## SAT0393 EFFECTIVENESS AND SAFETY OF INFLIXIMAB, GOLIMUMAB AND USTEKINUMAB IN PSORIATIC ARTHRITIS PATIENTS FROM A PROSPECTIVE OBSERVATIONAL REGISTRY

Proton Rahman[1], Regan Arendse[2], Isabelle Fortin[3], Andrew Chow[4], Majed Khraishi[5], Suneil Kapur[6], Michel Zummer[7], Jon Chan[8], Larissa Lisnevskaia[9], Raheem Kherani[10], Emmanouil Rampakakis[11], Odalis Asin Miilan[11], Allen Lehman[11], Meagan Rachich[12], Francois Nantel[11]. *[1]Memorial University of Newfoundland, St. John's, Canada*; *[2]University of Saskatchewan, Saskatoon, Canada*; *[3]Centre Rhumatologie de l'Est, Rimouski, Canada*; *[4]University of Toronto, Toronto, Canada*; *[5]Nexus Clinical Research, St. John's, Canada*; *[6]University of Ottawa, Ottawa, Canada*; *[7]University of Montreal, Montreal, Canada*; *[8]Artus Health Centre, Vancouver, Canada*; *[9]Oshawa Clinic, Oshawa, Canada*; *[10]University of British Columbia, Richmond, Canada*; *[11]Janssen Inc, Toronto, Canada*; *[12]Janssen Inc., Toronto, Canada*

**Background:** Long-term registries are essential to evaluate new therapies in a patient population that differs from clinical trials and usually varies over time.

**Objectives:** To describe the profile of psoriatic arthritis (PsA) patients selected for treatment with infliximab (IFX), golimumab (GLM) or ustekinumab (UST) treatment in Canadian routine care and to describe the long-term real-world effectiveness and safety of these agents.

**Methods:** 462 PsA patients treated with IFX, GLM or UST were enrolled into the Biologic Treatment Registry Across Canada (BioTRAC) registry between 2006-2015, 2010-2017 and 2014-2017, respectively. Study visits occurred at baseline and every 6 months thereafter. Effectiveness was assessed with changes in TJC28, SJC28, skin, enthesitis, dactylitis, pain, HAQ, acute phase reactants. Safety was evaluated with the incidence of adverse events (AEs) and drug survival rates.

**Results:** Of the 111 IFX-, 281 GLM- and 70 UST-treated patients, the proportion of males were 52.3%, 46.3% and 37.1%, the mean age was 48.4, 52.8 and 53.1 years and the mean disease duration was 5.8, 6.1 and 5.7 years, respectively. Most patients were bio-naive (85.6%, 77.9% and 55.7% for IFX, GLM and UST, respectively (p<0.001). A reduction in mean baseline duration of morning stiffness was observed in the IFX cohort (from 69.8 to 42.6 to 23 min in 2006-2008 to 2009-2012 to 2013-2015; p=0.003). Most other baseline disease parameters remained similar over time in all three cohorts. However, UST-treated patients had lower mean baseline DAS28 CRP (3.4 vs 3.9; p=0.0031), SJC (3.8 vs 5.3; p=0.0046) and higher PASI (4.8 vs 2.2; p=0.0061) compared to patients treated with GLM.

Treatment with IFX, GLM and UST was associated with significant improvements in all disease parameters over time (P<0.001) from baseline up to 84, 84 and 40 months, respectively with similar efficacy between agents. The only exception was the proportion of patients in minimal disease activity at 12, 24 and 36 months which reached 40.7%, 50.0% and 55% in IFX-patients; 64.7%, 68.8% and 78.9% in GLM-patients and 58.8%, 60.0% and 83.3% in UST-patients (p=0.004 and p<0.001 vs IFX).

AEs were reported for 74.8%, 69.8% and 52.9% (138, 114 and 115 events/100 PYs) and SAEs for 19.8%, 8.5% and 5.7% (8.8, 19.6 and 28.6 events/100 PYs) covering 325, 567 and 87 years of exposure for IFX-, GLM- and UST-treated patients, respectively. One, one and no death occurred IFX-, GLM- and UST-treated patients, respectively. The proportion of patients who discontinued treatment were 63.1%, 50.9% and 50.0% over a mean exposure of 2.9, 1.9 and 1.2 years to IFX, GLM and UST, respectively.

**Conclusion:** Differences in baseline characteristics between patients treated with an anti-TNF over an anti-IL12/23 agent suggest that the level of joint to skin involvement might be driving physician choice when the time comes to choose a biologic agent. IFX, GLM and UST treatment significantly reduced disease activity and improved functionality in a similar fashion and were well tolerated in patients with PsA.

