

Evaluating The Adjunctive Role Of Probiotics Compared To Placebo Across Multiple Clinical Outcomes In The Pharmacological Management Of Inflammatory Bowel Disease: A Comprehensive Meta-analysis Of RCTs



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MAY 3-6, 2025 | SAN DIEGO, CA

BACKGROUND

Inflammatory Bowel Disease (IBD) is a chronic inflammatory condition with significant morbidity. Probiotics, which modulate the gut microbiome and immune response, have emerged as a potential adjunctive therapy to enhance treatment outcomes. Despite increasing interest, the efficacy of probiotics remains controversial when compared to a placebo, necessitating a comprehensive meta-analysis to synthesize the available evidence.

AIM

This study aims to systematically review literature and provide a meta-analysis on the efficacy of probiotics compared to placebo when added to traditional pharmacological treatments for IBD.

MATERIAL & METHODS

A comprehensive and systematic search was conducted using PubMed, Cochrane Library, Google Scholar, Biomed Central, PLOS-ONE, and ClinicalTrials.gov for studies published till November 1, 2024. Open access Randomized controlled trials (RCTs) comparing oral probiotics with a placebo as adjunctive therapy in patients with IBD were included. Key outcomes analyzed were clinical remission, sustained remission, positive clinical response, relapse rate, and endoscopic remission. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated as the measure of effect size. Both fixed-effects (Mantel-Haenszel method) and random-effects models were employed to account for clinical and methodological heterogeneity. All statistical analyses were performed using RevMan 5.4.1, with statistical significance set at $p < 0.05$. Publication bias was assessed using the funnel plots.

RESULTS

From 5,493 studies retrieved, 14 randomized controlled trials (RCTs) involving 924 patients with either ulcerative colitis or crohn's disease met the inclusion criteria. The clinical trials lasted from 4 weeks to 52 weeks. Probiotics significantly improved clinical remission rates compared to placebo (OR: 1.56, 95% CI: 1.00-2.42, $p = 0.05$, $I^2 = 0\%$) and enhanced positive clinical response (OR: 2.09, 95% CI: 1.19-3.67, $p = 0.01$, $I^2 = 15\%$). However, probiotics did not significantly affect sustained remission rates (OR: 0.97, 95% CI: 0.59-1.60, $p = 0.90$, $I^2 = 0\%$), clinical relapse (OR: 0.57, 95% CI: 0.21-1.50, $p = 0.25$, $I^2 = 60\%$), or endoscopic remission (OR: 1.23, 95% CI: 0.44-3.44, $p = 0.69$, $I^2 = 58\%$), moderate heterogeneity observed in some outcomes.

