

REAL-WORLD EFFECTIVENESS AND SAFETY OF USTEKINUMAB IN PATIENTS WITH ULCERATIVE COLITIS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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INTRODUCTION

Studies evaluating effectiveness in the real-world setting are relevant to provide generalizable clinical efficacy that confirm results reported by RCTs. Given the wide range of therapeutic options available for UC, it is of particular interest to assess the real-world effectiveness and safety of ustekinumab to enable patients and clinicians to make an informed decision.

AIM

The aim of this systematic review was to summarize reported evidence on the real-world outcomes of ustekinumab for UC and to conduct a meta-analysis of effectiveness and safety data.

METHOD

- A systematic search was conducted in electronic databases PubMed, Web of Science, EMBASE, and Science Direct, and conference proceedings until 15 September 2022 for real-world studies evaluating ustekinumab for UC.
- A random-effects meta-analysis model was used to calculate the pooled rates of clinical and safety outcomes.
- We evaluated the outcomes at week 8, weeks 12 to 16, month 6, and month 12.
- Need for colectomy and adverse events (AE) were reported as percentages and incidence rates (IRs) per 100 patients-year (PY) of exposure.
- Joanna Briggs Institute (JBI) Critical Appraisal tool was used to assess the study quality and the risk of bias.
- The heterogeneity of each study was assessed with the I² statistic according to the recommendations of Cochrane Handbook for Systematic Reviews of Interventions

RESULTS

Of the 254 citations identified, **19 studies** were included with **3786 patients**. According to JBI criteria for quality assessment, 14 studies showed low risk of bias, and 5 articles showed moderate risk

Sixteen studies reported **prior exposure to biologics or JAK inhibitors** and included 1003 patients, of whom 92.3% were previously treated with any biologic, 61.1% with both anti-TNF and vedolizumab, and 16.4% with any biologic and tofacitinib (**Figure 1**).

Remission was achieved in 45.4% of patients at week 8 (95% confidence interval 30.1-60.6%), 43.8% (38.4-49.2%) at weeks 12 to 16, 44.6% (35.9-53.3%) at month 6, and 50.6% (36.3-64.8%) at month 12 (**Figure 2**).

Response was achieved in 61.2%, 59.4%, 65.2%, and 76.8% of patients at week 8, weeks 12 to 16, month 6, and month 12, respectively (**Figure 3**).

Corticosteroid-free remission was achieved in 18.7%, 36.8%, 34.5%, and 39% of patients at week 8, weeks 12 to 16, month 6, and month 12, respectively.

Endoscopic improvement was achieved in 29.9%, 24.3% %, and 58.2% of patients at weeks 12 to 16, month 6, and month 12, respectively.

Almost 30% of the patients needed **dose escalation**, which was effective in 40% of these patients.

The pooled rate of **persistence with ustekinumab** was 76.9% and 73.3% at month 9 and month 12, respectively.

The IRs of **colectomy, AE, serious AE, and serious infections** were 5.1, 7.9, 1 and 0.5 per 100 PY, respectively (**Figure 4**).

CONCLUSIONS

- The results of this meta-analysis of observational studies confirm the effectiveness of ustekinumab in a highly treatment-refractory population of patients with moderate-to-severe UC.
- The acceptable safety data presented here support the positive long-term benefit-risk profile of ustekinumab in the treatment of UC.
- These real-world effectiveness and safety results were consistent with clinical trials and provide a broader perspective that can be used to aid treatment decisions in a more heterogeneous clinical setting.

