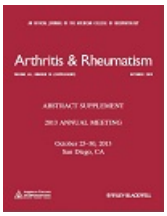

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Assessing Janus Kinase Inhibitor's Place In Therapy In Established Rheumatoid Arthritis Patients – From A Simplified Indirect Comparison Versus Tumor Necrosis Factor Inhibitors To A Bayesian Probability Of Response – The Value Of Transparency.

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Background/Purpose:

Bayesian style network meta-analyses and mixed treatment comparisons help address potential bias from effect modifying trial covariates within indirect comparisons and are theoretically easier to incorporate into decision making, but are not commonly used today by providers when making treatment decisions. Health care reform is paving the way for potentially easier access to tools like this, however quick interpretation still requires as simple an indirect comparison as is reliable, with a preference for greater transparency. From provider perspective, compare tumor necrosis factor inhibitors (TNFi) to Janus kinase inhibitor tofacitinib (TOFA) in established RA patients when used with non-biologic disease modifiers (DMARDs).

Methods:

A systematic review focused on randomized controlled trials (RCTs) with unsatisfactory response to prior DMARD, placebo comparator, active treatment with add-on DMARD, lowest labeled dose and 24-week ACR20 endpoint. Outcomes were extracted double-blind and analysed using a payer validated simulation tool. Indirect comparisons followed ISPOR taskforce on good research practices. ACR20 response was also analyzed within a Bayesian framework, estimating the percentage of time TNF inhibitors had a greater response than tofacitinib. Results presented as relative risks (RR) with confidence intervals where appropriate. Probabilities did not include statistical analyses. Each trial result versus placebo was graphically presented, for transparency, and rank ordered based on relative risk (RR) versus placebo.

Results:

Eight TNFi and three TOFA RCTs were identified that reported ACR20 results at 24 weeks. Trials differed primarily in placebo response and intent-to-treat (ITT) reporting methodology. Based on published ITT evidence, it was not possible to extract ACR50 and ACR70 scores for all TOFA trials. For ACR20, six of eight TNFi trials had RR values larger than combined TOFA 5mg results. The indirect RR (and confidence interval) of TNFi versus TOFA for ACR20 was 1.48 (1.02 to 2.14). I2heterogeneity values were zero for TOFA trial data, and were > 85% for TNFi trials. The probability the risk difference (RD) > 0 from the Bayesian analysis was 85.4% and 80.6% when unadjusted and adjusted for baseline risk respectively. RR > 1.0 and RD>0 favor TNFi. DAS Remission and HAQ-DI results were not significantly different TNFi versus TOFA. Results may be sensitive to trials included and time point selected.

Conclusion:

Visual inspection of original trial results and the multiple traditional meta-analyses helped identify how and why TNFi compares favorably to TOFA on the most common trial primary outcome (ACR20). Simple indirect comparisons demonstrate analyses of relative treatment effects available to providers, based on published evidence and with access to simulation tools. Supplementing with easily interpretable and adjustable probability of response versus placebo analysis, allows for a more transparent discussion on place in therapy of new treatments. Based on this analysis, time point and outcome, TNFi are likely to be more effective than TOFA more often, when considering biologics used concomitantly with DMARDs.

Disclosure: M. P. Ingham, Janssen Scientific Affairs, LLC, 3; P. Song, Janssen Scientific Affairs, LLC, 5; S. Cartier, Janssen Scientific Affairs, LLC, 5; K. Lawson-Remer, Janssen Scientific Affairs, LLC, 5; E. Murray, Janssen Scientific Affairs, LLC, 5.

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