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## THU0398 SECUKINUMAB SUSTAINS INDIVIDUAL CLINICAL RESPONSES OVER TIME IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS: 2-YEAR RESULTS FROM A PHASE 3 TRIAL, MEASURE 2

X. Baraliakos[1], M. Schiff[2], K. Pavelka[3], A. Widmer[4], B. Porter[5], C. Gaillez[4] on behalf of the MEASURE 2 study group. *[1]Ruhr-University Bochum, Herne, Germany; [2]University of Colorado, Denver, United States; [3]Charles University, Prague, Czech Republic; [4]Novartis Pharma AG, Basel, Switzerland; [5]Novartis Pharmaceuticals Corporation, East Hanover, United States*

**Background:** The assessment of achieving, maintaining or improving clinical response to biologics in ankylosing spondylitis (AS) is a part of treat-to-target recommendations aimed at optimising treatment goals.[1]
**Objectives:** To evaluate patient (pt)-level secukinumab data and assess the likelihood of achieving, maintaining or improving an Assessment of SpondyloArthritis international Society (ASAS) response from Week (Wk) 2 (early response) to Wk 16 (primary endpoint) and from Wk 16 to Wk 52 or 104 (sustained effect) in pts with active AS from the MEASURE 2 trial.[2,3]
**Methods:** This is a *post-hoc* analysis of AS pts originally randomised to secukinumab 150mg (approved dose) who completed the 16-wk double-blind treatment period, followed by long-term uncontrolled treatment. Shift analyses on ASAS response between Wks 2 and 16 and Wks 16 and 52 or 104 were performed on subgroups of secukinumab 150mg treated pts categorised by their highest ASAS criteria response at the earlier time point (ASAS non-responder [ASAS NR], ASAS20 responder, ASAS40 responder) and evaluating whether this response was improved, sustained, or worsened at the later time point, based on observed analysis.
**Results:** Overall, 65, 61 and 59 pts treated with secukinumab 150mg had available data to determine ASAS responses for shift analyses from Wk 2 to 16 and Wk 16 to 52 or 104, respectively. At baseline, mean age was 41.9±12.5 years, mean time since diagnosis was 7.0±8.2 years and mean Bath Ankylosing Spondylitis Disease Activity Index score was 6.6±1.5. Approximately half of the ASAS NR pts at Wk 2 or 16 subsequently developed an ASAS 20 or 40 response at the later time point of Wk 16 or 52, respectively. A total of 79% pts improved their response from ASAS20 to ASAS40 at Wk 16 (Wk 2 to 16) and another 44% pts improved their response from ASAS20 to ASAS40 from Wk 16 to 52. A majority (64% and 84%) of ASAS40 responders at Wk 2 or 16 maintained this response at Wk 16 or 52, respectively. Similar trends were observed in responses from Wk 16 to 104 (Figure).
**Conclusions:** In this *post-hoc* pt-level analysis, the majority of secukinumab 150mg treated pts maintained or improved their ASAS responses over time, consistent with the sustainability of group-level ASAS responses reported previously.[2,3] In particular, the majority of pts who achieved either an ASAS20 or ASAS40 response at Wk 2 or 16 maintained or improved their response at Wks 16, 52 or 104, respectively.
**References:**
[1] Smolen JS, et al. Ann Rheum Dis 2014;73:6–16.
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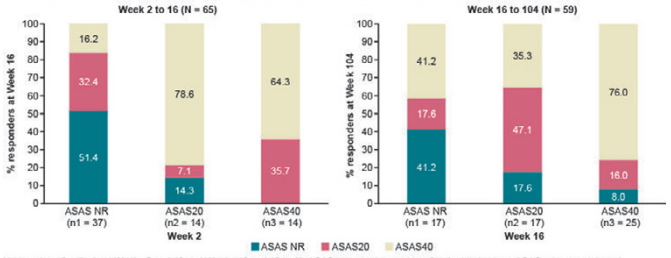
[3] Marzo-Ortega H, et al. Ann Rheum Dis 2016;75:812–3.

