Use of a Baseline Risk Score to Identify the Risk of Serious Infectious Events in Patients with Rheumatoid Arthritis During Certolizumab Pegol Treatment

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ADDITIONAL FILE 1

ADDITIONAL METHODS

Testing of RABBIT risk score in the All CZP group

As a sensitivity analysis, the German biologics register (RABBIT) risk score[1] was tested in the All CZP group. Predicted rates of SIEs were based on patients' RABBIT risk scores at baseline, adjusted for duration of CZP exposure. Patients were then stratified into three subgroups, according to the expected SIE risk established by the RABBIT risk score; these three subgroups were similar to the first three deciles of expected risk published in Zink *et al.*[1] The SIE rates predicted by the RABBIT risk score were compared with observed SIE rates.

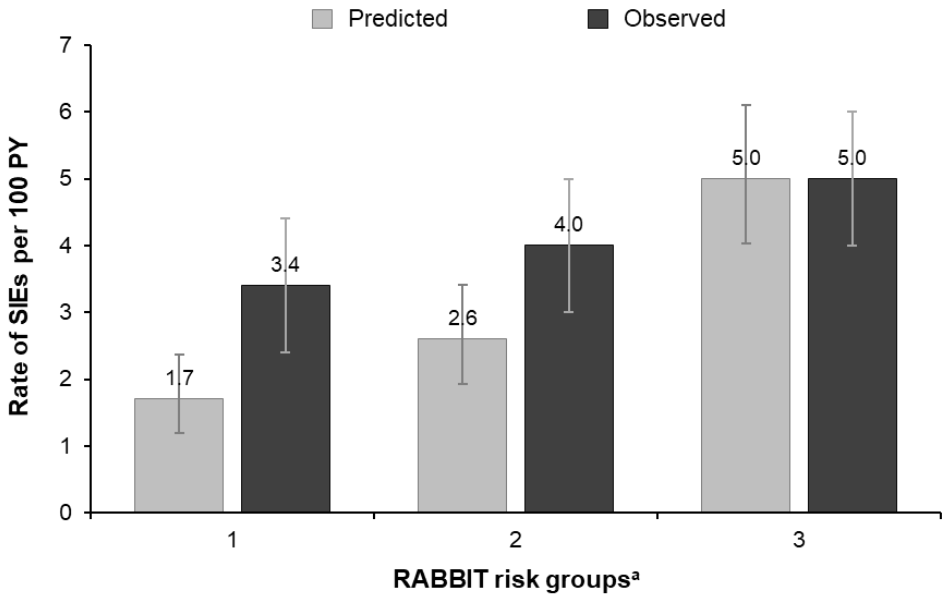
The risk factors included in the calculation of RABBIT risk scores were age >60 years (Yes; No), HAQ-DI, chronic lung disease (Yes; No), mean glucocorticoid dose (7.5–14 mg/day; ≥15 mg/day), and anti-TNF treatment ("Yes" for all patients). The remaining risk factors which feature in the RABBIT risk score were set to zero, either because no patients included in the study population presented those characteristics (chronic renal disease, >5 previous treatment failures), or due to insufficient information (history of prior SIEs). Patients with a history of chronic infection, recent serious or life-threatening infection within 6 months from screening, or with signs or symptoms that may have indicated an infection, were excluded from participating in RAPID1/RAPID2, as were patients with current or recent history of severe, progressive, and/or uncontrolled renal disease.[2, 3]

Additional Table S1. Observed number of SIEs in patients categorized by AACI

	RCT CZP (n=1224; 798.5 PY)		**All CZP (n=1506; 5778.6 PY)**	
	Patients, n	SIEs (n, %)[a]	Patients, n	SIEs (n, %)[a]
AACI=0	429	9 (9, 2%)	530	61 (52, 10%)
AACI=1	545	17 (17, 3%)	681	100 (88, 13%)
AACI=2	39	2 (2, 5%)	45	11 (8, 18%)
AACI=3	150	6 (5, 3%)	179	45 (37, 21%)
AACI=4	13	0	15	8 (5, 33%)
AACI=5	36	4 (4, 11%)	41	6 (6, 15%)
AACI=6	8	2 (2, 25%)	8	2 (2, 25%)
AACI=7	4	1 (1, 25%)	6	3 (3, 50%)
AACI=8	0	0	1	0
AACI≥2	250	15 (14, 6%)	295	75 (61, 21%)

[a]Results are shown as total number of observed SIEs (number of patients affected by SIEs, corresponding percentage among patients with the same AACI score). SIE: serious infectious event; RCT: randomized controlled trial; CZP: certolizumab pegol; PY: patient-years; AACI: age-adjusted comorbidity index

Additional Figure S1. Predicted and observed SIE rates in All CZP patients according to the RABBIT risk score



Predicted rates of SIEs were based on patients' RABBIT risk scores, adjusted for duration of CZP exposure, and were compared to the observed SIE rates; vertical bars correspond to 95% confidence intervals. [a]Patients were stratified into three subgroups, according to the expected SIE risk established by the RABBIT risk score; these three subgroups were similar to the first three deciles of expected risk published by Zink *et al.*[1] SIE: serious infectious event; CZP: certolizumab pegol; RABBIT: Rheumatoide Arthritis Beobachtung der Biologika-Therapie (Rheumatoid Arthritis Observation of Biologic Therapy, the German biologics registry); PY: patient-years.

REFERENCES

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