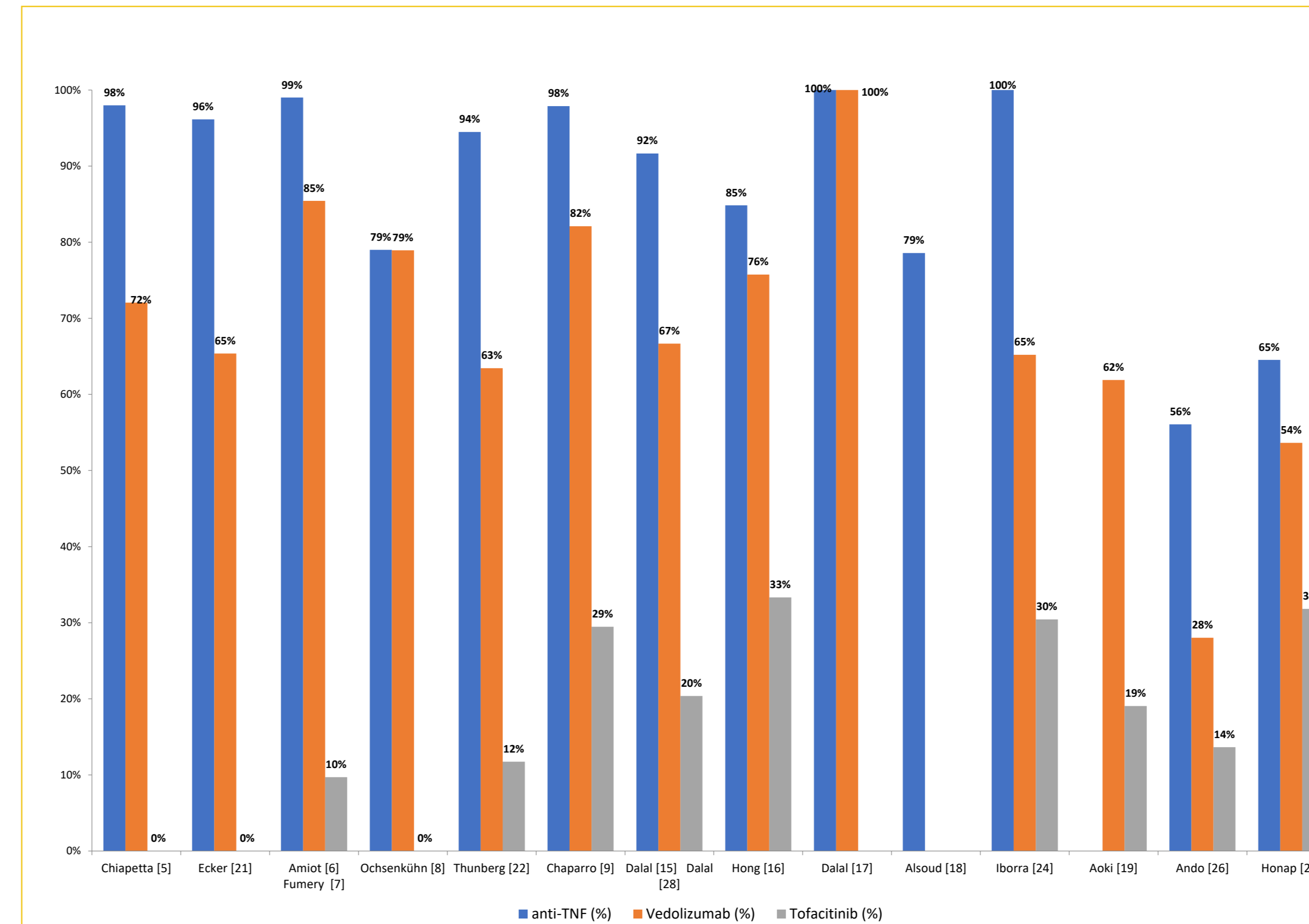


Figure 1. Proportion of patients with prior exposure to anti-TNF, vedolizumab, or tofacitinib, alone or consecutively.

