Table 1. Proportion and 95% confidence interval (CI) of patients who achieved therapy effectiveness and the individual criteria

Effectiveness criteria	DMARD		Biologics		Tofacitinib	
	%	95% CI	%	95% CI	%	95% CI
Non-adherence	75.1	73.5; 76.7	54.5	53.6; 55.3	69.1	59.1; 79.2
Switch/add biologic or tofacitinib	16.1	14.8; 17.5	34.6	33.8; 35.4	18.5	10.1; 27.0
Switch/add DMARD	13.0	11.7; 14.2	16.6	16.0; 17.3	16.0	8.1; 24.0
Increase in dose or frequency	8.6	7.6;9.7	6.9	6.5; 7.3	0	0
Glucocorticoid joint injection	7.8	6.9; 8.9	14.0	13.4; 14.6	9.6	3.4; 16.4
Increase in dose of oral glucocorticoid	19.0	17.6;20.5	17.6	17.0;18.2	22.2	13.2;31.3
Effective therapy (none of the criteria)	15.5	14.2; 16.8	17.9	17.2; 18.5	14.8	7.1; 22.6

References:
[1] Curtis JR et al. Derivation and preliminary validation of an administrative claims-based algorithm for the effectiveness of medications for rheumatoid arthritis. Arthritis Res Ther. 2011;13(5).
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SAT0150 PROSPECTIVE, INTERVENTION, MULTICENTER STUDY OF UTILITY OF BIOLOGIC DRUG MONITORING WITH RESPECT TO THE EFFICACY AND COST OF ADALIMUMAB TAPERING IN PATIENTS WITH RHEUMATIC DISEASES: PRELIMINARY RESULTS OF INGEBIO STUDY

E. Ucar[1], Í. Gorostiza[2], C. Gómez[1], C.E. Pérez[1], J.R. De Dios[3], B. Alvárez[3], A. Ruibal[3], C. Stoye[3], M. Vasques[3], J. Belzunegui[4], A. Escobar[2], Z. Trancho[2], A. Ruiz del Agua[5], A. Martínez[5], C. Jorquera[2], D. Nagore[5]. *[1]Rheumatology; [2]Research Unit, Basurto University Hospital, Bilbao; [3]Rheumatology, Hospital Univeristario Araba, Vitoria; [4]Rheumatology, Donostia University Hospital, San Sebastian; [5]R&D, Progenika-Grifols, Derio, Spain*

Background: Adalimumab (ADL) tapering based on clinical assessment is a usual practice especially in patients who have achieved clinical remission.
Objectives: To analyze how personalized management guided by biological drug monitoring (BDM) in rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS) patients impacts the annual direct costs to the Health System and the quality-adjusted life year with respect to conventional practice in Spain. To evaluate the effectiveness of BDM in the reduction of the number of days with high disease activity compared with conventional practice.
Methods: In a pragmatic, non-randomized, non-inferiority clinical study, adult patients treated with ADL (40 mg sc) who remained clinically stable for at least 6 months were recruited in 3 sites. Patients were grouped in Control (CG) and Intervention groups (IG) according to the site. ADL frequency was adjusted based on physician criteria. Patients are assessed at 8 timepoints (8 visits) for up to 18 months. Trough ADL and anti-ADL antibodies levels are measured with Promonitor-ADL and Promonitor-ANTI-ADL (Progenika, SA). BDM data were released only to the IG, and blinded to the CG (managed according to clinical assessment only). Physicians in the IG were not obliged to follow any therapeutic algorithm based on BDM results but could use tests to alter doses based on their judgement. Endpoints include DAS28, BASDAI, BASFI and HAQ-DI scores at every timepoint. Cost-effectiveness will be evaluated according to associated costs and QALY.
Results: A total of 169 patients were recruited (disease, N IG, N CG, %) (RA, 30, 33, 37.3%; PsA, 33, 21, 32%; and AS, 46, 6, 30.8%). Median disease duration was 117, 98.5 and 101.5 months for RA, PsA and AS, respectively. At baseline, 10 (16.7%) and 29 (26.6%) patients had low disease activity, 50 (83.3%) and 80 (73.4%) patients were in remission, and median trough ADL levels were 5,5 and 5,3 mg/L in the CG and IG, respectively. Mean follow-up (FU) was 505 and 499 days in the CG and IG, respectively. ADL doses were tapered in 22/60 (36,7%) and 39/109 (35,8%) patients in the CG and IG, respectively. Patients were in remission an average of 329 vs 344 days in the CG and IG, respectively. The number of flares in the CG and IG was 53 and 69, respectively. The rate of flares per patient-year of FU is 0,639 vs 0,463 in the CG and IG, respectively (difference of -0,176; CI95%: -0,379 to 0,0289). The risk of flare is 27,5% lower in the IG (IRR=0,7252; CI95%: 0,4997 to 1,0578). Quality of life (EQ-5D-5L) was significantly better in the IG at visits 2 (p=0,001) and 3 (p=0,035); EQ-5D-5L was higher (although not statistically significant) in the IG in the remaining visits. Average cost of ADL per patient-year was 11.898,60€ vs 11.240,81€ (-657.78€) in the CG and IG, respectively.
Conclusions: Preliminary results show that rheumatic patients have better quality of life, lower risk of flares and incur in lower treatment costs if patient management is complemented with BDM data.
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SAT0151 EFFICACY AND SAFETY OF BIOLOGIC THERAPY IN ELDERLY RHEUMATOID ARTHRITIS PATIENTS COMPARED TO YOUNG - A SYSTEMATIC REVIEW