FOREST PLOTS SHOWING COMPARISON OF CLINICAL OUTCOMES BETWEEN PROBIOTICS AND PLACEBO

Fig 1.1: Outcome: Induction of Clinical Remission

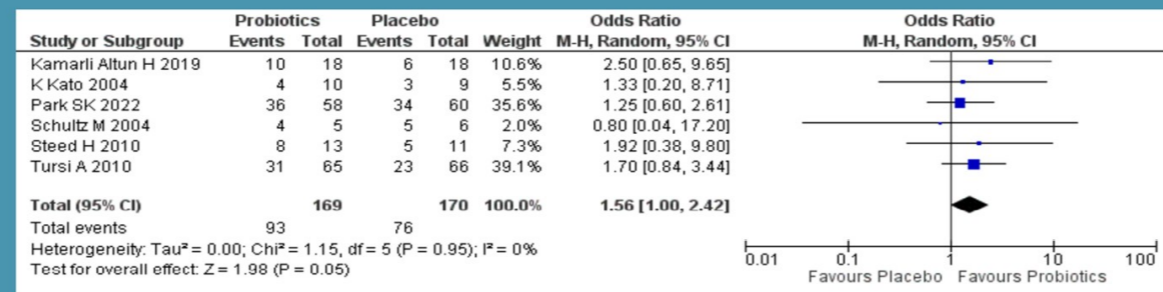


Fig 1.2: Outcome: Sustained Remission

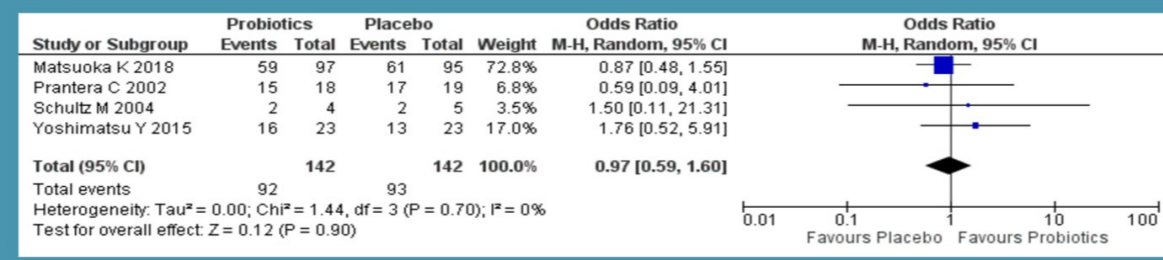


Fig 1.3: Outcome: Positive Clinical Response

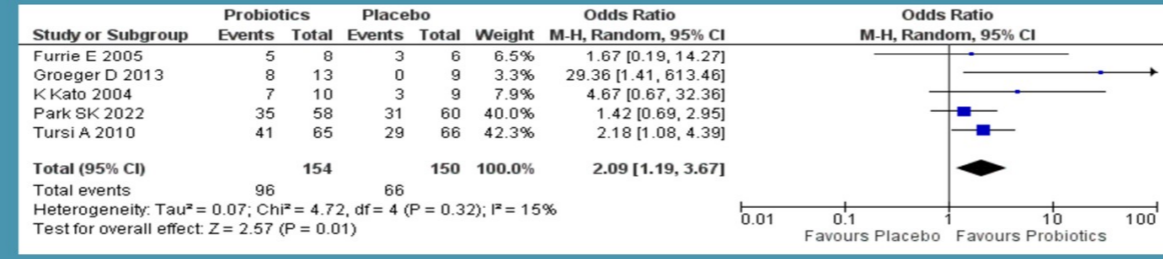


Fig 1.4: Outcome: Clinical Relapse

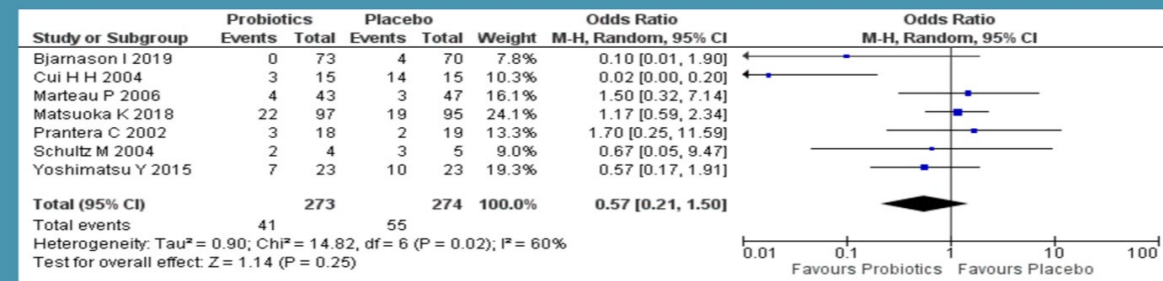
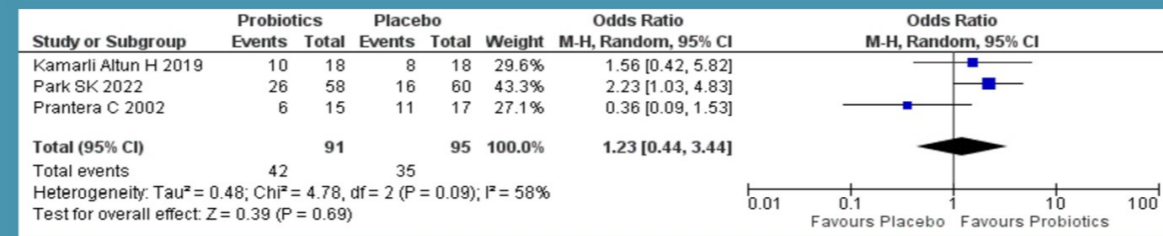


Fig 1.5: Outcome: Endoscopic Remission



KEY FINDINGS

- Probiotics significantly improved clinical remission rates compared to placebo.
- No significant difference was observed between probiotics and placebo for maintaining sustained remission
- Probiotics demonstrated significant advantage over placebo in improving clinical response
- Probiotics did not significantly reduce relapse rates compared to placebo.
- No significant improvement in endoscopic remission rates was observed with probiotics compared to placebo