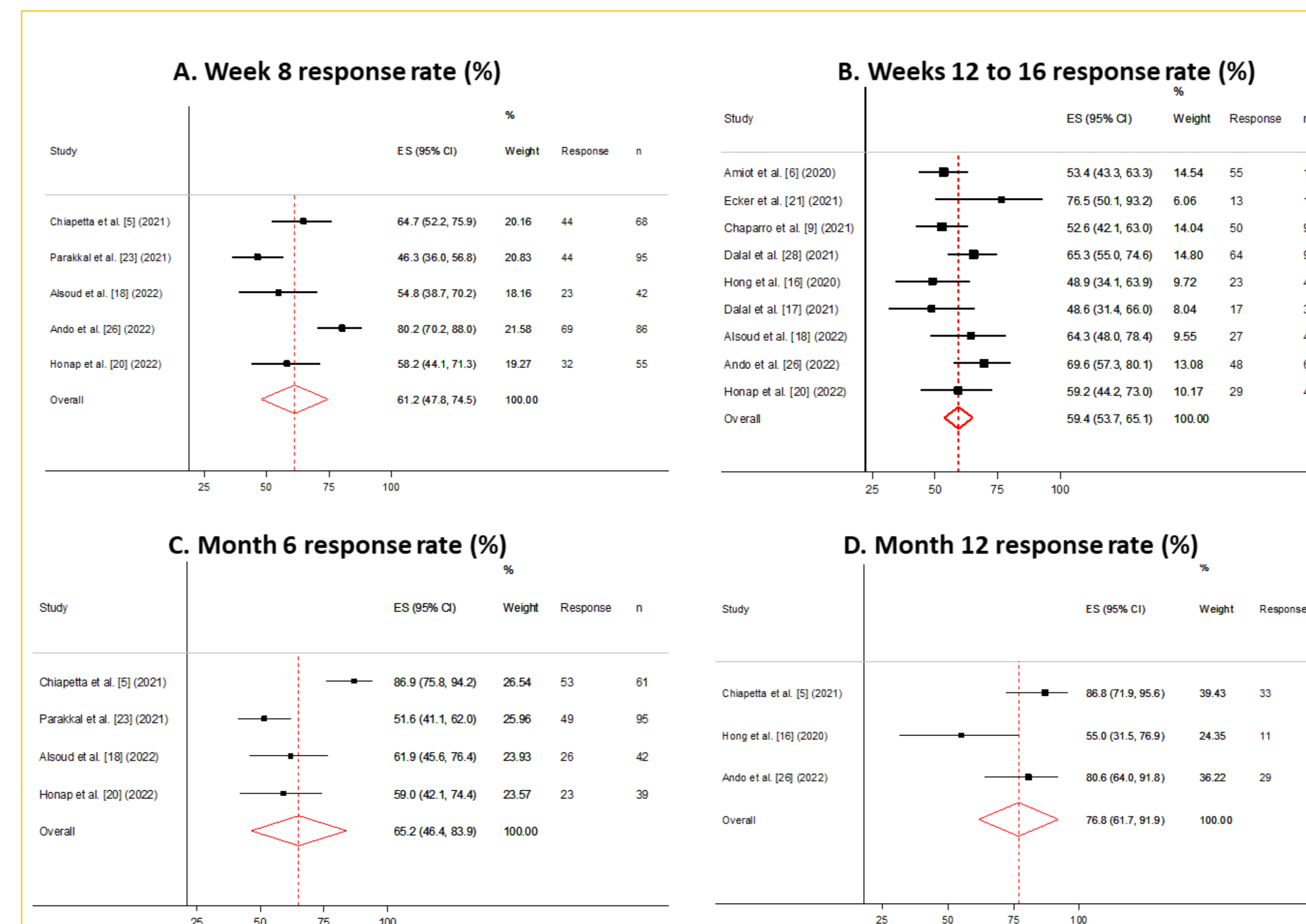


Figure 3. Pooled response rates at weeks 8 and 12-16, and months 6 and 12.