**Figure. Shift analyses on ASAS responses in secukinumab 150mg from Week 2 to 16 and 16 to 104**




N = number of patients at Weeks 2 and 16 and Weeks 16 and 104 with ASAS status; n1 = number of patients who were ASAS non-responders at Week 2 or 16; n2 or n3 = number of patients who achieved ASAS20 or ASAS40 at Week 2 or 16; Percentages were calculated by considering n1 to n3 as denominator at Weeks 16 and 104. Patients with multiple responses are counted once at Week 2 and counted once in best response at Week 16 or 104.

**Disclosure of Interest:** X. Baraliakos Grant/research support from: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB, Werfen, Consultant for: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB, Werfen, Speakers bureau: AbbVie, BMS, Celgene, Chugai, Merck, Novartis, Pfizer, UCB, Werfen, M. Schiff Consultant for: Abbvie, BMS, Lilly, J&J, Speakers bureau: Abbvie, K. Pavelka Speakers bureau: MSD, AbbVie, Roche, UCB, Amgen, Hospira, Egis, Pfizer, Medac, BMS, A. Widmer Shareholder of: Novartis, Employee of: Novartis, B. Porter Shareholder of: Novartis, Employee of: Novartis, C. Gaillez Shareholder of: Novartis, BMS, Employee of: Novartis

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## THU0399 TAPERING THERAPY OF TNF-INHIBITOR FOR MRI CHANGES IN SPONDYLOARTHRITIS

Y. Song, Y. Cui, X. Zhang, H. Zeng, Y. Zeng. *Goungdong General Hospital, Goungzhou, China*

**Background:** TNF-inhibitors could significantly improve disease activity of SpA patients, however, there is still no answer to the effect of prolonged the interval of TNF-inhibitors on MRI changes.
**Objectives:** The aim of the study was to investigate whether prolonged the interval of TNF-inhibitor injection could maintain SpA at low disease activity and improve imaging changes of sacroiliac joint.
**Methods:** A total of 98 SpA patients were included and 67 of them received TNF-i with or without conventional DMARDs. TNF-i included Etanercept, Infliximab and Adalimumab. The full dosage treatment was defined as patients received Etanercept 50 mg per week, Infliximab 4 mg/kg at 0, 2, 6 week and Adalimumab 40 mg every two weeks. The dose of Etanercept was gradually reduced to 50 mg every two weeks, 50 mg every three weeks and then 50 mg per month. The infusion of Infliximab was reduced to every 8 weeks, every 12 weeks and then every 16 weeks. The interval of Adalimumub injection was changed from 3 weeks to 4 weeks and then to two months. After full dose treatment in the first 3 months, patients who administrated TNF-i were evaluated every 3–6 months. According to laboratory tests including ESR, CRP and IgA levels, BASDAI, BASFI, ASDAS results and sacroiliac joint SPARCC scores, the interval of TNF-i treatment was prolonged gradually. Fat metaplasia, bone erosion, sclerosis and ankylosis changes on MRI were compared between baseline, 4–6 months and 1–2 years.
**Results:** After 3 months of treatment, inflammatory indexes, BASDI, BASFI, ASDAS and SPARCC scores were significantly lower than baseline ($P<0.05$). After 4–6 months of treatment, ESR, CRP and IgA levels were greatly lower than before (8 (3,25) *vs.* 2 (1,3) mm/h, 4.97 (1.83,14.5) *vs.* 1.71 (1.24,2.82) mg/l, 2.96±1.34 *vs.* 2.20±1.01mg/l, Table 1, $P<0.01$). Compared to baseline, significant reduction of BASDAI and BASFI score was observed in TNF-inhibitor

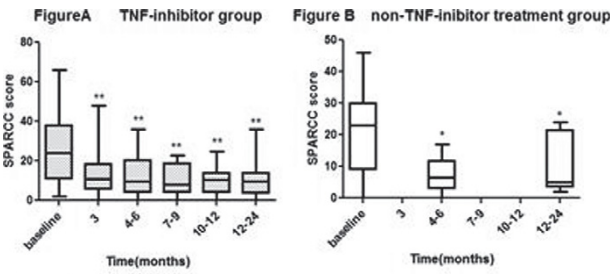


Figure 1 SPARCC score changes in TNF-inhibitor(A) and non-TNF-inhibitor(B) treatment group

