Background: Rheumatoid arthritis (RA) patients are at increased risk of gastro-intestinal (GI) perforations compared with non-RA patients, resulting in increased mortality. Clinical trials, post-marketing studies and registries have reported an increased risk of GI perforations in RA patients treated with tocilizumab.

Objectives: The aim of our study was to assess the incidence of GI complications among RA patients receiving bDMARDs in observational cohort studies.

Methods: A systematic literature review was carried out through September 2020 on the Pubmed, Embase and international congress databases, selecting observational cohort studies assessing the incidence of GI complications, including perforations and diverticulitis, in RA patients receiving bDMARDs. Keywords were “gastrointestinal perforation,” “gastrointestinal disease,” “diverticulitis,” “biological DMARDs” and “rheumatoid arthritis” with no publication date limit. Studies were selected independently by two readers. Data were extracted and meta-analysed with Review Manager Software, with random-effects models, when-by one investigator and independently checked by another. A meta-analysis was performed including more patients to assess retention rate of bDMARDs and identify predictors of discontinuation.

Results: The search revealed 232 articles and abstracts of potential interest, and further examination resulted in 7 studies fulfilling required criteria. Among bDMARDs, Tocilizumab was associated with an increased incidence of GI perforations, with an overall incidence of 2.40 per 1000 person-years (95% confidence interval [95% CI] 1.45-3.35). The overall incidences of GI perforations were 1.01 per 1000 PY [0.75-1.27] for TNF inhibitors, 1.07 per 1000 PY [0.53-1.62] for abatacept and 1.12 per 1000 PY [0.16-2.08] for rituximab (Figure 1). In RA patients treated with tocilizumab, most of the perforations were located in the lower GI tract, with an incidence of 2.24 per 1000 PY [1.24-3.52]. The incidences of upper GI perforations were similar across the different bDMARDs. The incidences of diverticulitis were 4.99 per 1000 PY [4.08-5.99] in RA patients receiving tocilizumab and 1.81 per 1000 PY [1.47-2.19] in those receiving TNF inhibitors.

Conclusion: In our meta-analysis, focused in RA patients receiving bDMARDs in observational cohort studies, tocilizumab was associated with an increased incidence of GI perforations, mainly located in the lower GI tract. An history of diverticulitis and long-term corticosteroid therapy were associated with an increased risk of GI perforations.

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