D. Dalal[1], J. Duran[2], T. Brar[1], R. Alqadi[3], C. Halladay[4], A. Lakhani[1], J. Rudolph[4]. *[1]Medicine, Brown University School of Medicine, Providence, United States; [2]Medicine, Pontificia UniversidadCatolica de Chile, Santiago, Chile; [3]Medicine, Roger William Medical Center; [4]Medicine, VA Medical Center, Providence, United States*

Background: Rheumatoid arthritis (RA) patients are disproportionately older (33% >60 years). With improved biologic therapy for RA, there is a need to understand the efficacy and safety of biologic therapies in older RA (oRA) patients.
Objectives: To systematically review published literature to summarize the available evidence of efficacy and safety of biologic agents in oRA compared to young RA (yRA) patients.
Methods: A search in EMBASE, MedLine, Toxline, clinicaltrials.gov and Cochrane database was performed to identify clinical trials (RCT) and observational (OBS) studies of >6 months comparing the efficacy and safety of biologic agents in oRA relative to yRA. The biologics of interest were all anti-TNF agents, abatacept (ABA), tocilizumab (TCZ), rituximab (RTX) and tofacitinib (TOF). English language studies conducted in adult RA that reported age-associated outcomes were included. Studies assessing juveniles, inflammatory arthritis or not reporting older age outcomes were excluded. Safety outcomes included infections, adverse drug reactions (ADR), and malignancy. 2 independent rheumatologists reviewed abstracts, full text articles, and abstracted data from included articles. Conflicts were resolved by a 3rd reviewer. Abstracted data was summarized and evaluated for use within a meta-analysis
Results: Of 5353 abstracts, 187 were identified for full text review and 32 articles were included in this review. Articles were focused on efficacy (n=9), safety (n=15), or both (n=8). Most articles (n=22; 69%) focused on anti-TNF agents, then TCZ (n=4), ABA (n=2), TOF (n=2), RTX (n=1) and all biologics (n=1). Most studies were OBS studies (n=28, 88%) and fewer (n=4) were post-hoc analyses of RCT. In total, 99947 unique patients were identified, of which ~24% were older. Most studies used valid definitions of RA and outcomes; only 25% of the studies have <20% loss to follow up. There was heterogeneity in reporting outcomes and time of follow up.
Out of the 12 efficacy studies focusing on anti-TNF agents, 9 (75%) showed a reduced efficacy in oRA on DAS28, HAQ, CDAI, SDAI, EULAR or ACR response scales relative to yRA. Studies focusing on TCZ (n=2) and RTX (n=1) also showed a reduced efficacy in oRA. OBS studies in ABA (n=2) showed comparable efficacy in oRA and yRA. Meta-analysis was limited by heterogeneity.
Safety was the focus of anti-TNF (n=15), TCZ (n=3), 2 on TOF (n=2), 1 on ABA (n=1), RTX and all biologics (n=1) studies. Among these 23 safety studies, 74% (n=17) demonstrated worse safety outcomes in oRA. like in oRA. Of studies focusing on infection in anti-TNF agents, 82% (9 of 11) reported increased risk in oRA. Among the anti-TNF studies, 2 out of the 4 (50%) measured more ADR in oRA. A meta analysis of 4 studies reporting infectious outcomes in anti-TNF agents at >1 year found a pooled risk estimate was 1.59 (95% CI 1.45–1.76).

Figure 1: Forest plot of studies of anti-TNF agents measuring risk ratio of efficacy on EULAR or DAS28 response scale

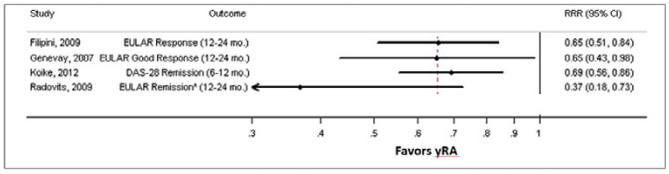
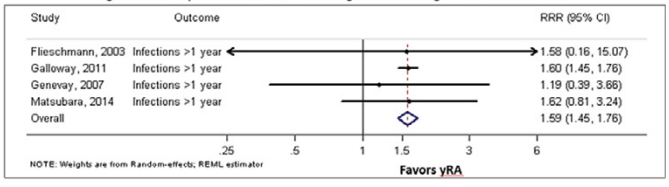


Figure 2: Forest plot of studies of anti-TNF agents measuring risk ratio of infections



Conclusions: There is heterogeneity within the literature of biological agents in RA, particularly when age is considered. Given the anticipated population increase in the oRA, there is an urgent need for analysis of these medications in oRA patients for both safety and efficacy.
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