**Abstract THU0399** – Table 1. ESR, CRP and IgA changes before and after treatment

| | | Baseline | 3 months | 4–6 months | 7–9 months | 9–12 months | 12–24 months |
|---|---|---|---|---|---|---|---|
| ESR (mm/h) | TNF-inhibitor | 8 (3,25) | 2 (1,3.75)** | 2 (1,3)** | 7 (2,9) | 2.93 (2,6) | 5.05 (2,17.75) |
| | non-TNF-inhibitor | 10 (5,36) | – | 2 (2,8) | – | – | 4 (0.5,10.5) |
| CRP (mg/L) | TNF-inhibitor | 4.97 (1.83,14.5) | 1.54 (1.03,3.02)* | 1.71 (1.24,2.82)** | 4.89 (1.95,8.75) | 2.01 (1.25,4.37) | 4.21 (1.0,10.83) |
| | non-TNF-inhibitor | 6.85 (3.11,16.05) | – | 1.95 (1.59,5.34) | – | – | 4.72 (1.8,7.43) |
| IgA (mg/L) | TNF-inhibitor | 2.96±1.34 | 1.88±1.38 | 2.20±1.01** | 1.92±1.63 | 1.78±1.32 | 2.45±1.63 |
| | non-TNF-inhibitor | 3.47±1.63 | – | 1.95±1.35 | – | 1.79±2.53 | 1.47±1.48 |

*P<0.05, **P<0.01.

group. The SPARCC scores in TNF-i group also decreased significantly (Figure1, $P<0.01$). There was no significant progress in fat metaplaisa, bone erosions, sclerosis and ankylosis during the follow-up period ($P>0.05$). Even though the inflammatory indexes and clinical evaluation of non-TNF-i group did not improved remarkably, SPARCC score were significantly reduced at 4–6 months and 1–2 years ($P<0.05$).
**Conclusions:** TNF-i could reduce clinical and imaging inflammatory degree. Prolonged the interval of TNF-i treatment could maintain low disease activity and improve bone marrow edema, whereas fat metaplasia, bone erosion, sclerosis and ankylosis were not exacerbated.
**Disclosure of Interest:** None declared
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### THU0400 RISK FACTORS OF SAGITTAL TRANSLATION AFTER PEDICLE SUBTRACTION OSTEOTOMY ON ANKYLOSING SPONDYLITIS

Y.-S. Park, J. Kim, J.-S. Park. *Department of Orthopaedic Surgery, Hanyang University Guri Hospital, Guri city, Korea, Republic Of*

**Background:** Few studies on sagittal translation and its risk factors after pedicle subtraction osteotomy (PSO) in ankylosing spondylitis (AS) patients have been conducted. There is also no study on overall evaluation of radiologic parameters as the candidate of its risk factor.
**Objectives:** The aim of this study was to report the cases of sagittal translation which developed after PSO in AS patients with kyphotic deformity and to analyze its risk factors
**Methods:** The subjects of this study were 53 AS patients (58 cases) who underwent PSO to correct their kyphotic deformity between March 2006 and August 2016. The 53 subjects consisted of 45 males and 8 females. Their mean age was 39.3 12 Tit'>7.9 (range: 29–67). After osteotomy, the patient was examined for the presence of sagittal translation in the correction site through intraoperative radiograph. The low modified Stoke AS spine score (mSASSS) was measured before the surgery. The vertebral parameters such as lumbar lordosis angle, thoracic kyphotic angle, and sagittal vertical axis, and the pelvic parameters such as pelvic incidence, pelvic tilt, and sacral slope were also measured before and after the surgery.
The subjects were grouped according to the presence and absence of sagittal translation, and their radiologic parameters were compared. In addition, the correlation between sagittal translation and each parameter was analyzed. Complications that developed during and after the surgery were also analyzed.
**Results:** Sagittal translation developed in 16 subjects (30%) or 17 cases (29.3%). The mean lumbar lordosis angle and the mean sagittal vertical axis of both the sagittal translation (ST) group and the non-sagittal translation (Non-ST) group were successfully corrected (p=0.000, respectively). A significant difference in preoperative mean sacral slope was observed between the groups (p=0.045). The ST group showed a significantly higher mSASSS (48.1±20.7) than the Non-ST group (36.8±16.2) (p=0.002). In the multivariate regression analysis, sagittal translation was positively correlated with mSASSS (odds ratio 1.34, P=0.002) and the preoperative sacral slope (odds ratio 1.46, P=0.009), and negatively correlated with the difference between preoperative and postoperative thoracic kyphotic angle (odds ratio 0.68, P=0.01). Both groups showed no finding of permanent neurologic complication after the surgery.
**Conclusions:** The incidence of sagittal translation after pedicle subtraction osteotomy was closely related with the severity of ankyloses in AS patients. Therefore, when pedicle subtraction osteotomy is performed for AS patients with severe ankyloses and high sacral slope, it is required that surgeon consider sagittal translation which could induce neurologic complication.
**Disclosure of Interest:** None declared
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**THURSDAY, 15 JUNE 2017**

