with IAEs, for which immunotherapy was not suppressed. However, the medication was suppressed in the remaining 40% of the cases. Exceptionally, one patient underwent a severe IAE (pneumonitis) that resulted in death. In terms of the occurrence of IAEs, there was no difference between sexes (men 6.3%, women 6.4%). The rheumatic IAEs responded well to treatment with corticosteroids without further biological treatments or DMARDs.

Conclusion: Immunotherapy is changing the typology of side effects in cancer patients, including IAEs. The cases analysed showed a relatively small number of rheumatic events that were easily solved with corticosteroids (nor the immunotherapy treatment was suppressed or immunosuppressive treatment was necessary). The study highlights the benefits of involving multidisciplinary medical teams to manage oncologic patients treated with immunotherapy towards the early detection and treatment of IAEs.

REFERENCES

Disclosure of Interests: None declared

DIRECT COMPARISON OF CERTOLIZUMAB PEGOL, ABATACEPT AND BIOSIMILAR INFLIXIMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED IN ROUTINE CARE. OBSERVATIONAL DATA FROM THE DANISH DANBIO REGISTRY ANALYZED LIKE A RANDOMIZED CLINICAL TRIAL

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Background: Nationwide Danish guidelines regarding RA patients (pts) initiating bDMARDs are issued approximately annually. For bio-naive pts on concomitant methotrexate (MTX) the recommended drugs (year, recommended compliance) were: certolizumab pegol(CTZ)/ABA/CT-P13: 33%/215/225). Baseline characteristics were similar across drugs. CTZ/P13 remission-rates after 6 and 12 months were: 37%/34%/44% and 37%/33%/36%, respectively. Adjusted odds ratios for achieving DAS28 remission were at 6 months: 0.96(95% CI: 0.61,5) for ABA and 1.38(0.92,2.1) for CT-P13; 12 months: 0.74(0.5,1.2) and 0.96 (0.6,1.5), CTZ reference drug(fig). The adjusted hazard ratios for withdrawal were 1.16(95% CI: 0.84,1.60) for ABA and 0.83 for CT-P13 (0.59,1.17)(table).

Objectives: To assess compliance to guidelines (justifying the assumption of surrogate randomization) and compare effectiveness of CTZ/ABA/CT-P13 in Danish RA patients treated according to guidelines.

Methods: Observational cohort study analyzed like a randomized clinical trial (RCT, intention-to-treat). RA patients were identified in DANBIO. Compliance in each calendar period was defined as number of pts adherent to guideline/norms of all bio-naive pts initiating bDMARD(+MTX). Outcomes were DAS28-remission rates (at 6 and 12 months) and one-year retention rates, compared according to treatments (confounder-adjusted full multivariable logistic and Cox regression analyses).

Results: Compliance to guidelines was 70%/65%/59%, and 776 patients were included (CTZ/ABA/CT-P13: 336/215/225). Baseline characteristics were similar across drugs. DAS28 remission-rates after 6 and 12 months were: 37%/34%/44% and 37%/33%/36%, respectively. Adjusted odds ratios for achieving DAS28 remission were at 6 months: 0.96(95% CI: 0.61,5) for ABA and 1.38(0.92,2.1) for CT-P13; 12 months: 0.74(0.5,1.2) and 0.96 (0.6,1.5), CTZ reference drug(fig). The adjusted hazard ratios for withdrawal were 1.16(95% CI: 0.84,1.60) for ABA and 0.83 for CT-P13 (0.59,1.17)(table).

Table. RA patients starting first bDMARD according to Danish national guidelines during the three calendar periods. Baseline characteristics and adjusted hazard ratios (HR) for withdrawal during the first year of treatment (Cox regression analyses).

<table>
<thead>
<tr>
<th></th>
<th>CT-P13 N=225</th>
<th>Abatacept N=215</th>
<th>Certolizumab pegol N=336</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected compliance to guideline</td>
<td>80%</td>
<td>80%</td>
<td>80%</td>
</tr>
<tr>
<td>Actual compliance to guideline</td>
<td>70%</td>
<td>65%</td>
<td>59%</td>
</tr>
<tr>
<td>Age, years</td>
<td>57 (48-65)</td>
<td>57 (48-65)</td>
<td>59 (50-66)</td>
</tr>
<tr>
<td>Female</td>
<td>71%</td>
<td>72%</td>
<td>68%</td>
</tr>
<tr>
<td>Hazard ratio for withdrawing from treatment 0-90 days</td>
<td>HR (95% CI)</td>
<td>HR (95% CI)</td>
<td>HR (95% CI)</td>
</tr>
<tr>
<td>Adjusted for age and gender</td>
<td>1.0 (ref)</td>
<td>0.78 (0.45 to 1.36)</td>
<td>0.63 (0.35 to 1.13)</td>
</tr>
<tr>
<td>Fully adjusted*</td>
<td>1.0 (ref)</td>
<td>0.70 (0.39 to 1.27)</td>
<td>0.58 (0.33 to 1.10)</td>
</tr>
<tr>
<td>91-365 days</td>
<td>HR (95% CI)</td>
<td>HR (95% CI)</td>
<td>HR (95% CI)</td>
</tr>
<tr>
<td>Adjusted for age and gender</td>
<td>1.0 (ref)</td>
<td>1.15 (0.85 to 1.56)</td>
<td>0.74 (0.53 to 1.04)</td>
</tr>
<tr>
<td>Fully adjusted*</td>
<td>1.0 (ref)</td>
<td>1.16 (0.84 to 1.60)</td>
<td>0.83 (0.59 to 1.17)</td>
</tr>
</tbody>
</table>

Variables are median (IQR) unless otherwise mentioned. *age, gender, DAS28, HAQ, smoking, CCI Abbreviations: CCI: Charlson Comorbidity Index: CI: confidence intervals, DAS28: Disease Activity Score of 28 joints, HAQ: Health assessment questionnaire

Conclusions: Compliance to guidelines was high. Direct comparison showed that remission and retention rates were highest for CT-P13, intermediate for certolizumab and lowest for abatacept. Results should, however, be interpreted with caution due to wide CIs and risk of residual confounding.

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