Health-Related Quality of Life in Ulcerative Colitis Patients Treated With Tofacitinib In Randomised Controlled Trials: A Systematic Review and Meta-Analysis

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Introduction and Objectives

- Ulcerative colitis (UC) negatively affects health-related quality of life (HRQoL) of patients, but an effective treatment can increase the quality of life and the condition can reach normal or near normal levels. However, the evidence on this topic is scarce.[1]
- The objective of the current study is to determine the HRQoL in UC patients treated with tofacitinib in randomised controlled trials (RCTs).

Methodology

- Medline® and Embase® databases via Ovid and Google scholar databases were searched, reviewed and extracted to identify the relevant English studies.
- In addition, clinicaltrials.gov was manually searched for relevant studies.
- Two reviewers independently searched for articles, reviewed and extracted data, with differences resolved through consensus.
- The Cochrane risk of bias (ROB 2) tool was used to assess the quality of included studies.
- A meta-analysis using random effects model was conducted to calculate pooled effect estimates with 95% confidence intervals (CI) for HRQoL.
- RCTs including patients with UC treated with tofacitinib were included.
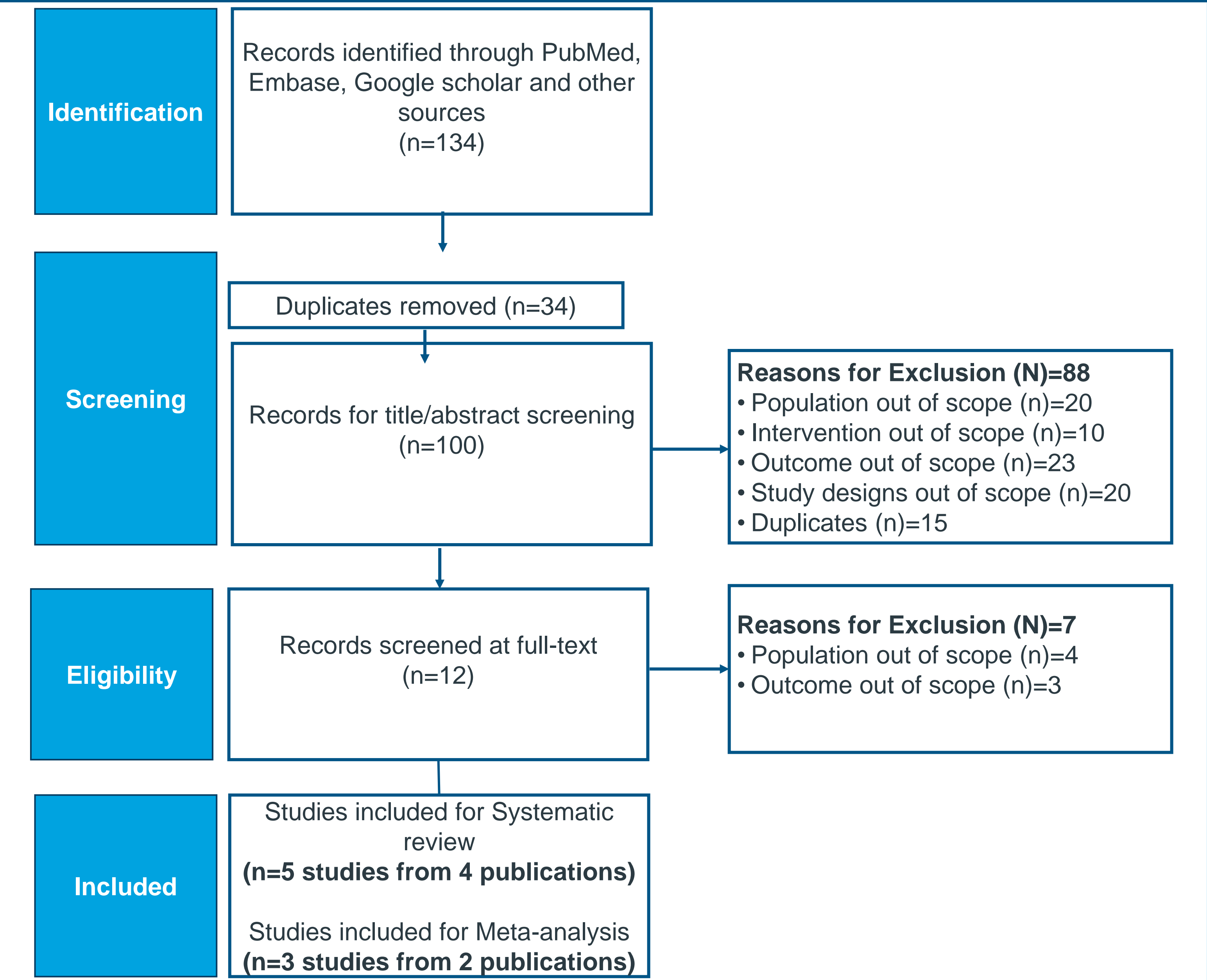
Table 1: Study eligibility criteria

