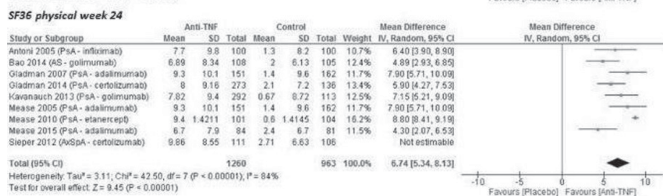
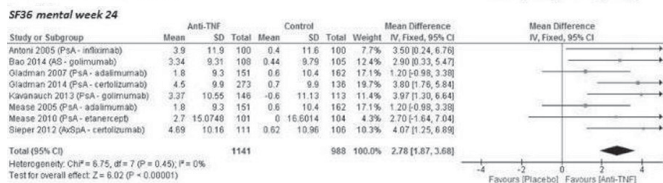
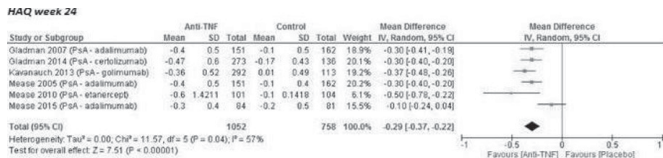


Twelve studies were eligible for a meta-analysis of anti-TNF effect on SF36 physical form. We observed a similar and significant improvement at 12 and 24 weeks. The effect at week 24 was 6.74 [95% CI: 5.34 – 8.13], with an important heterogeneity ($I^2=84\%$; see figure)

Fatigue was evaluated in 3 studies. Adalimumab induced a significant improvement in FACIT score at 12 and 24 weeks in one study. Two studies using different scores (Fatigue Assessment Scale, BASDAI fatigue item) to assess certolizumab effect highlighted similar findings: an early improvement in fatigue at week 12, remaining significant and stable at week 24.



Conclusions: Anti-TNFs agents significantly improve disability, quality of life and fatigue in patients with PsA.

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Disclosure of Interest: None declared

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AB0704 HIP ARTHROPLASTY IN PATIENTS WITH ANKYLOSING SPONDYLITIS - CLINICAL AND FUNCTIONAL EFFICIENCY

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Objectives: To evaluate the results of the hip joints replacement in patients with SpA under the dynamic supervision of a rheumatologist and orthopedic within the first year after the operation.

Methods: As part of special program for rheumatology patients hip endoprosthesis was done in 12 patients (mean age - 44,2±15,3 years) with SpA, 8 of them with ankylosing spondylitis (AS) and 4 with psoriatic arthritis (PsA). Duration of the disease - 13,3±7,9 years, positive for HLA B27 in 9 (75%) patients. High activity for ASDAS was at 58.3% of the patients. Took NSAIDs at the time of the operation - 11 (91.6%) patients, sulfasalazine 5 (41.6%), methotrexate- 2 (16.7%). 1 (8.3%) patient received etanercept, 1 (8.3%) patient - infliximab. Dynamic observation of rheumatologist and orthopedic was carried out before, just after surgery, after 6 and 12 months, with the assessment of VAS, BASDAI, ASDAS, BASFI.

Results: The reduction of pain intensity on the VAS was observed in the first month after the surgery (47,3±18,6 mm), initially it was 74,0±24,1 mm, 42,5±9 after 6 months ($p<0.05$), after 12 months - up to 22,5±9,9 mm ($p<0.05$). ASDAS significantly ($p<0.05$) reduced from 2,94±2,01 to 1,68±1,35 - in 6 months and 1,26±0,88 - 12 months after operation; BASDAI: from 6,24±3,91 to 2,75±2,20 - 6 months, 2,65±1,53 at 1 year follow-up. BASFI index before surgery - 5,48±3,29, 6 months - 2,78±2,31, 1 year - 2,32±1,60 points. No complications after surgery were registered.

Conclusions: Hip joints endoprosthesis in patients with SpA is effective not only in improving functional ability and pain relief, but also a reduction of disease activity. Dynamic rheumatologist observation in perioperative period leads to positive dynamics in relation to the activity of SpA and quality of life of patients during the first year after surgery

Disclosure of Interest: None declared

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AB0705 CONTINUED EFFECTIVENESS OF A BIOSIMILAR ADALIMUMAB AFTER STOPPAGE OF INITIAL TREATMENT IN PATIENTS WITH ANKYLOSING SPONDYLITIS

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Background: Adalimumab, an anti TNF- α agent, has been proven to be safe and effective in treatment of ankylosing spondylitis (AS). A biosimilar adalimumab was approved for use by Indian regulators in 2014. It is a "fingerprint match" of the reference adalimumab in terms of purity, potency, safety and clinical efficacy.^{1,2} In the absence of availability of adalimumab in India, this biosimilar adalimumab currently serves as an accessible, cost-effective option for treatment of AS patients.