GRAPHICAL COMPARISON OF NUMBER OF OUTCOMES

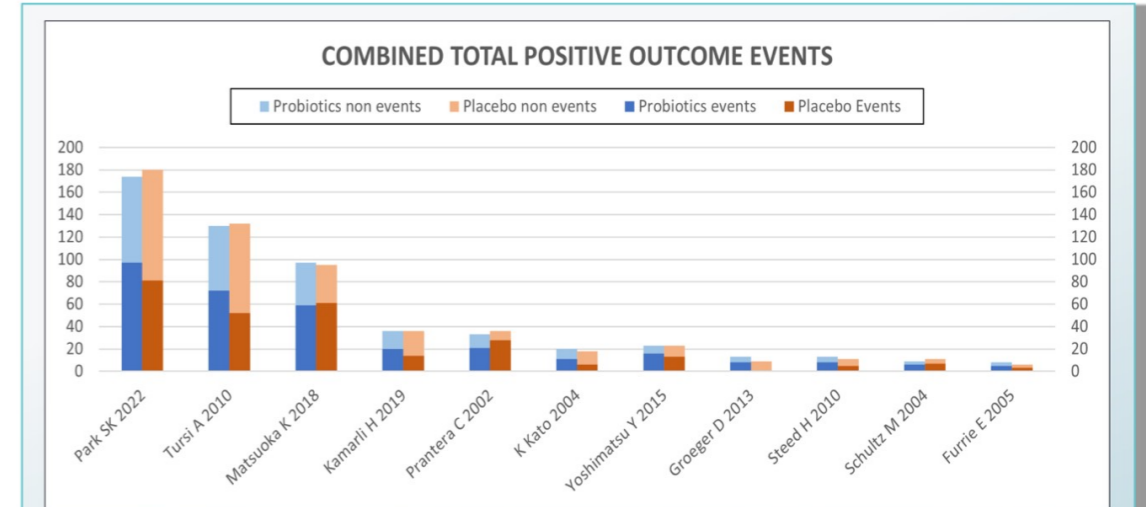


Fig 2.1: Positive outcomes = number of "clinical response/improvement" + number of "clinical remission" + number of "sustained remission" + number of "endoscopic remission"

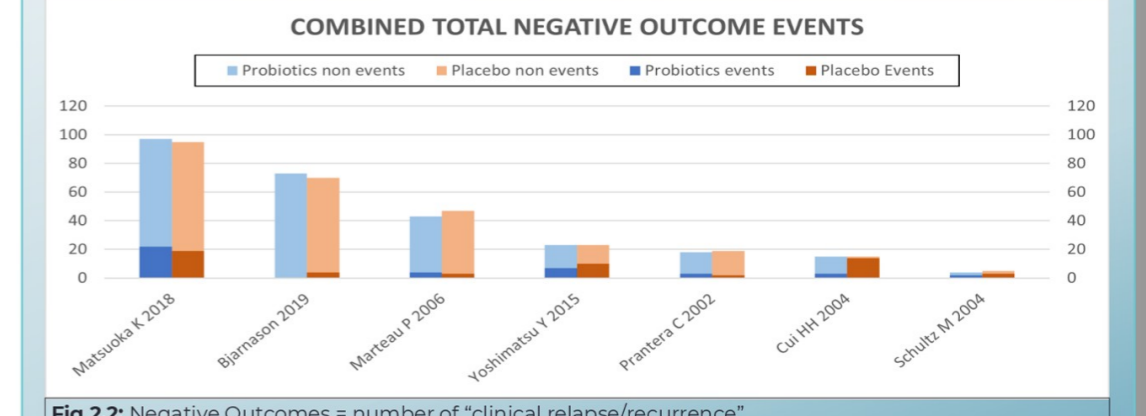


Fig 2.2: Negative Outcomes = number of "clinical relapse/recurrence"

SUMMARY / CONCLUSION

Probiotics, when added to standard pharmacological treatment, improve clinical response and remission rate in patients with inflammatory bowel disease. However, their impact on sustained remission, relapse prevention, and endoscopic outcomes remains uncertain, warranting further research to clarify their role in IBD management.