AB0250

REAL-WORLD OUTCOMES IN STABLE ORIGINATOR BIOLOGIC-TREATED ADULT PATIENTS WHO STAYED ON THE THERAPY VERSUS THOSE WHO SWITCHED TO BIOSIMILAR: A RETROSPECTIVE CHART REVIEW STUDY IN EUROPE

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Background: Biologic therapies have considerably improved clinical management of autoimmune diseases. Over the past few years, several biosimilars have been introduced in Europe for these conditions. Limited information is available evaluating the impact of switching stable patients from originators to their respective biosimilars in clinical practice for non-medical reasons.

Objectives: This real-world study reported and compared patient characteristics, clinical outcomes, and healthcare resource utilization (HRU) associated with stable patients who switched from the originator biologic etanercept to its biosimilar (switchers) vs. those who stayed on the originator (non-switchers) in adults with a rheumatic condition such as ankylosing spondylitis (AS), psoriatic arthritis (PsA), or rheumatoid arthritis (RA).

Methods: Medical record data were retrospectively collected anonymously from rheumatologists in the UK and Germany. Adult patients who were diagnosed with RA, AS, or PsA, treated with originator etanercept for at least 6 months with a stable dosing schedule, and had no emergency department visit or hospitalization for the disease of interest over the 6-month period were eligible for the study. The index date for a non-switcher was the prescription date closest to one year after the initiation of originator etanercept and with a stable dosing for at least 6 months. The index date for a switcher was the biosimilar initiation date. Chart data available for at least 12 months prior to and post the index date were required. Patient characteristics, disease severity, symptoms and signs, and HRU were extracted anonymously. Unadjusted and adjusted comparisons of the outcomes between non-switchers and switchers were conducted among all patients and for each individual disease.

Results: Data were extracted from 242 patient records (non-switchers = 123, 50.8%; switchers = 119, 49.2%; AS=26.4%; PsA=26.0%; RA=47.5%) from 162 rheumatologists. At baseline, non-switchers were significantly younger than switchers (44.5 vs. 48.4 years, p<0.05), had a significantly shorter time on the originator etanercept (11.7 vs. 23.8 months), and more patients had been treated with NSAIDS (55.3% vs. 37.8%). Significantly more non-switchers had moderate, or severe disease (27.6% vs 16.0%, p<0.05; 26.8% vs 5.9%, p<0.01) and non-switchers on average had worse joint or spine pain (4.4 vs 2.4, p <0.01) than switchers. During the follow-up period, significantly more non-switchers' disease status improved (58.5% vs. 25.2%. p<0.01), resulting comparable disease severity (moderate: 10.6% vs 10.9%; severe: 0% vs 0%) and joint or spine pain scale (2.0 vs 1.0) between the two cohorts. After adjusting for potential confounding factors, compared to switchers, more AS and PsA non-switchers improved in disease severity (AS: p<0.05; PsA: p<0.01), and RA non-switchers had a fewer number of swollen joints (0.5 vs 1.5, p<0.01). Non-switchers generally had numerically lower HRU than switchers during the one-year follow-up period (patients with outpatient visits: 76.4% vs 89.1%; average number of outpatient visits: 1.8 vs 2.0).

Conclusion: When compared with stable patients who underwent non-medical switching, stable patients who continued therapy with the originator biologic demonstrated significantly more improvement in disease severity. Other outcomes such as HRU appeared more similar between patients who underwent non-medical switching and patients who continued therapy with the originator biologic. The value of biosimilar non-medical switching requires continued evaluation in real-world clinical practice.

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AB0251

ASSESSMENT OF CARDIOVASCULAR RISK IN RHEUMATOID ARTHRITIS AND ITS RELATION WITH LEPTIN AND INTERLEUKIN-6

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Background: In rheumatoid arthritis patients the risk of cardiovascular affection is 2–3 times higher than the general population (Hollan, Meroni et al. 2013), with increased morbidity and mortality(Perles, Sánchez et al. 2013). This is due to increase in the traditional and nontraditional risk factor(Skeoch and Bruce 2015).

Objectives: The aim of this study is to determine the cardiovascular risk in patients with RA using four established CV risk algorithms Framingham Risk Score (FRS), Systematic Coronary Risk Evaluation Score (SCORE], Reynolds Risk Score (RRS), Q II Risk Score and there relation with serum levels of leptin and interleukin-6 (IL-6).

Methods: Sixty seven RA patients were enrolled in this study. The 10-year CVR for RA patients were calculated using FRS, SCORE, RRS and Q II Risk Score. Serum leptin and IL-6 were estimated.

Results: The results showed a significant difference between higher leptin values and disease activity, obesity, positive RF and longer disease duration, On the other hand, we found a significant difference between higher IL-6 values and disease activity, and hypertriglyceridemia.

As regarding correlations of IL-6 and Leptin with different cardiovascular scores, there were no significant correlations with exception of moderate significant correlation between IL-6 and RRS (r= 0.42, *P*< 0.001).

Conclusion: New models of CVD risk prediction incorporating RA specific variables or imaging techniques are needed.