Objectives: This retrospective analysis evaluates effectiveness of biosimilar adalimumab (bADA), in terms of disease activity, safety and outcomes in real-life Indian AS patients treated for initial 24 weeks and then followed for next 24 weeks off biologic treatment.

Methods: Medical records of AS patients with Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Bath Ankylosing Spondylitis Functional Index (BASFI) >4 , who were prescribed bADA therapy between January to December 2015 were analysed. For patients, who stopped bADA treatment after 24 weeks, standard AS outcome-measurement scores including ESR, CRP, BASDAI, BASFI, and Health Assessment Questionnaire (HAQ) at baseline, week 24 and at week 48 were measured to evaluate ongoing efficacy, were compared using paired Student's T-test. Patients were allowed to continue methotrexate and salazopyrin as part of routine medical care.

Results: During the study period, 52 AS patients were prescribed bADA 40 mg s/c; 24 of these patients, who had stopped treatment after 6 months, were considered for this analysis. Mean age for this group was 36.57±10.81 years; 10 females. At the end of 24 weeks' treatment, there were significant reductions in levels of inflammatory markers ESR, CRP, as well as in BASDAI, BASFI and HAQ scores. Eight patients continued to receive methotrexate and 8 patients sulfasalazine as concomitant medications. After week 48 (24 weeks post stoppage), BASDAI and BASFI scores did not deteriorate despite discontinuation of bADA treatment. The patients' HAQ scores were also indicative of similar trends of continuing improved health status post the therapy.

Table 1. Disease activity scores and patient outcomes at 24 weeks after completion of biosimilar adalimumab therapy

Parameters	Baseline	Week 24 (last dose)	P value (baseline – week 24)	Week 48 (24 weeks bADA free period)*	P value (baseline – week 48)
BASFI	8.35±0.72	2.87±0.77	$p<0.001$	2.55±0.65	$p<0.001$
BASDAI	7.70±0.84	2.45±0.58	$p<0.001$	2.41±0.58	$p<0.001$
ESR	49.50±28.78	13.97±11.19	$p<0.001$	30.33±26.23 ^Δ	$p=0.02$
CRP	19.71±12.24	3.58±3.6	$p<0.001$	6.13±9.41	$p<0.001$
HAQ (Pain)	67.71±7.22	27.08±8.2	$p<0.001$	28.13±9.42	$p<0.001$
HAQ (Health)	60.83±8.43	28.13±8.45	$p<0.001$	25.63±10.56	$p<0.001$

Data presented as Mean±standard deviation. *p = not significant for any parameter when compared for changes from week 24 to week 48. ^Δ $p=0.006$ as compared to week 24 for rise in ESR during the bADA free period.

Conclusions: Biosimilar adalimumab therapy was effective in treating AS patients. The disease activity and health assessment scores continued to remain stable with no worsening after the stoppage of treatment for 6 months, indicating a post-therapy effectiveness in these patients with no reported adverse event.

References:

[1] Bandyopadhyay S, et al. Biosimilars. 2015;5:1–18.

[2] Jani RH et al. *Int J Rheum Dis.* 2015 Jul 14.

Disclosure of Interest: None declared

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AB0706 ANKYLOSING SPONDYLITIS PATIENTS WITH UVEITIS HAD BETTER ADALIMUMAB RETENTION RATE: HUR-BIO REAL LIFE RESULTS

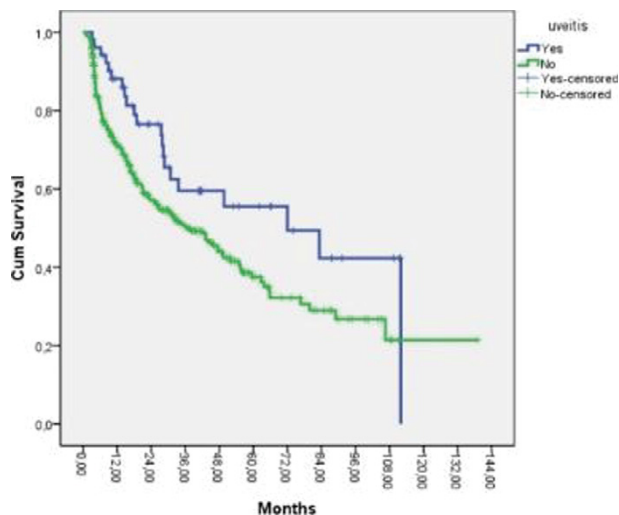
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Background: Retention of biological drugs in inflammatory arthritis may be affected from different obvious and unknown factors. It can be related with patient characteristics or disease features. In ankylosing spondylitis (AS), retention rate of biological drugs may be related with extra-articular presentation of AS such as uveitis, as well.