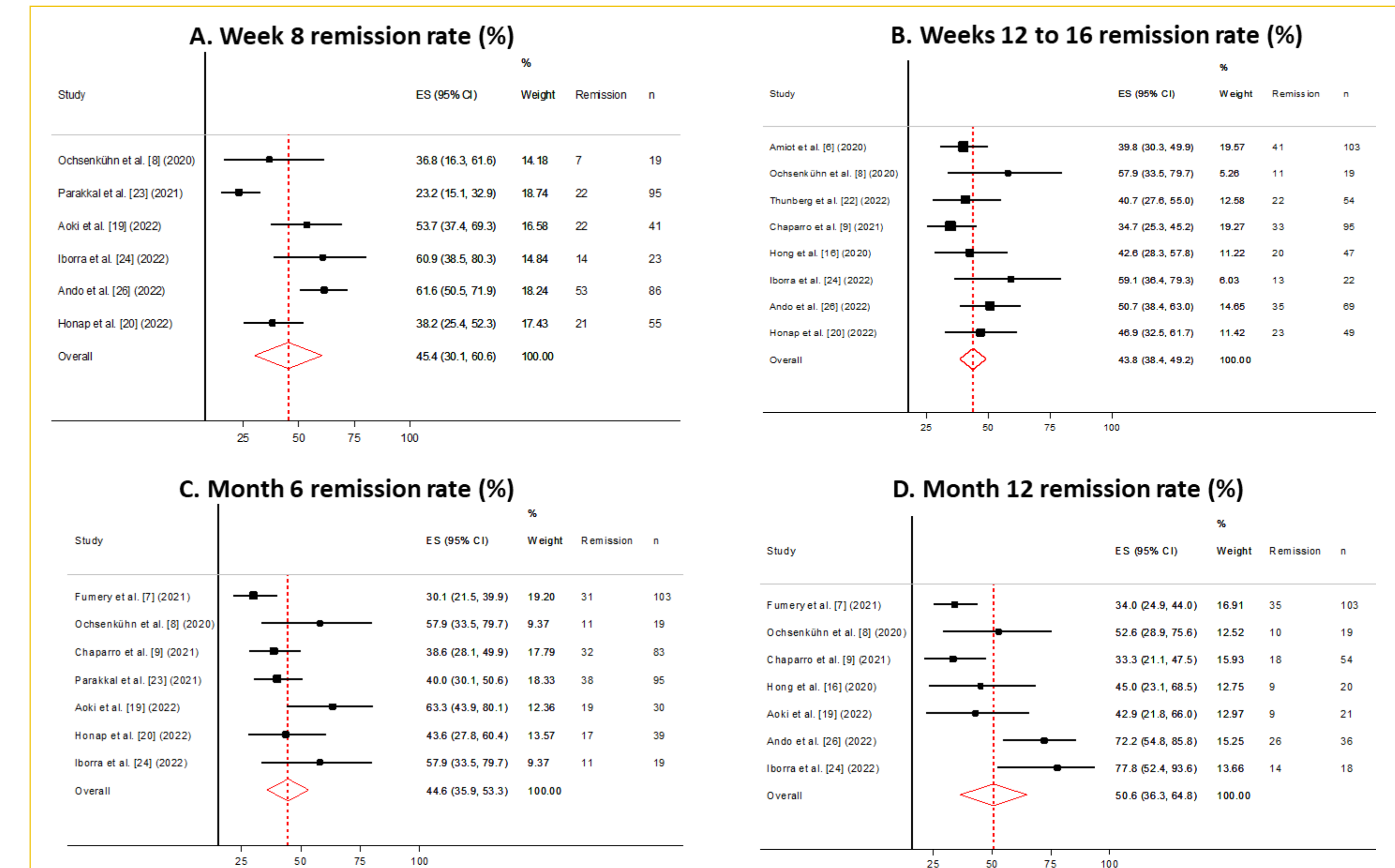


Figure 2. Pooled remission rates at weeks 8 and 12-16, and months 6 and 12.