## Crystal diseases, metabolic bone diseases and bone diseases other than osteoporosis

### THU0401 ULTRASOUND EVALUATION IN FOLLOW-UP OF URATE-LOWERING THERAPY IN GOUTY PATIENTS: THE USEFUL STUDY

M. Forien[1], E. Norkuviene[2], P. Richette[3], G. Mouterde[4], H.-K. Ea[3], F. Lioté[3], M. Petraitis[2], T. Bardin[3], J. Ora[3], P. Dieudé[1], S. Ottaviani[1]. *[1]Rheumatology, Hôpital Bichat, Paris, France; [2]Rheumatology, Lithuanian University of Health Sciences, Kaunas, Lithuania; [3]Rheumatology, Lariboisière Hospital, Paris; [4]Rheumatology, Lapeyronie Hospital, Montpellier, France*

**Background:** Ultrasonography (US) has demonstrated its ability to detect urate deposition in gouty patients. Some US features have been suggested to be specific such as tophus and the double contour (DC) sign. In contrast to the usefulness of US for diagnosis, data are lacking on its role in follow-up of gout deposition after initiation of urate-lowering therapy (ULT).
**Objectives:** We aimed to determine the ability of US to show disappearance of urate deposits in gouty patients requiring ULT.
**Methods:** We performed a 6-month multicentre prospective study. To be included in the study, patients needed to have: i) a proven gout (identification of monosodic urate crystal in synovial fluid analysis or tophus aspiration), ii) presence of US features of gout (tophus and/or DC sign) at knee and/or first metatarsophalangeal joints (MTP1s). Serum uric-acid (SUA) level was assessed at baseline, M3 and M6. US evaluations were performed at baseline, M3 and M6 after starting ULT, by one local rheumatologist, blinded to SUA levels and clinical data. The primary outcome was the decrease (absolute value and percentage of decrease) of US tophus after 6 months of ULT, according to the final SUA levels. The secondary outcome was the mean percentage of joint sites with DC sign disappearance. Three stages of SUA levels were defined (high SUA levels: >360 μmol/l, low SUA: 300 -360 μmol/l, very low SUA: <300 μmol/l.
**Results:** A total of 79 gouty patients (mean ± SD age 61.8±14 years, 91% of males) were included. The mean disease duration was 6.3±6.1 years. Tophi were found at clinical exam in 29% of patients. Baseline SUA levels were 530±97 μmol/l. At least one US tophus and DC sign were found in 74 (93.7%) and 68 (86.1%) of patients, respectively. Allopurinol and febuxostat was started in 26 (33%) and 53 (67%) patients, respectively. A total of 67 patients were completers at 6 months. Among those M6 completers, 39 and 18 patients achieved a very low and low SUA levels, respectively. The 10 remaining patients maintained high SUA levels. Comparison of US features of gout modifications between the 3 groups of final SUA levels revealed a higher decrease of US tophus size and higher proportion of DC sign dissolution among patients with lowest SUA levels (Table 1). Additionally, final M6 SUA levels was associated with: decrease size of tophus (r=0.5093 [0.3012; 0.6711], P<0.0001), percentage of decrease of the tophus size (r=0.5352 [0.3332; 0.6902], P<0.0001) and inversely correlated with the proportion of DC sign dissolution (r=-0.624 [-0.763; -0.4298]).