Objectives: The objective of this study was to assess whether uveitis affected retention of adalimumab in AS patients in our single center biological cohort.

Methods: Hacettepe University Biological registry is single-center biological registry since 2005. HURBIO had 2165 spondyloarthritis patients of which 1190 patients had AS according to NY criteria. Until now, in 510 of 1190 patients have used adalimumab and 350 of 510 patients had available for uveitis. Patients

were assessed for demographic characteristics, disease duration, HLA-B27, DMARD and biological usage, biological switch ratio. Baseline disease activity was assessed with BASDAI, BASFI VAS (pain, fatigue and patients global assessment), ESR and CRP. Patients were compared according to having uveitis or not. Retention rate of adalimumab assessed by Kaplan-Meier survival analysis. **Results:** Total 350 (59.4% male) AS patients analyzed. Mean age was 43 (12), mean disease duration and symptom duration were 10.5 (7.8) and 14.8 (9.6) years, respectively. 52 patients (14.8%) had uveitis. Median adalimumab survival time according to having uveitis were 71.9 (95% CI 25.4–118.6) months vs 36.4 (95% CI 23.3–49.4) months (log-rank $p=0.014$) (figure). Patients with uveitis were more frequently male (18.2% vs 9.8%, $p=0.03$), HLA-B27 positive (75.0% vs 49.5%, $p=0.022$). Patients with uveitis had more frequently SpA family history, as well (23.1% vs 10.8%, $p=0.003$). Age (49 (11) vs 41 (11) years, $p<0.001$), disease duration (14.4 (10.1) vs 9.8 (7.1) years, $p<0.001$), and symptom duration (22 (12) vs 14 (8) years, $p<0.001$) were higher in patients with uveitis. Baseline and last visit disease activities were similar regarding to uveitis.



Conclusions: Determination of possible risk factors for retention of TNFi drugs is an important clinical problem for routine practise. It is well known that adalimumab is one of the treatment option for uveitis whether uveitis related with SpA or not. Our biological cohort supported that AS patients with uveitis had better adalimumab survival. For routine practise, adalimumab could be considered for AS patients with uveitis.

Disclosure of Interest: None declared

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AB0707 COMPARATIVE EFFECTIVENESS OF SECUKINUMAB AND GOLIMUMAB IN ANKYLOSING SPONDYLITIS ASSESSED BY MATCHING-ADJUSTED INDIRECT COMPARISON USING PIVOTAL PHASE 3 CLINICAL TRIAL DATA

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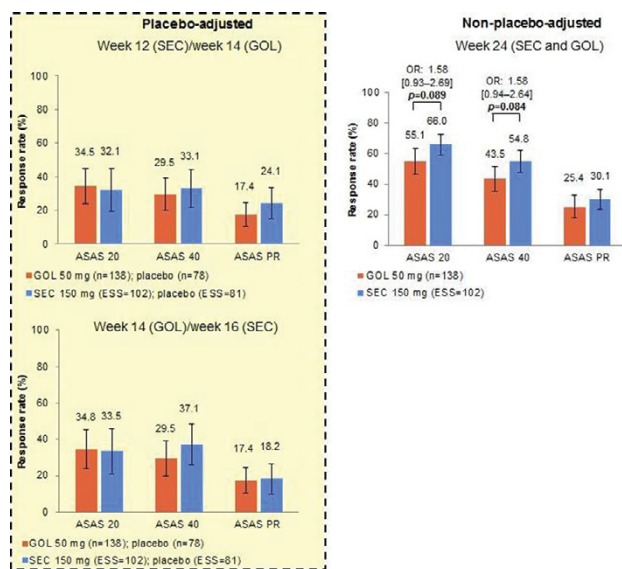
Background: No data are available from head-to-head RCTs between secukinumab 150 mg (SEC; an anti-IL-17A) and golimumab 50 mg (GOL; a TNFi) in patients with active ankylosing spondylitis (AS). Matching-Adjusted Indirect Comparison (MAIC) can be used to estimate comparative effectiveness and enables treatment outcomes to be compared across effectively balanced trial populations. MAIC is an established method in health technology assessments and NICE have published guidance on appropriate methodology, and especially for addressing imbalances in observed covariates between trials.¹

Objectives: To assess the comparative effectiveness of SEC and GOL up to week 24 using MAIC with pooled individual patient data (IPD) from the RCTs MEASURE 1 (M1) and MEASURE 2 (M2) and published aggregate data from the RCT GO-RAISE.