PICOS	Inclusion criteria
Populations	Ulcerative colitis
Interventions/	Tofacitinib
Comparators	Placebo
Outcomes	Change from baseline in IBDQ total score at week 4, week 8
Study designs	Randomized clinical trials

Results

Study Selection:

- Out of 100 articles screened, five studies[1-4] (N=134) were included in this systematic review.
- Three RCTs[1,4] comparing tofacitinib with placebo were included for meta-analyses.

Figure 1: PRISMA chart of included studies

- The pooled analysis of two trials (n=1109) at week 4 showed better HRQoL measures (mean change from baseline in total IBDQ score) in ulcerative colitis patients treated with tofacitinib 10 mg BID in comparison with placebo mean difference

[MD] 16.94; 95% CI 11.99 to 21.89) as presented in **Figure 2**.

- At week 8, pooled analysis of three trials (n=1125) showed better HRQoL measures (mean change from baseline in total IBDQ score) in patients treated with tofacitinib 10 mg BID versus placebo (Mean difference, MD 18.44; 95% CI 13.54 to 23.33) as presented in **Figure 3**.
- The mean change from baseline in total IBDQ score in East Asian patients (Japan, Korea, and Taiwan)[3] was found to be numerically greater with tofacitinib 10 mg BID at week 8 than week 4 (27.4 vs 22.5, one study) versus placebo whereas in Japanese patients[2], tofacitinib 10 mg BID showed quantitatively higher mean change from baseline in total IBDQ score at week 4 and week 8 versus placebo.

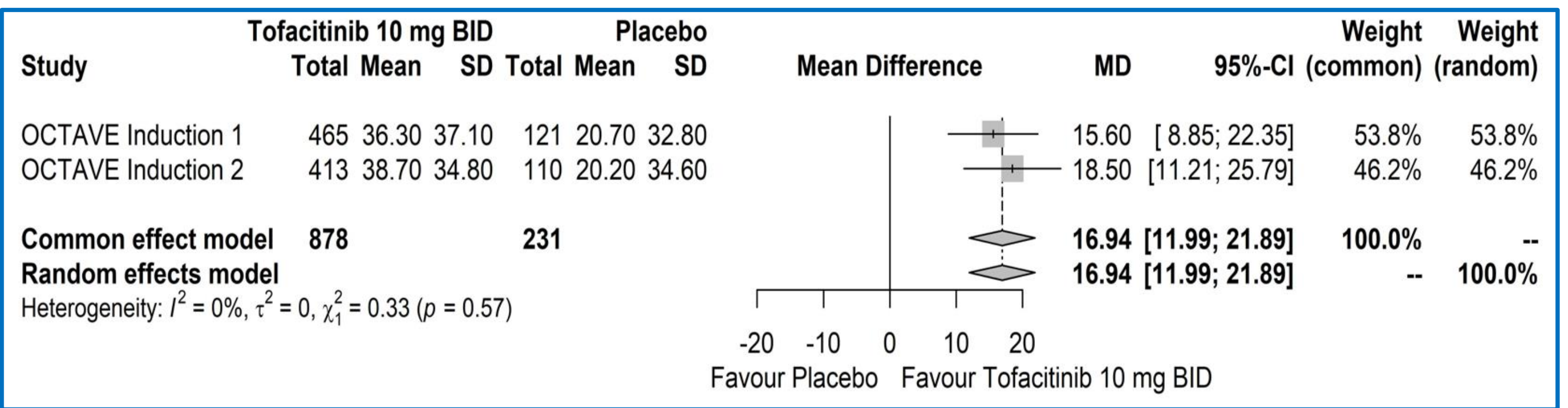### Figure 2: Mean change from baseline in IBDQ total score at week 4