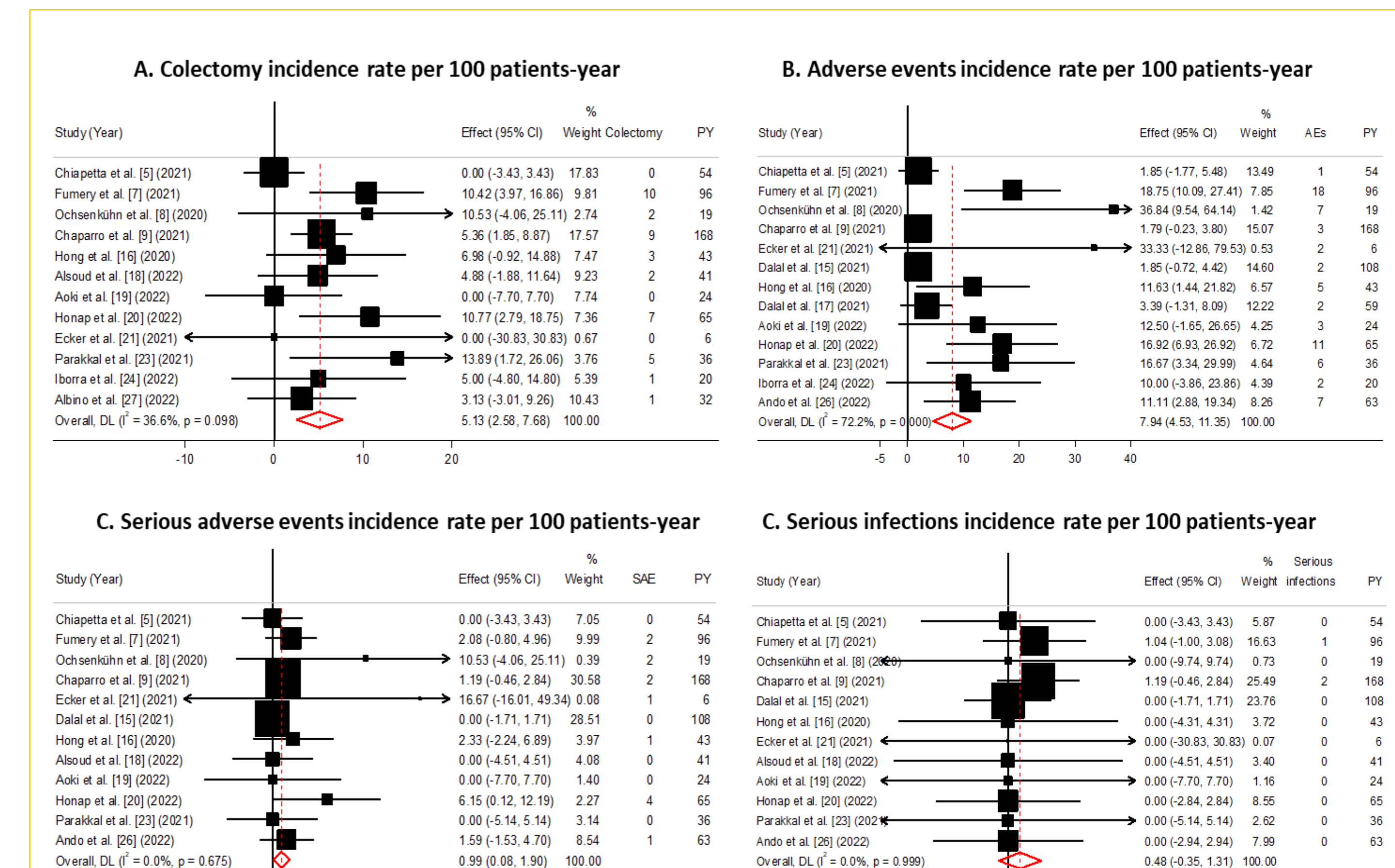


Figure 4. Pooled incidence rates of colectomy, adverse events (AE), serious AE, and serious infections

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