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## SAT0394 POSSIBLE POTENTIAL INTERACTIONS BETWEEN OBESITY, QUALITY OF LIFE, PSYCHOLOGICAL STATUS AND CLINICAL PARAMETERS IN PSORIATIC ARTHRITIS

Kevser Gok[1], Kemal Nas[2], Erkan Kilic[3], Betul Sargin[4], Sevtap Acer Kasman[5], Hakan Alkan[6], Nilay Sahin[7], Gizem Cengiz[8], Nihan Cuzdan[9], Ilknur Albayrak Gezer[10], Dilek Keskin[11], Cevriye Mülkoğlu[12], Hatice Resorku[13], İsmihan Sunar[14], Ajda Bal Hasturk[15], Mehmet Tuncay Duruöz[5], Okan Kucukakkas[16], Ozan Volkan Yurdakul[16], Meltem Alkan Melikoglu[17], Yildiray Aydin[2], Figen Ayhan[12], Hatice Bodur[18], Mustafa Calis[8], Erhan Capkin[19], Gul Devrimsel[20], Sami Hizmetli[21], Ayhan Kamanli[2], Yasar Keskin[16], Hilal Kocabas[22], Oznur Kutluk[23], Nesrin Şen[24], Omer Faruk Sendur[25], Ibrahim Tekeoğlu[26], Murat Toprak[27], Sena Tolu[16], Tiraje Tuncer[23]. *[1]Ankara Numune TraiandRes Hospt, Ankara, Turkey*; *[2]Sakarya Unv, Sakarya, Turkey*; *[3]Afyon Hospt, Afyon, Turkey*; *[4]Aydin Hospt, Aydin, Turkey*; *[5]Marmara Unv, Istanbul, Turkey*; *[6]Pamukkale Unv, Denizli, Turkey*; *[7]Balikesir Unv, Balikesir, Turkey*; *[8]Erciyes Unv, Kayseri, Turkey*; *[9]Sanliurfa TraiandRes Hosptl, Sanliurfa, Turkey*; *[10]Selçuk Unv, Konya, Turkey*; *[11]Kirikkale Unv, Kirikkale, Turkey*; *[12]Ankara TraiandRes Hospt, Ankara, Turkey*; *[13]Onsekiz Mart Unv, Canakkale, Turkey*; *[14]Ankara Unv, Ankara, Turkey*; *[15]Diskapi TraiandRes Hospt, Ankara, Turkey*; *[16]Bezmiâlem Unv, Istanbul, Turkey*; *[17]Atatürk Unv, Erzurum, Turkey*; *[18]Yildirim Beyazit Unv, Ankara, Turkey*; *[19]Karadeniz Technical Unv, Trabzon, Turkey*; *[20]Recep Tayyip Erdoğan Unv, Rize, Turkey*; *[21]Cumhuriyet Unv, Sivas, Turkey*; *[22]Necmettin Erbakan Unv, Konya, Turkey*; *[23]Akdeniz Unv, Antalya, Turkey*; *[24]Kartal Dr. Lütfi Kirdar TraiandRes Hosptl, Istanbul, Turkey*; *[25]Adnan Menderes Unv, Aydin, Turkey*; *[26]SakaryaUnv, Sakarya, Turkey*; *[27]Yuzuncu Yil Unv, Van, Turkey*

**Background:** Psoriatic arthritis (PsA), a chronic rheumatic disease associated with reduced quality of life. Obesity is an important clinical problem which may interfere with loss of functioning and quality of life. Obesity is usually an overlooked entity in patients with PsA. Several studies were invastigated prevalence and the impact of obesity on disease activity in patients with PsA, however relationship between psychological status and quality of life have not been evaluated comparatively.

**Objectives:** To assess the impact of obesity on quality of life, psychological status and clinical parameters in patients with PsA.

**Methods:** Patients with PsA were recruited who met CASPAR classification criteria enrolled by Turkish League Against Rheumatism-NETWORK (TLAR-NETWORK) derived from 24 different centers of our country. Patients with BMI $\geq$30 kg/m$^2$ were considered obese. Differences among patients with or without obesity were assessed.VAS fatigue, psychological status and health related quality of life measures [SF-36; HAQ; Psoriatic arthritis quality of life (PsAQoL); Hospital Anxiety and Depresson Scale], FACIT-Fatigue, DAS28, BASDAI, BASFI, BASMI, Maastrich Ankylosing Spondylitis Enthesitis *Score* (MASES) and Psoriasis area severity index (PASI) scores were compered between this groups.

**Results:** A total 1130 patients with PsA (36.0% male, 64.0% female) included in this study. In this cohort 37.6% obese and 62.4% non-obese. The presence of peripheral arthritis, enthesitis, dactylitis, uveitis and spine involvement, PASI scores as well as MASES scores were quite similar between patients with and without obesity. Obese patients had significantly higher scores in VAS fatigue and disease activity, poorer QoL and physical functions compared to non-obese patients (p<0.05). Obese patients had high risk for anxiety and depression (p <0.05).

**Conclusion:** Obesity associated with the risk of depression and anxiety, fatigue, poorer QoL and higher disease activity.These findings suggest that obesity should be considered while assessing patients with PsA.

