BiOTRAC
Biologic Treatment Registry across Canada - P02843

This study was conducted by Janssen Inc.

Real-World Efficacy of Anti-TNF in Psoriatic Arthritis Patients with Enthesitis and Correlation of Enthesitis with Tender / Swollen Joints

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Disclosures

- Clinical research, Advisory boards, Speaker

- Janssen
- Abbvie
- Amgen
- Merck
- Novartis
- UCB
- Pfizer
- Celgene
- BMS

Introduction

- Previous studies have shown that psoriatic arthritis (PsA) patients with enthesitis present with increased disease activity compared to patients without.
- Tender and swollen joints imply the presence of inflammation.
- Although tender joint count appears to be reliably assessed, there are still challenges in interrater reliability in swollen joint counts

Mease PJ, Arth Care & Res, 2011

Objectives

- To evaluate the effectiveness of anti-TNF agents in PsA patients with enthesitis at baseline treated in a Canadian routine clinical practice setting
- To explore the relative localization of enthesitis and joint swelling/tenderness
- To determine which of these conditions (swollen joints or enthesites) is more taken into account by physicians in a routine practice

Methods - Study Design and Population

- BioTRAC: Biological Treatment Registry Across Canada
- Multi-centre, prospective, observational study
- Patients treated with infliximab, golimumab, ustekinumab
- 116 rheumatology practices across Canada
- Initiated in February 2002 and is ongoing

Analysis Population

- 202 PsA patients with available baseline enthesitis information who were treated with IFX or GLM during 2005-2016 and 2010-2016, respectively, were included Patients were anti-TNFα naïve or treated with one biologic before enrolment
- Patients were assessed in a standardized fashion every 6 months provided this was as per routine clinical care

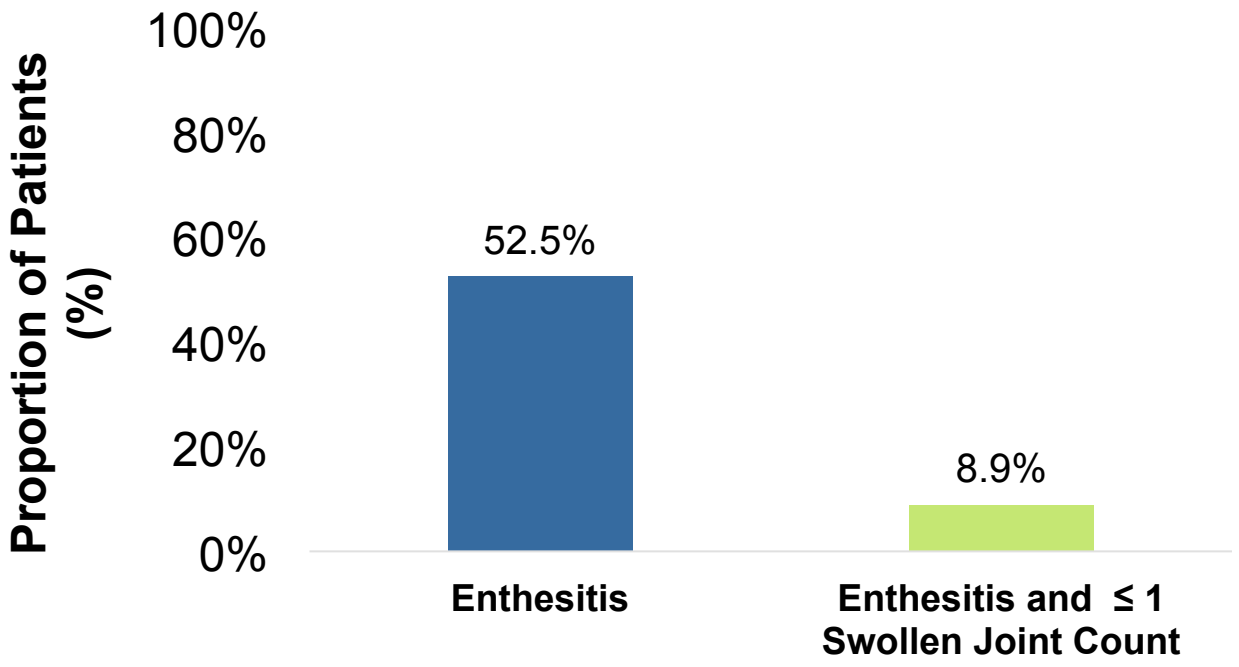
Methods - Statistical Methods

- For the comparison of the co-localization of enthesitis and joint involvement in the shoulders, elbows and knees the independent-samples t-test was used.
- Improvements over time in continuous variables were assessed for statistical significance with the paired t-test.
- Correlation between swollen joints, enthesitis count and physician global was assessed with Spearman's coefficient (r_s).