Table 1. Modifications of US features of gout after 6 months of ULT

| M6 SUA levels, mmol/l | SUA <300 N=39 | SUA 300–360 N=18 | SUA >360 N=10 | P* |
|---|---|---|---|---|
| Delta size tophus, mean ± SD mm | -6.5±4.1 | -4.4±3.0 | -0.0±1.5 | P=0.00046 |
| % of decrease of tophus | -56.6±32.9 | -31.5±24.3 | -10.3±17.2 | P=0.00028 |
| % of joint site with DC sign dissolution | 80.8 | 59.9 | 1.1 | P<0.0001 |

*Kruskal-Wallis test. DC: double contour; SD: standard deviation; SUA: serum uric acid levels.

**Conclusions:** US is able to detect decrease or disappearance of US urate deposits after ULT. Additionally, the decrease of US deposits is strongly correlated with lowest SUA levels. These data suggest that US could be useful for ULT management in gouty patients.
**Disclosure of Interest:** None declared
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### THU0402 ULTRASONOGRAPHY AND DUAL-ENERGY CT (DECT) DO NOT PROVIDE THE SAME QUANTIFICATION OF URATE DEPOSITION IN GOUT: RESULTS FROM A CROSS-SECTIONAL STUDY

T. Pascart[1], A. Grandjean[2], L. Norberciak[3], V. Ducoulombier[2], M. Motte[2], H. Luraschi[2], M. Vandecandelaere[2], C. Godart[2], E. Houvenagel[2], N. Namane[2], J.-F. Budzik[4]. *[1]Rheumatology; [2]Hopital Saint Philibert, LOMME, France; [3]Biostatistics; [4]Radiology, Hopital Saint Philibert, LOMME, France*

**Background:** Gout is due to monosodium urate (MSU) deposition in joints and soft tissues. Ultrasonography (US) and dual-energy CT (DECT) have been shown to be effective in detecting MSU deposits. Both techniques can examine tophi size. DECT is effective to identify soft-tissue MSU deposits and US can show joint deposition with the double contour (DC) sign. It is unknown if these two techniques provide the same quantification of the extent of urate deposition on a given patient.
**Objectives:** The main objective of this study is to compare the tophus size measured by US and by DECT. The secondary objective is to evaluate the correlation between the prevalence of the US DC sign and the global volume of urate deposits measured by DECT.
**Methods:** This prospective cross-sectional study included patients fulfilling the 2015 ACR/EUALR criteria for gout. Patients underwent US and DECT examinations of their knees and feet. The largest US tophi was selected as the index tophus. US examination of the DC sign was performed on the femoro-patellar joints, talo-crural joints and 1st metatarsophalangeal joints. Total volume of urate deposits of knees and feet was measured by DECT. The primary endpoint was the intra-class correlation coefficient (ICC) of the volume of the index tophus measured by US and DECT [CI 95%].
**Results:** A total of 64 patients were included in the study, of which 35 patients presented with at least one US tophus. Patients were in average 64.5±16.3 years old, 84.4% were male, had an average ACR/EULAR score of 13.6±2.5, and disease duration was 12±14.7 years. Overall, 44 patients (68.8%) were currently taking urate lowering therapy and 22 patients (34.4%) had clinical tophi. Out of the 35 US selected largest tophi, 6 tophi were not seen in DECT. Of the tophi identified with both techniques, 21 were localized in the feet and 8 in the knees. The ICC of the tophus volume assessment by US and DECT was 0.45 [0.12–0.69]. The average volume of the largest US tophi was 2.7±6.5 $cm^3$ and 1.5±3.3$cm^3$ when measured by DECT. If the index tophus was localized in the knee, the ICC was 0.36 [0–0.82] and was 0.68 [0.37–0.86] if the tophus was in