved in combination with methotrexate only 53% of the patients received this combination.

		n	%	Mean DAS28 at baseline (SD)
RTX	without DMARDs	146	24.9	5.7 (1.1)
	with Methotrexat	254	52.7	5.5 (1.2)
	with Leflunomide	65	13.5	5.5 (1.2)
	with Sulfasalazin	16	3.3	5.2 (1.2)
	with HCQ	21	4.4	5.8 (1.3)
	with TNF-α Blocker	3	0.6	6.8 (1.2)

Table 2. Treatment combinations with RTX

EULAR-Response after 6 months

Follow-up assessment after 6 months was available for 174 patients. Moderate and good DAS28 response were achieved by 38% and 16% of patients respectively (Fig. 2).

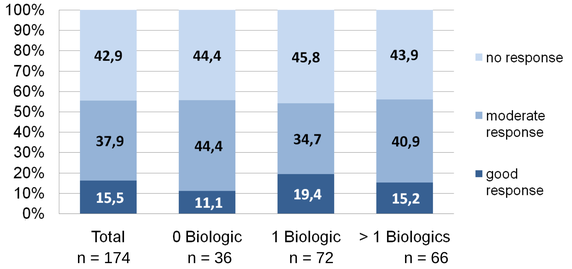

Figure 2. EULAR – Response after 6 months by no. of previous biologics

Response to RTX did not depend on number of previous biologic therapies.

Adverse events

Adverse events during infusion of RTX occured in 27 (5.6%) of the patients. Most frequently nausea and pruritus were reported. At least one serious adverse event occured in 33 (6.8%) of the patients throughout the observation.

	Infections	Cardio-vascular diseases	Diseases of the nervous system	Hemato-logic disorders	Neoplasms
n	5	4	3	1	4
Rate per 1000 ptyrs	24.0	19.2	14.4	4.8	19.2

Tabelle 3. Serious adverse events per 1000 patient years (ptyrs).

Conclusion

These are the first register data of RTX in daily practice in Germany. Rheumatologists prescribe RTX in accordance with current guidelines. The spectrum of AEs corresponds with the observations in clinical trials. EULAR response was independent of the number of previous biologics.

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