Table 1. Relationship between serum leptin levels and cardiovascular risk factors

Variables	Serum concentrations of leptin (ng/ml)		*P*
	Yes	No	
Age > 40 years	25.25 (2.50- 160)	9.8 (2.7- 116)	0.05
Body mass index> 30 kg/m^2	39.1 (2.50- 160)	18.15 (3- 116)	**0.02**
Diabetes mellitus	28.40 (10.60- 120)	20.30 (2.50- 160)	0.29
Hypertension	28.40 (4- 120)	19.3 (2.50- 160)	0.26
Cholesterol ≥ 200 mg/dl	31.75 (8.60- 98.50)	18.10 (2.50- 160)	0.05
LDL ≥ 130 mg/dl	28.75 (2.70- 98.50)	18.8 (2.50- 160)	0.34
HDL*	28.40 (28.40- 160)	20.30 (2.50- 160)	0.83
Triglyceride≥ 150 mg/dl	30.1 (6.60- 120)	18.8 (2.50- 160)	0.06
DAS-28 ESR > 2.3	31.20 (2.70- 160)	18.8 (2.50- 130)	**0.04**
Duration of illness > 10 year	31.50 (2.70- 130)	17 (2.50- 160)	**0.04**
Positive RF	25.70 (2.70- 160)	18.95 (2.50- 120)	**0.03**

Table 2. Relationship between IL- 6 levels and cardiovascular risk factors

Variables	Serum concentrations of IL- 6		*P*
	> 5 pg/ml (n= 37)	< 5 pg/ml (n= 30)	
Age > 40 years	31 (83.8%)	19 (63.3%)	0.05
Body mass index> 30 kg/m^2	24 (64.9%)	22 (73.3%)	0.31
Diabetes mellitus	4 (10.8%)	3 (10%)	0.61
Hypertension	9 (24.3%)	8 (26.7%)	0.52
Cholesterol ≥ 200 mg/dl	12 (32.4%)	4 (13.3%)	0.06
LDL ≥ 130 mg/dl	9 (24.3%)	5 (16.7%)	0.32
HDL*	12 (32.4%)	13 (43.3%)	0.83
Triglyceride≥ 150 mg/dl	12 (32.4%)	2 (6.7%)	**0.02**
DAS-28 ESR> 2.3	28 (75.7%)	13 (43.3%)	**<0.001**
Duration of illness > 10 year	14 (37.8%)	16 (53.3%)	0.15
Positive RF	18 (48.6%)	18 (60)	0.25

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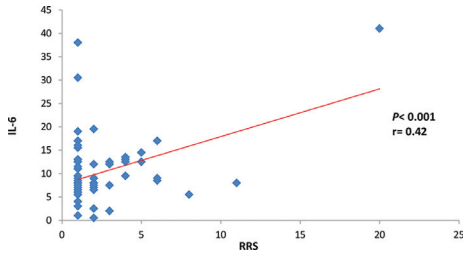

Figure 1. Correlation of RRS with IL-6

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AB0252 RACIAL DISPARITIES IN OUTCOMES FOR PATIENTS WITH RHEUMATOID ARTHRITIS UNDERGOING TOTAL KNEE OR TOTAL HIP ARTHROPLASTY

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Background: Race is linked to delays in healthcare. Black and Hispanic patients with osteoarthritis have worse pain and function than Whites before arthroplasty. Whether Black and Hispanic patients with RA similarly delay care is unknown.
Objectives: To assess whether Black and/or Hispanic (minority) RA patients have worse pain, function and disease activity at the time of arthroplasty.
Methods: We used prospectively acquired data on RA patients between 10/2013 and 11/2018 prior to total knee arthroplasty (TKA) or total hip arthroplasty (THA). Pain, function, and disease activity were assessed using the visual analogue scale (VAS), the Multidimensional Health Assessment Questionnaire (MD HAQ), and the Disease Activity Score (DAS28). Race, ethnicity, education, income, insurance and medications were collected via self-report questionnaire. Multivariable linear and logistic models examined whether minority status predicted pain, function and disease activity.
Results: 37 (23%) of the 164 patients were minorities (Table 1). MD HAQ and DAS28 were worse in minorities, only VAS was significant (p-value= 0.029). There was no significant difference in education. Unadjusted comparisons indicated no difference in pain, function, disease activity or medication use between groups. Insurance varied significantly between groups (p= <0.0001). In the multivariable analyses (Table 2), minority status was not significantly associated with worse function (MD HAQ) [p=0.26], disease activity (DAS28-ESR) [p=0.658], or VAS pain [p=0.18]. Increased age was significantly associated with better function (p=0.004).
Conclusion: For Black and/or Hispanics with RA undergoing THA or TKA at a high-volume specialty hospital, minority status was not significantly associated with pain, disability or RA disease activity at the time of elective arthroplasty.
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Table 1. Cohort