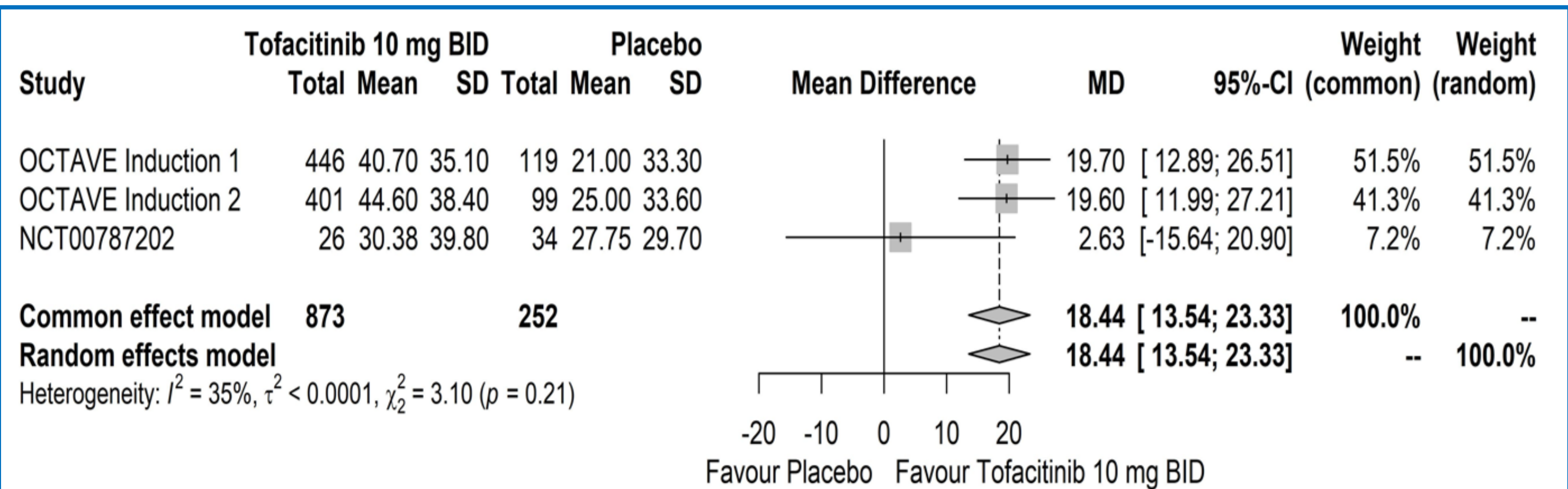### Figure 3: Mean change from baseline in IBDQ total score at week 8

Figure 4: Cochrane Risk of Bias

Conclusions

- The evidence suggest that the tofacitinib 10 mg BID can be considered as an effective treatment for significantly improving in the IBDQ total score compared to placebo at week 4 and week 8.
- The improvement in the HRQoL is continued over 52 weeks of maintenance therapy with tofacitinib 5 mg and 10 mg BID.
- Further high-quality RCTs are needed to support the current research question.

References

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