of pts per treatment had history of VTE (Figure 1). NHI for tofacitinib 5 and
10 mg BID, respectively, vs TNFi were 783 and 198 PY for VTE, 1347
and 589 PY for DVT, and 870 and 229 PY for PE, or, over 5 yrs, 153 and 40
pts for VTE, 269 and 118 pts for DVT, and 174 and 46 pts for PE. Identified BL
risk factors for PE across treatments included history of VTE, antidepressant
use, body mass index ≥30 kg/m2, corticosteroid use, male sex, age ≥65 yrs,
oral contraceptives/hormone-replacement therapy (HRT) use, and history of
hypertension (Table 1).

Conclusion: Generally, in ORAL Surveillance, VTE, DVT and PE IRs were
numerically higher for tofacitinib (10 > 5 mg BID) vs TNFi across 6-month
intervals, and for pts with vs without history of VTE. Multivariate Cox mod-
els identified BL risk factors for PE that may help support future treatment
decisions.

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Table 1. Comparison of baseline demographic and clinical characteristics between 1st and 2nd generation tsDMARDs

<table>
<thead>
<tr>
<th>All population</th>
<th>Bio naïve patients</th>
<th>Bioexperienced patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st generation tsDMARDs</td>
<td>2nd generation tsDMARDs</td>
<td>1st generation tsDMARDs</td>
</tr>
<tr>
<td>number</td>
<td>433</td>
<td>1210</td>
</tr>
<tr>
<td>Age (years)</td>
<td>60.8 ± 12.6*</td>
<td>57.3 ± 13.1*</td>
</tr>
<tr>
<td>Gender (men)</td>
<td>304 (72.6%)</td>
<td>833 (74.6%)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>73.3 ± 15.3</td>
<td>74.2 ± 15.3</td>
</tr>
<tr>
<td>Disease duration (years)</td>
<td>9.0 ± 8.9</td>
<td>10.0 ± 9.7</td>
</tr>
<tr>
<td>HAQ (0-3)</td>
<td>1.9 ± 0.6*</td>
<td>1.3 ± 0.8</td>
</tr>
<tr>
<td>PGA (0-100)</td>
<td>63.5 ± 19.2</td>
<td>63.0 ± 21.5</td>
</tr>
<tr>
<td>CRP (mg/l)</td>
<td>12.8 ± 11.0</td>
<td>11.7 ± 10.7</td>
</tr>
<tr>
<td>ESR (mm/h)</td>
<td>25.3 ± 20.1*</td>
<td>22.5 ± 18.3*</td>
</tr>
<tr>
<td>TJC</td>
<td>8.8 ± 6</td>
<td>8.4 ± 5.7</td>
</tr>
<tr>
<td>SJC28</td>
<td>6.1 ± 4.6</td>
<td>5.9 ± 4.6</td>
</tr>
<tr>
<td>DAS28</td>
<td>4.8 ± 10</td>
<td>4.7 ± 11</td>
</tr>
<tr>
<td>Bio-Experienced (yes)</td>
<td>226 (51.1%)*</td>
<td>728 (62%)</td>
</tr>
</tbody>
</table>

Number given are mean ± SD or number, proportion. b=biologic; ts= targeted synthetic; HAQ= health assessment questionnaire, PGA= Patient Global assessment; CRP= C-reactive protein; ESR= erythrocyte sedimentation rate; TJC= tender joint count; SJC= Swollen joint Count; DAS28 = disease activity score based on the 28joints; N= number. * Signifies p<0.05.