FRI0123

BIOLOGICAL THERAPIES SURVIVAL IN RHEUMATOID ARTHRITIS PATIENTS IN CLINICAL PRACTICE: RESULTS FROM THE METEOR REGISTRY

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Background: Several biologic disease modifying anti-rheumatic drugs (bDMARDs) are currently available, but comparisons among these different drugs in clinical trials are rare and follow-up duration in trials is often limited. A comparison of these bDMARDs in daily practice can provide clinically relevant knowledge on treatment survival of all currently available bDMARDs.

Objectives: To assess the survival of each and every one of the biological therapies available in patients with rheumatoid arthritis (RA).

Methods: The METEOR registry is a multinational project that includes data on > 40,000 patients with RA from its diagnosis and prospectively, with proven reliability, in clinical practice. Inclusion criteria: patients > 18 years in biological treatment (bDMARD). Variables under study: disease onset date, bDMARD initiation and discontinuation date, bDMARD type (infliximab, certolizumab, adalimumab, golimumab, etanercept, rituximab, tocilizumab and abatacept), concomitant treatment, line of treatment. Clinical variables: TJC, SJC, ESR, CRP, BMI, patient's VAS, and RF and ACPA levels; smoking status. Cox regression analysis that was adjusted for several potential confounders.

Results: From the 47,263 patients registered in the total METEOR database, 11,132 were eligible for inclusion of the current study. Of these, 9,516 had sufficient data available and were included in the analyses. Included patients (n=9,516) less often smoked than non-included patients (n=1,616), but other baseline characteristics were very similar between groups (data not shown). Baseline features of all patients were similar.

Median time on bDMARD as 1st line treatment for each drug is shown in Table 1, infliximab showed the longest median time on treatment. Using infliximab as 'reference' treatment, Table 2 shows abatacept, certolizumab, rituximab and tocilizumab showed higher hazard risk to finish the treatment prematurely, while adalimumab, golimumab or etanercept had similar results than infliximab.

Conclusion: after adjusting by several confounders, analysed data showed that most anti-TNF (infliximab, adalimumab, etanercept and golimumab) had a similar hazard to stop treatment in clinical practice. Other than anti-TNF bDMARD showed higher hazard to switch treatment than infliximab.

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FACTORS ASSOCIATED WITH PERSISTENT DRUG-FREE REMISSION IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Persistent drug-free remission of RA is a condition that is close to 'cure' of the disease. However, long-term drug-free remission is considered to be rare and very challenging to reach. Also, little data are available that report how often persistent drug-free remission can be achieved and what kind of clinical characteristics are associated with such state.

Objectives: To evaluate factors associated with persistent drug-free remission in patients with rheumatoid arthritis

Methods: We analyzed the long-term observational follow-up phase of the randomized controlled RETRO (REduction of Therapy in RA Patients in Ongoing Remission) study on tapering and stopping of DMARDs in RA patients in stable remission (DAS28-ESR <2.6) (1,2). We included patients having completed the 1-year randomized controlled phase of RETRO, in which DMARD treatments were either continued, tapered or stopped. In the long-term extension, (i) patients who successfully stopped, continued DMARD stop, (ii) patients who relapsed in any of the 3 groups continued DMARD treatment, (iii) patients in the continuation arm remaining in remission underwent 50% DMARD tapering followed by stopping after 6 months if still being in remission and (iv) patients in the tapering arm remaining in remission underwent DMARD stop. We assessed the percentage of patients in persistent drug-free remission in the overall population and the three randomization groups, the probability of persistent drug-free remission in the intervention groups compared to controls adjusted by baseline aCCP, erosive changes and use of biologic DMARDs in a logistic regression model and the baseline characteristics associated with reaching persistent drug-free remission.

Results: All 141 patients being in the long-term observational follow-up phase of the RETRO study for at least 1 year were analyzed. Among them DMARDs were initially continued (Control, n=38), tapered (Taper, n=50) or stopped (Taper/Stop n=53). 19/141 patients were lost to follow-up and the worst case scenario was assumed that all of them did not reach persistent drug-free remission. Median time after study entry (Q1-Q3) was 69 (37-96) months as by December 2018. Overall number of patients in drug-free remission was 34/141 (24.1%), 10/38 (26%) in the control group, 6/50 (12%) in the taper group and 18/53 (34%) in the taper/stop group. After adjustment for baseline risk factors in the likelihood to reach persistent drug-free remission between the groups (OR:0.76, 95%CI: 0.29-1.99) was highly uncertain. Positive ACPA (OR: 3.38, 1.01 – 11.31) and erosive-state (3.05, 1.32 – 7.06) at baseline were associated with a lower likelihood to reach persistent drug-free remission.

Conclusion: These data show that persistent drug-free remission can be reached in a subset of RA patients following a structured DMARD tapering approach after being in stable long-term DMARD control.

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FRI0125

INDIVIDUAL PATIENT DATA META-ANALYSIS OF THE EFFECTIVENESS OF TOCILIZUMAB ON INHIBITING RADIOGRAPHIC PROGRESSION IN RHEUMATOID ARTHRITIS

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Background: Several studies have shown that treatment with tocilizumab (TCZ) may reduce radiograph progression compared to treatment with methotrexate (MTX) in rheumatoid arthritis (RA). However, individual studies were not powered to detect differences in the incidence of progression. By combining several studies, a more precise estimate can be

obtained. Furthermore, by using individual patient data (IPD), outcome definitions and methods can be harmonized for a valid combined analysis.

