Abstract #: 3

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Title: **Effectiveness and safety of tofacitinib in Canadian patients with rheumatoid arthritis with vs without cardiovascular risk factors: a subgroup analysis of the multicentre, observational CANTORAL study**

Objective(s): ORAL Surveillance, a post-authorisation safety study of rheumatoid arthritis (RA) patients aged ≥50 years with ≥1 additional CV risk factor, demonstrated an increased risk of MACE and malignancies excluding NMSC for tofacitinib vs TNFi.(1) This pre-specified subgroup analysis of the ongoing Canadian observational CANTORAL study evaluated effectiveness/safety of tofacitinib in patients enriched for CV risk, using criteria adapted from ORAL Surveillance, and in patients not meeting CV risk criteria.

Method(s): Patients with moderate-to-severe RA initiating tofacitinib between 11/2017-07/2020 were enrolled across 45 Canadian sites and managed per routine clinical care. Data from an interim analysis (data-cut: 16/07/2021) were stratified as CV+ (patients aged ≥50 years with ≥1 of the following additional CV risk factors: current smoking; hypertension; diabetes mellitus; history of CAD; RA-associated extra-articular disease) or CV- (≥18 years without above CV risk factors). Effectiveness outcomes (all patients) to Month (M)18: proportions of patients achieving CDAI LDA (<10), CDAI remission (<2.8), DAS28-4(CRP) <3.2 and <2.6, and change from baseline (Δ) in HAQ-DI over time. Safety (patients with ≥1 post-baseline assessment) and persistence (all patients) were evaluated to M36.

Result(s): 272/232 patients were included in the CV+/CV- cohorts. Patients in the CV+ vs CV- cohort were older, with longer RA duration and higher frequency of comorbidities. At M3, patients in the CV+/CV- cohorts attained generally similar rates of CDAI LDA (41.3%/44.8%) and remission (9.9%/14.6%), and DAS28-4(CRP) <3.2 (43.0%/40.1%) and <2.6 (24.7%/27.1%); ΔHAQ-DI was -0.32/-0.34. Effectiveness results were generally maintained to M18. In the CV+/CV- cohorts, respectively, IRs (events/100 patient-years) for treatment-emergent AEs and serious AEs were 138.5/112.5 and 17.0/5.6. Serious infections, HZ, MACE, malignancies excluding NMSC, NMSC, and arterial/venous thromboembolism IRs were 5.5/1.7, 1.4/1.1, 1.6/0.0, 2.1/0.3, 0.7/0.6, and 0.5/0.0; deaths occurred in 3/1 patients (IRs: 1.2/0.3) in the CV+/CV- cohorts. Persistence was generally comparable between cohorts.

Conclusion(s): Tofacitinib effectiveness/persistence over time were generally similar in CV+/CV- cohorts. AEs were more common in CV+ patients, who were older with more comorbidities. These findings support the need for appropriate CV risk management in RA patients.(2) Limitations included small sample sizes due to subgrouping.

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1. Ytterberg SR, et al. N Engl J Med 2022;386:316–326.
2. Agra R, et al. Ann Rheum Dis 2017;76:17-28