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**Background:** Randomized controlled trials (RCTs) in psoriatic arthritis (PsA) have traditionally enrolled a homogenous subgroup of patients with more polyarticular disease, and the outcome measure used in PsA RCTs (ACR20) may not be ideal to measure differences between two active therapies nor capture change in patients with lower joint counts.

**Objectives:** We conducted a simulation study to determine how changing the inclusion criteria and the primary outcome measure would impact the outcome of a future RCT.

**Methods:** We used the Tight Control of PsA (TICOPA) trial to inform simulation of two hypothetical head-to-head trials comparing MTX to TNFi with 100 patients per arm. Within TICOPA, we identified MTX and TNFi new users; the visit at drug initiation became the hypothetical trial baseline visit, and the follow up visit was 12 weeks later. These data informed prediction models to simulate enrolled patients. We used propensity score-adjusted outcome models to account for potential confounding by indication. Trial 1, modeled after the SEAM-PsA trial, used typical enrollment criteria (≥3 tender joint count (TJC) and ≥3 swollen joint count (SJC)) and not severe (not meeting ≥3 TJC and ≥3 SJC) are shown in Table 1. Among “severe” patients, the mean probability of achieving ACR20 across simulations was approximately 0.27 in both arms and the observed relative risk (RR) TNFi vs MTX severe cohort across simulations was 1.03 (95% CI: 1.00-1.07). The full cohort had an RR of 1.03 (95% CI: 1.00-1.06).

**Results:** Among 188 patients in TICOPA, 179 patients initiated MTX, and 43 patients initiated TNFi within the first 36 weeks. Among these, 107 MTX initiators and 15 TNFi initiators had ≥3 TJC and ≥3 SJC at drug initiation. Baseline characteristics of those in the “severe” (≥3 TJC and ≥3 SJC) and not severe (not meeting ≥3 TJC and ≥3 SJC) are shown in Table 1. Among “severe” patients, the mean probability of achieving ACR20 across simulations was approximately 0.27 in both arms and the observed relative risk (RR) TNFi vs MTX severe cohort across simulations was 1.03 (95% CI: 1.00-1.07). The full cohort had an RR of 1.03 (95% CI: 1.00-1.06). The full cohort had an RR of 1.03 (95% CI: 1.00-1.06). The full cohort had an RR of 1.03 (95% CI: 1.00-1.06). The full cohort had an RR of 1.03 (95% CI: 1.00-1.06).

**Conclusion:** Including patients with lower joint counts in an RCT reduced the ability to detect change with therapy. Additionally, among the outcome measures used to detect a difference between two active therapies, PASDAS, cDAPSA, and RAPID3 outperformed ACR20.

**Disclosure of Interests:** Alexia Ogdie Grant/research support from: Pfizer, Novartis, Consultant of: Abbvie, Amgen, BMS, Celgene, Corrona, Janssen, Lilly, Pfizer, Novartis, Sarah Weinstein: None declared. Laura C Coates: None declared. Philip Helliwell: None declared. Alisa Stephens-Shields: None declared

**References:**


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**Table 1. Observed characteristics at drug initiation**

<table>
<thead>
<tr>
<th></th>
<th>Severe (n=148)</th>
<th>Not Severe (n=75)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MTX</strong> (n=127)</td>
<td>TNI (n=21)</td>
<td>SMD</td>
</tr>
<tr>
<td><strong>TICOPA Arm (no. (%))</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard Care</td>
<td>57 (45%)</td>
<td>4 (19%)</td>
</tr>
<tr>
<td>Intensive Management</td>
<td>70 (55%)</td>
<td>17 (21%)</td>
</tr>
<tr>
<td>Female (no. (%))</td>
<td>65 (51%)</td>
<td>11 (52%)</td>
</tr>
<tr>
<td><strong>SJC</strong> (mean (SD))</td>
<td>17.8 (15.3)</td>
<td>19.1 (17.3)</td>
</tr>
<tr>
<td><strong>SJC</strong> (mean (SD))</td>
<td>9.2 (2.4)</td>
<td>10.2 (12.1)</td>
</tr>
</tbody>
</table>

**Severe = ≥3 tender and ≥3 swollen joints**

**Not-severe = <3 tender or <3 swollen joints**

*Pseudo-baseline characteristics were at the time of drug initiation. In cases where the patient started a TNFi between visits, these were the values at the previous visit.

**Abbreviations:** SMD = standardized mean difference, TJC=tender joint count, SJC=swollen joint count

**Figure 1.** Risk Ratios (TNFi vs MTX) by Outcome Across 1000 Simulations

**Figure 2.** Risk Differences (TNFi – MTX) by Outcome Across 1000 Simulations

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**SAT0434 MINIMAL CLINICALLY IMPORTANT DIFFERENCE IN OUTCOME MEASURES FOR USE IN CLINICAL CARE AND PRAGMATIC TRIALS IN PSA**

A. Ogdie1, M. E. Husni2, J. Scher3, E. Craig4, S. Reddy1, J. A. Walsh1

1University of Pennsylvania, Philadelphia, United States of America; 2University of Iowa, Iowa City, United States of America; 3University of Utah, Salt Lake City, United States of America

**Background:** While several outcome measures have been studied for use in clinical studies of psoriatic arthritis, little is known about thresholds of meaning such as minimal clinically important improvement (MCII).

**Objectives:** To investigate the distribution of scores for candidate outcome measures for pragmatic trials in PsA and to calculate the MCII for each outcome measure.

**Methods:** We performed a longitudinal cohort study within the Psoriatic Arthritis Research Consortium (PARC), a multi-center study based in the US. Patients completed validated PROs (patient reported outcomes) and rheumatologists completed skin, joint, enthesis and dactylitis scores at therapy initiation and follow-up visits 12-16 weeks later. In addition, patients completed a global assessment of response at the follow up visit, categorizing their status as improved, stayed the same, or worsened and then rated the importance of the change on a scale from 0-7. We then calculated and plotted the change in each of the following outcomes:

1. Routine Assessment of Patient Index Data (RAPID3),
2. Disease Activity Score (DAPSA),
3. Clinical Disease Activity Score (cDAPSA),
4. PsA Disease Activity Score (PASDAS),
5. Psoriatic Arthritis Response Index with possible scores of $0-7$.

**Results:** Among 148 unique patients, 233 therapy change visits were eligible for analysis. The average age was 52.5 years, 52% were female and mean BMI was 29.6. Baseline RAPID3 was 11.1 (SD 6), cDAPSA 179 (SD 13.9), PROMIS PH 42 (SD 8), patient global 4.2 (SD 2.5), TJC 5.9 (SD 7.5), and SJC 2.9 (SD 4.5). TNFi comprised 61% of drug initiations, 21% were IL17i and the remainder were other biologics and oral systemic therapies. At follow up, 63 (27%) patients rated themselves as improved whereas 103 (44%) stayed the same and 67 (29%) reported