Baseline Characteristics

Parameter	N = 202
Age, years, mean (SD)	50.6 (11.8)
Disease duration, years, mean (SD)	5.8 (7.4)
DAS28, mean (SD)	4.4 (1.4)
HAQ, mean (SD)	1.1 (0.66)
SJC28, mean (SD)	5.2 (4.5)
TJC28, mean (SD)	7.4 (6.4)

Presence of Enthesites at Baseline



Joint swelling was higher in majority of anatomical sites with enthesites at Baseline

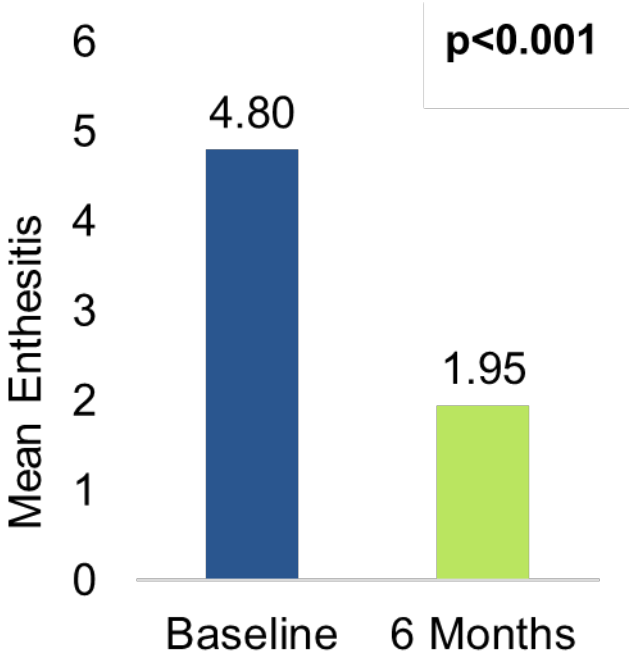
Presence of Enthesitis by Anatomical Site among Patients with Swollen Joints

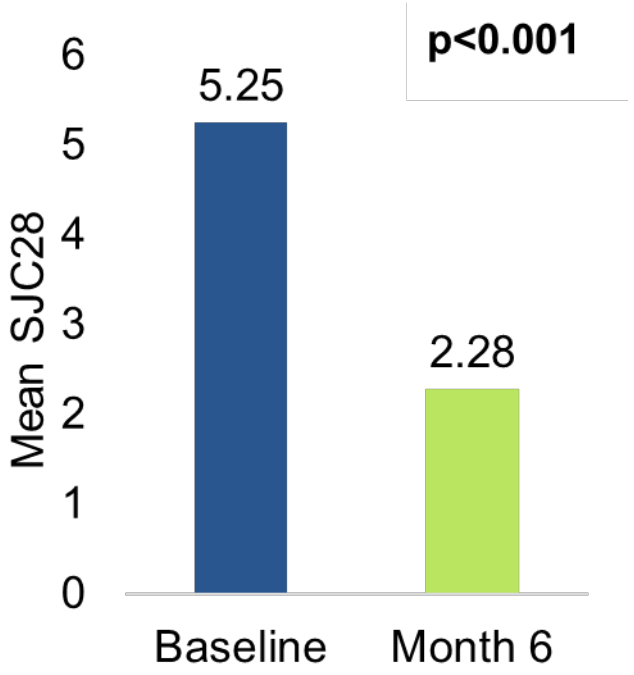
Anatomical Site	Enthesitis	No Enthesitis	p-value
Left Shoulder, %	11.8	3.0	**0.048**
Right Shoulder, %	10.8	3.7	*0.092*
Left Elbow, %	23.8	5.1	**0.001**
Right Elbow, %	25.0	6.8	**0.002**
Left Knee, %	43.2	14.8	**<0.001**
Right Knee, %	27.3	21.9	*0.543*

Joint tenderness and swelling was significantly ($P<0.05$) higher in all anatomical sites (shoulders, elbows, and knees) with enthesitis with the exception of the right knee and the right shoulder

Assessed with Chi-Square analysis.
Statistical significance denoted by bold font.

Statistically Significant Improvement in Enthesitis Count and in SJC Over Time





In correlation analysis, SJC28 showed a strong correlation (r_s=0.643) with physician global (MDGA) compared to enthesitis count where a moderate correlation (r_s=0.406) was observed with MDGA.

Joint tenderness was significantly higher in all anatomical sites with enthesites at Baseline

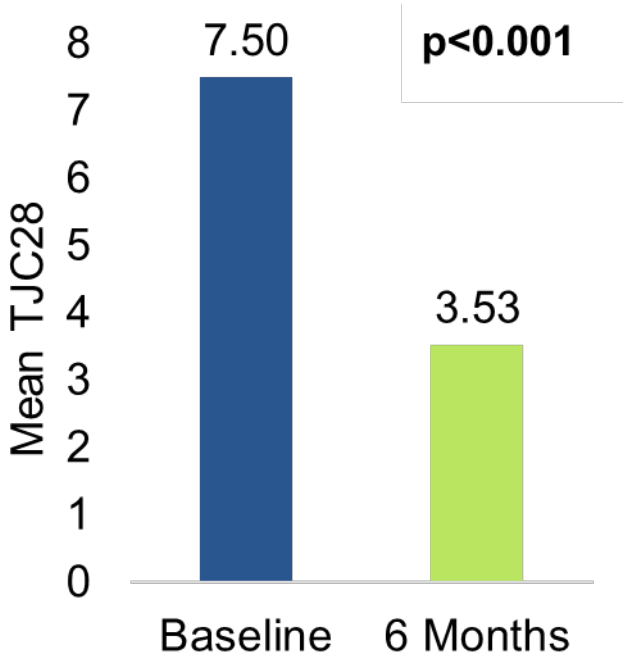
Presence of Enthesitis by Anatomical Site among Patients with Tender Joints