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SAT0395

## RESPONSIVENESS AND CLINICAL TRIAL DISCRIMINATION OF SWOLLEN AND TENDER JOINT COUNTS FOR THE MEASUREMENT OF MSK DISEASE ACTIVITY IN PSORIATIC ARTHRITIS

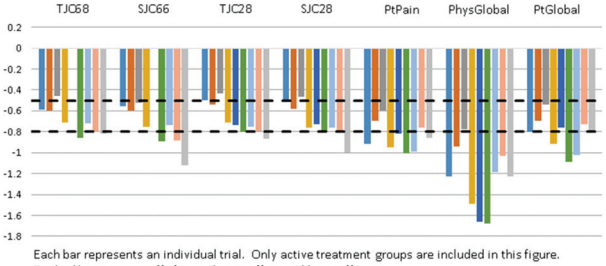
Ali Duarte-Garcia[1], Lihi Eder[2], Niti Goel[3], Maarten de Wit[4], Dafna D. Gladman[5], Oliver Fitzgerald[6], Philip J. Mease[7], Ying Ying Leung[8], Ana-Maria Orbai[9], Bev Shea[10], Vibeke Strand[11], Philip Helliwell[12], Alisa Stephens-Shields[13], William Tillett[14], Laura C. Coates[15], Alexis Ogdie[13], GRAPPA-OMERACT Psoriatic Arthritis Working Group. *[1]Mayo Clinic, Rochester, MN, United States of America; [2]Women's College, University of Toronto, Toronto, ON, Canada; [3]Patient Research Partner, Durham, NC, United States of America; [4]Patient Research Partner, Amsterdam, Netherlands; [5]Toronto Western, University of Toronto, Toronto, ON, Canada; [6]7St Vincent's University Hospital and Conway Institute for Biomolecular Research, University College, Dublin, Ireland; [7]Swedish Medical Center/ Providence-St. Joseph's Health and University of Washington, Seattle, WA, United States of America; [8]Singapore General Hospital, Singapore, Singapore; [9]Johns Hopkins University, Baltimore, MD, United States of America; [10]University of Ottawa, Ottawa, Canada; [11]Stanford University, Palo Alto, United States of America; [12]University of Leeds, Leeds, United Kingdom; [13]University of Pennsylvania, Philadelphia, PA, United States of America; [14]Royal National Hospital for Rheumatic Diseases and the University of Bath, Bath, United Kingdom; [15]University of Oxford, Oxford, United Kingdom*

**Background:** While tender and swollen joint counts (TJC and SJC) are key instruments for the assessment of peripheral arthritis in PsA, little is known about the psychometric properties of TJC and SJC in randomized controlled trials (RCTs) and how these properties differ among patient subgroups. [1]

**Objectives:** To assess the responsiveness and discrimination of TJC and SJC in PsA using RCT datasets and evaluate subgroups of patients with early vs. established disease and 3 or less vs 4 or more active joints.

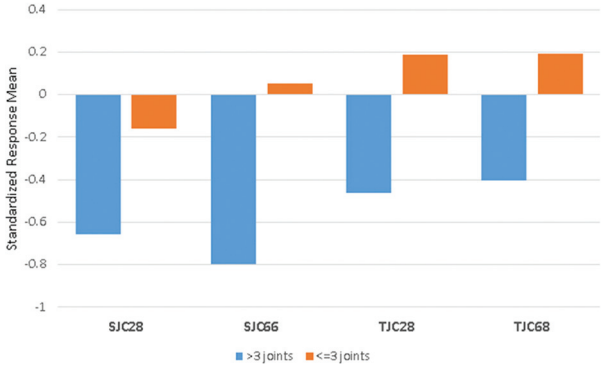
**Methods:** Patient-level data from 8 phase III RCTs and the TIght COntrol of Psoriatic Arthritis (TICOPA) trial were analyzed[2]. The standardized response mean (SRM, mean difference between baseline and follow up divided by the standard deviation (SD) of the mean difference) and standardized mean differences (SMD, mean difference in the treated group minus the mean difference in the placebo group divided by the pooled SD for the change) were used to address responsiveness and discrimination respectively. TJC28, SJC28, TJC68, and SJC66 were the primary measures of interest but physician and patient global assessments (PhGA and PtGA) and pain were included for comparison. SRMs were calculated in subgroups of patients with less than 3 (TJC68/SJC66 ≤ 3) or more than 3 (TJC68/SJC66) active joints as well as early (< 2 years) and established (≥2 years) disease.

**Figure 1. SRM among treated patients by trial**




Each bar represents an individual trial. Only active treatment groups are included in this figure. Dashed lines are cut offs for moderate effect and large effect.

**Figure 2. Responsiveness by Number of Active Joints**




**Results:** In traditional phase III RCTs, TJC and SJC were responsive and had good clinical trial discrimination. SRMs were similar and ranged from -0.8 to -0.4 ('moderate' responsiveness) (Figure 1). SMDs were similar among SJC28 and SJC66 and likewise between TJC28 and TJC68 but mostly within the small effect range (-0.2 to -0.5; not shown). PhGA and PtGA had higher SMDs than the joint counts. SRMs were substantially lower for joint counts (and also PtGA) among the low compared with the higher joint count groups (Figure 2). There were no substantial differences in SRMs between patients with early and established disease.

**Conclusion:** Joint counts are responsive to change and have reasonable discrimination in RCTs among patients higher disease activity at baseline. However, joint counts may not be ideal outcome measures in oligoarticular disease and have lower responsiveness and discrimination in this subgroup.

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