Impact of sex on disease pathogenesis and outcome

**POS0359 SEX-RELATED INEQUITY IN RANDOMIZED CONTROLLED TRIALS IN PSORIATIC ARTHRITIS: A SYSTEMATIC LITERATURE REVIEW AND META-ANALYSIS**

**Keywords:** Psoriatic arthritis, Spondyloarthritis, Clinical Trials

**Methods:** A systematic literature search of Medline, Embase and Central databases, and conference abstract archives from January 1, 2000 to June 30, 2022. We included RCTs that reported sex-disaggregated results and assessed the efficacy of an advanced therapy (biologic or targeted synthetic) in adult participants with PsA. Efficacy end points included the proportion of participants achieving minimal disease activity (MDA) or meeting the American College of Rheumatology 20 (ACR20) and ACR50 response criteria at the primary endpoint of the trial. We used random-effect models to calculate pooled effects for responses in males vs. females for the different classes of advanced therapies (Odds Ratio (OR) and 95% Confidence Interval (CI)).

**Results:** We included a total of 52 RCTs, accounting for 21,769 participants, in the review. An equal participation of male and female patients was found (50.1% male participants). Only 9 trials (17.3%, 5,604 participants) reported sex-disaggregated baseline characteristics, 16 trials (30.7%, 9,028 participants) reported sex-disaggregated efficacy endpoints and 2 trials (3.8%, 1,005 participants) reported sex-disaggregated safety endpoints. Female patients had significantly higher baseline psoriasis area and severity index (PASI) and CRP. Differences in pooled estimates of efficacy endpoints were evident for male and female patients across the different classes of advanced therapies. The probability of achieving ACR20 responses was significantly higher in males vs. females with all advanced therapies, except JAKi (OR 1.09, 95% CI 0.73, 1.62) [Figure 1B]. The probability of achieving MDA was higher in males across all classes of advanced therapies, including IL-17i (OR 1.99, 95% CI 1.50, 2.63), IL-23i (OR 1.79, 95% CI 1.29, 2.50), TNFi (OR 2.62, 95% CI 1.54, 4.44) and JAKi (OR 1.77, 95% CI 1.15, 2.73) and IL-12/23i (OR 1.82, 95% CI 0.97, 3.4) [Figure 1A].

**Conclusion:** Based on the reported results, female patients participating in RCTs are less likely to achieve efficacy endpoints for most classes of advanced therapies. Some differences in responses were found across classes of advanced therapies. RCTs should report sex-disaggregated results to identify sex-related differences in efficacy and safety outcomes which will inform patient-centered therapeutic strategies.

**REFERENCES:** NIL.

**Disclosure of Interests:** NIL.

**Discipline of Interests:** Li Eder Grant/research support from: Received educational and research grants from Abbvie, UCB, Pfizer, Janssen, Novartis, Eli Lilly, Sandoz, Fresenius Kabi, Sivakami Mylvaganam: None declared, Jordi Pardo: None declared, Jennifer Petkovic: None declared, Vibeke Strand: None declared. Philip J Mease: Speakers bureau: Abbvie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, Janssen, Novartis, Pfizer, UCB, Consultant of: Abbvie, Aclaris, Amgen, Armer, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Galagapos, Gilead, GlaxoSmithKline, Immungene, Janssen, Moonlake, Novartis, Pfizer, Sun Pharma, UCB, Grant/ research support from: Abbvie, Armer, Bristol Meyers Squibb, Eli Lilly, Galagapos, Gilead, Janssen, Novartis, Pfizer, Sun Pharma, UCB, Keith Colaco: None declared.

**DOI:** 10.1136/annrheumdis-2023-eular.1416

**POS0360 X-CHROMOSOME DOSAGE, RATHER THAN THE GONADAL SEX ITSELF, MAJORLY CONTRIBUTES TO SEX BIASES IN AUTOIMMUNITY IN HUMANS**

**Keywords:** Autoantibodies, Gender/diversity issues

**Background:** Most autoimmune diseases exhibit a profound female sex bias. Mechanisms underlying this sexual dimorphism remain unclear. We previously reported that the XX sex chromosome complement, as compared to XY, imparts greater susceptibility to autoimmune diseases such as lupus in experimental models (Smith-Bouvier D, et al, J Exp Med 2008). Gonadectomized XX female

**Ann Rheum Dis:** first published as 10.1136/annrheumdis-2023-eular.1416 on 30 May 2023. Downloaded from http://ard.bmj.com/ on July 22, 2023 by guest. Protected by copyright.