Anatomical Site	Enthesitis	No Enthesitis	p-value
Left Shoulder, %	52.9	22.1	**0.001**
Right Shoulder, %	56.8	24.4	**<0.001**
Left Elbow, %	45.2	9.7	**<0.001**
Right Elbow, %	55.8	11.0	**<0.001**
Left Knee, %	56.8	25.6	**0.001**
Right Knee, %	54.5	31.4	**0.007**

Statistical significance denoted by bold font.

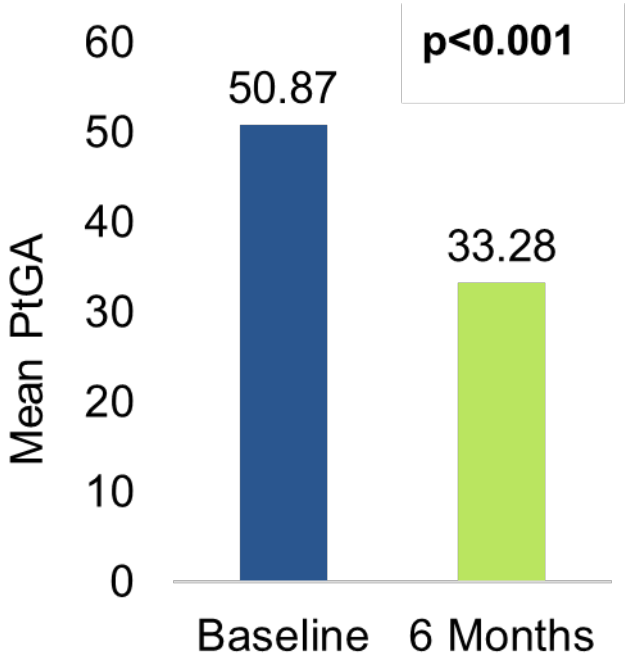
Assessed with Chi-Square analysis.

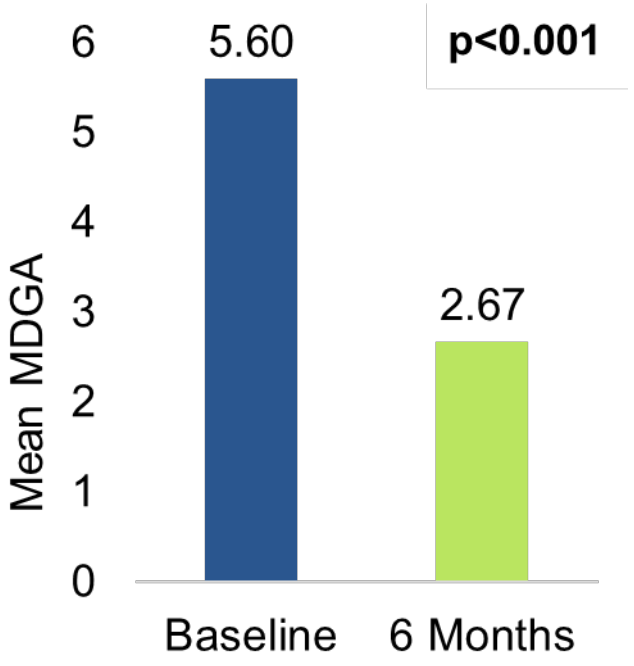
Statistically Significant TJC28 Improvement Over Time



Assessed with the paired samples t-test.
Statistical significance denoted by bold font.

Other Parameters





Statistically significant and clinically meaningful improvements in patient global and MDGA at 6 months of treatment

Conclusion

- A high prevalence of enthesitis was observed at anti-TNF treatment initiation (52.5%).
- Joint tenderness and swelling coincided with the entheseal points suggesting localized inflammation. However, physicians were found to take swollen joints more into account than the presence of enthesitis in routine practice.
- Treatment with IFX or GLM for 6 months was associated with a significant reduction in enthesitis, SJC, TJC as well as PtGA and MDGA (in a PsA population presenting with enthesitis at baseline)

Questions

- Does SJC or enthesitis drive treatment decisions more?
- Should enthesitis alone result in treatment decisions, without firm documentation by ultrasound? Is enthesitis confused with FMS?
- Should evaluation of enthesitis be a more standardized part of the physical exam?

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