	Overall (N=164)	Minority* (N=37)	Non-minority (N=127)	p-value
Age, years, median [IQR]	62.5 [54.7, 71.2]	56.8 [51.0, 68.8]	64.0 [55.1, 71.5]	0.063
VAS Pain Score, median [IQR]	**6.0 [4.0, 8.0]**	**7.5 [4.0, 8.0]**	**6.0 [4.0, 8.0]**	**0.029**
MD HAQ Score, mean ± SD	11.8 ± 5.3	12.3 ± 5.1	11.6 ± 5.3	0.528
DAS28, mean ± SD	3.8 ± 1.3	4.1 ± 1.3	3.8 ± 1.2	0.181
Sex				
Males	22 (13.41%)	3 (8.11%)	19 (15.08%)	0.412
Education				
Graduated HS	18 (11.76%)	4 (12.90%)	14 (11.48%)	0.762
Some college or above	135 (88.24%)	27 (87.10%)	108 (88.52%)	
Insurance				
Commercial	**54 (33.13%)**	**9 (29.03%)**	**45 (41.28%)**	**<0.001**
Medicare	77 (47.24%)	13 (41.94%)	64 (58.72%)	
Medicaid	9 (5.52%)	9 (29.03%)	0 (0.0%)	
N/A	23 (14.11%)	6 (16.22%)	17 (13.49%)	
Biologics				
Yes	90 (55.56%)	23 (62.16%)	67 (53.60%)	0.452

*Minority status: Black or African American, Hispanic or Mixed.
IQR: Interquartile Range
VAS: Visual Analogue Scale
MD HAQ: Multidimensional Health Assessment Questionnaire
DAS28: Disease Activity Score28
HS: High School

Table 2. Multivariable analysis to determine the risk of DAS28, VAS Pain Score, and MD HAQ Score (Generalized Logistic Model)

	DAS28-ESR Odds ratio (95% CI)	VAS Pain Score β ± SE	MD HAQ Score β ± SE
Minority (Yes)	1.29 (0.41, 4.05)	0.87 ± 0.66	1.44 ± 1.27
Education (Some college +)	**9.57 (2.17, 42.21)**	0.12 ± 0.77	-0.24 ± 1.49
Medicaid*	4.30 (0.28, 66.69)	-0.13 ± 1.37	-2.60 ± 2.66
Medicare*	1.48 (0.49, 4.45)	0.22 ± 0.67	2.31 ± 1.28
Age	0.97 (0.92, 1.02)	0.02 ± 0.03	**-0.17 ± 0.06**
Sex (Female)	2.35 (0.74, 7.49)	0.16 ± 0.70	0.26 ± 1.37
Biologics (Yes)	0.64 (0.27, 1.48)	0.81 ± 0.50	0.13 ± 0.97
MD HAQ Score	**1.09 (1.00, 1.17)**	**0.17 ± 0.05**	

*Ref: Commercial
Significant variables in bold

AB0253 BIOMARKERS OF CLINICAL RESPONSE TO IL6-R BLOCKADE IN DMARDS INCOMPLETE RESPONDERS (AR-BIOM TRIAL): IL23 AND BAFF AS BIOLOGICAL TARGETS, AND ALBUMIN AS BIOLOGICAL PREDICTOR

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Background: The therapeutic algorithm in persistently active Rheumatoid Arthritis, despite conventional synthetic DMARDs(csDMARDs), identifies TNFα blockers and other biologics as first line treatment, without clear indications of which biologic should be adopted first in persistently active patients.
Objectives: In the AR-BIOM trial we analyzed several biomarkers to define which one could help to identify the best responder to IL6-R blockade.
Methods: Sixty-nine RA persistently active despite csDMARDs treatment, were enrolled in this Interventional Phase IV, prospective, multicenter, non-randomized, no-profit study(Clinical Trial:n.2012-001760-30) and followed for 18 months after Tocilizumab(TCZ) treatment monotherapy or in combination with csDMARDs. The study was conducted in 10 outpatient clinics of "Gruppo Italiano di Studio sulle Early Arthritis" network(GISEA Study Group) in Italy. The primary end point was the clinical response to TCZ, as LDA(DAS<2.4) at 12 months follow-up(FU), correlated with Matrix 1 (pathway of Innate inflammation:IL-8,MCP1,Chemerin) vs Matrix 2(Pathway of IL1/IL6/TH17:IL1α,IL1β,IL17,IL23) along with the Pathway of regulatory T cells activity(IL-10,BAFF) and acute phase reactants (Albumin, Fibrinogen,CRP,ESR) as biomarkers of interest. DAS and SDAI remission were secondary end-points at 12 and 18 months FU. A ROC analysis of soluble biomarkers was performed to obtain thresholds allowing the prediction of DAS-remission or LDA at 12 months FU. A multivariate logistic analysis, in which "LDA or DAS/SDAI remission at 12 months FU" were the dependent variables, was performed.
Results: During the 18 months of the study, 9/69 patients(13.0%) discontinued the study because of treatment failure, 2(2.9%) for an AE, 2 for a SAE, and 5(7.2%) for other reasons. At 12 months FU, LDA was achieved in 75.0% and DAS-R and SDAI-R in 63.3% and 41.7%