Objectives: To determine the effectiveness of treatment with TCZ on radiographic progression compared to MTX in RA patients over two years.

Methods: Randomized controlled trials in RA patients using TCZ as one of the treatment arms with radiographic damage assessed on radiographs at baseline and after two years were identified and IPD obtained.

The primary endpoint was defined as any radiographic progression over two years. Secondary endpoint was the amount of joint damage progression (points per time unit, expressed as incidence rate). Analyses were performed on total scores and for erosions and joint space narrowing (JSN) separately. TCZ strategies were compared with the control strategies. Within the TCZ strategies, a comparison between monotherapy and the combination with MTX was made.

A two-step IPD meta-analysis was performed. In the first step, data of the individual trials were analysed using logistic regression and zero-inflated Poisson models. In the second step association measures (odds ratio's (OR) and incidence rate ratio's (IRR)) of individual trials were pooled using random effect models in Review Manager¹. A subgroup analysis was performed on early versus established RA. All analyses were adjusted for baseline DAS28 and Sharp van der Heijde (SvdH) score to provide a more precise treatment effect estimate.

Results: Five trials were identified, one trial² using a tight-control treat-to-target approach, and the four other RCTs³⁻⁶ allowed the control group to start TCZ after 6 months or 1 year when the treatment target was not reached. Two trials were performed in early RA¹⁻². The dose of TCZ was tapered down in two studies^{2,6}. IPD of 4 trials could be obtained and were included (n=2439 randomized to TCZ arm and n=791 to control arm, MTX in all cases)²⁻⁵.

The radiographs, performed at baseline and after two years, were all assessed with the SvdH method. Due to missing radiographic data, 1766 patients were evaluated in the TCZ arms and 543 patients in MTX arms. Patient characteristics are shown in Table 1. The occurrence of any radiographic progression was statistically significantly less in the TCZ arms compared to MTX arms (pooled OR 0.76 [95%CI 0.67 to 0.86]). The effect for erosions (OR 0.77 [95%CI 0.67 to 0.88]) was stronger than for JSN (OR 0.88 [95%CI 0.78 to 0.98]) with both being in favour of TCZ. No clear differences between early and established RA were observed for any progression. Any radiographic progression did not occur statistically significantly more often in the TCZ monotherapy group compared to the combination group. No statistically significant difference were observed for the amount of radiographic progression.

Conclusion: Based on this individual patient data meta-analysis, radiographic progression was less common in TCZ-treated patients compared to MTX-treated patients in RCTs, possibly more for progression of erosions. No difference was observed between TCZ used as monotherapy or in combination with MTX.

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Table 1 Patient characteristics per individual trial

Trial	Act-Ray ³ n= 417	Function ⁵ n= 857	Lithe ⁴ n= 803	U-Act-Early ² n= 232
Female, n (%)	345 (83)	677 (79)	667 (83)	161 (69)
Age (years), mean (SD)	52.8 (12.1)	50.0 (13.0)	52.0 (11.9)	53.9 (12.4)
BMI (kg/m ²), mean (SD)	26.2 (5.1)	27.5 (6.2)	27.4 (5.9)	26.0 (4.4)
Duration RA (months), mean (SD)	96 (93)	6 (6)	116 (97)	1 (1)
Baseline DAS28, mean (SD)	6.3 (1.0)	6.7 (1.1)	6.3 (1.3)	5.1 (1.1)
RF positive, n (%)	-	776 (91)	658 (82)	166 (72)
Baseline SvdH score, median (IQR)	29 (17.5-50.5)	1.5 (0.5-5.5)	19.5 (8-44)	0 (0-1)
Baseline Erosion SvdH score, median (IQR)	15.5 (10-24)	1 (0-3.5)	14 (6-26.5)	0 (0-0)
Baseline JSN SvdH score, median (IQR)	13.5 (7-27)	0 (0-1.5)	5.5 (1-16.5)	0 (0-0)
Initial treatment strategies, n (%)				
- MTX monotherapy	-	211 (25)	258 (32)	74 (32)
- TCZ+MTX 8mg/kg	215 (52)	220 (25)	272 (34)	78 (34)
- TCZ+MTX 4mg/kg	-	211 (25)	273 (34)	-
- TCZ monotherapy 8mg/kg	202 (48)	215 (25)	-	80 (34)

n=number of patients, SD= standard deviation, BMI= body mass index, RA= rheumatoid arthritis, DAS28= disease activity score assessing 28 joints, RF= rheumatoid factor, SvdH= Sharp van der Heijde, JSN= joint space narrowing, MTX= methotrexate, TCZ= tocilizumab.

Table 1 Number of patients with any radiographic progression per treatment over 2 years and ratio of any radiographic progression or amount of joint damage between TCZ treatment and MTX treatment over 2 years, pooled outcomes

TCZ vs. MTX	TCZ n/N (%)	MTX n/N (%)	OR (95% CI)	IRR (95% CI)
Total Study	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
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- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Established RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
- Early RA	1873/2439 (77)	242/791 (31)	0.76 (0.67 to 0.86)	0.7