Methods: Pooled M1 and M2 data were used to maximize the effective sample size (ESS) for SEC. IPD from the SEC arms of M1 and M2 ($n=197$) were weighted to match the published baseline characteristics of the GOL arm of GO-RAISE ($n=138$). Placebo arms were matched in the same way; placebo-adjusted comparisons were possible only until week 16 because patients could receive active treatment from this time onwards. Logistic regression was used to determine weights for age, sex, BASFI, disease duration, CRP and previous TNFi therapy. Recalculated outcomes from M1 and M2 (SEC, ESS=102; placebo, ESS=81) were compared with data from GO-RAISE (GOL, $n=138$; placebo,

$n=78$). Pairwise comparisons – reported as odds ratios (ORs [95% CIs]) – were performed for ASAS 20, ASAS 40 and ASAS PR responses at nearest-equivalent time points across trials: week 12 (SEC)/14 (GOL), week 14 (GOL)/16 (SEC) and week 24 (SEC and GOL). Non-responder imputation (NRI) was available for all binary outcome data. Strict thresholds were avoided when interpreting p values, in line with American Statistical Association 2016 guidance.

Results: There was no evidence of differences in ASAS 20 and ASAS 40 responses between SEC and GOL at weeks 12/14 and 14/16 (both placebo-adjusted). At week 24, non-placebo-adjusted ASAS 20 and ASAS 40 responses using NRI were higher with SEC than GOL (OR [95% CI]: 1.58 [0.93–2.69], $p=0.089$ and 1.58 [0.94–2.64], $p=0.084$, respectively). There was no evidence of differences in ASAS PR responses between SEC and GOL at weeks 12/14, 14/16 and 24. A sensitivity analysis conducted after adding BASDAI score to the matching parameters yielded similar results.



ASAS 20/40 and PR responses are the absolute mean response rate (GO-RAISE) and the predicted mean response rates (MEASURE 1 and MEASURE 2). Error bars shown are 95% CIs. ASAS, Assessment of SpondyloArthritis International Society; ASAS 20/40, at least a 20%/40% improvement according to ASAS response criteria; ASAS PR, ASAS partial remission; CI, confidence interval; ESS, effective sample size; GOL, golimumab; OR, odds ratio; SEC, secukinumab.

Conclusions: There was no evidence of differences in ASAS responses between SEC and GOL in placebo-adjusted analyses. In non-placebo-adjusted analyses, SEC showed higher ASAS 20 and ASAS 40 responses than GOL at week 24.

References:

[1] Phillip DM et al. (2016) NICE DSU Technical Support Document 18. Available from: <http://www.nicedsu.org.uk>.

Disclosure of Interest: W. Maksymowych Grant/research support from: AbbVie, Pfizer and Sanofi, Consultant for: AbbVie, Amgen, Eli Lilly, Janssen, Merck, Novartis, Pfizer, Sanofi and UCB, E. Choy Grant/research support from: Pfizer, Roche and UCB, Consultant for: Chugai Pharma, Eli Lilly, Janssen, Novartis, Pfizer, Regeneron, Roche, R-Pharm and Sanofi, Y. Yazici Grant/research support from: Celgene, BMS and Genentech, Consultant for: Celgene, BMS and Novartis, J. Walsh Consultant for: Novartis, H. Thom Consultant for: Eli Lilly, F Hoffman-La Roche, Novartis Pharma AG and Pfizer, C. Kalyvas Employee of: Paid employee of the Mapi Group. The Mapi Group received funding from Novartis Pharma AG for this study, T. Fox Employee of: Novartis employee with stock, K. Gandhi Employee of: Novartis employee with stock, S. Jugl Employee of: Novartis employee with stock

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AB0708 TRANSITION FROM ONGOING INFlixIMAB REFERENCE PRODUCT TO ITS BIOSIMILAR: CAN WE TALK ABOUT A FAILURE?

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Background: Some recent publications support the fact that there is no clinically meaningful difference between infliximab biosimilar and the originator in naïve patients, but sole a few of them actually assessed the transition itself. Since May 2016, according to the European guidelines, the French Health Authorities have allowed interchangeability between a bioterapy reference product and its biosimilar. According to the last studies focusing on the safety and efficacy issues, avoiding the transition to biosimilar looks no longer justified.

Objectives: This work aimed to understand to which extent the use of infliximab biosimilar may result in the failure of the switch strategy in spondyloarthritis patients.

Methods: This is a retrospective study conducted from June to December