POOLED ANALYSIS OF TWO PHASE III STUDIES OF ORAL SULPHATE SOLUTION VERSUS 4L POLYETHYLENE GLYCOL IN ADULTS UNDERGOING ROUTINE COLONOSCOPY: FOCUS ON CLINICALLY RELEVANT SUBGROUPS

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Post-hoc pooled analysis of two phase III trials (588 patients) confirmed non-inferiority of split-dose oral sulphate solution to 4L polyethylene glycol for colonoscopy bowel preparation, with superiority in patients with BMI above 25 kg/m².

KEY POINTS

- Oral sulphate solution was non-inferior to polyethylene glycol for successful bowel preparation overall (93.7% vs 92.1%) and across most subgroups including males, females, patients with and without inflammatory bowel disease, BMI ≤25 kg/m², and age ≤65 years.
- In patients with BMI >25 kg/m², oral sulphate solution was superior to polyethylene glycol (97.0% vs 89.8%, p=0.029); non-inferiority was not confirmed in patients >65 years (91.6% vs 98.2%).
- Oral sulphate solution achieved higher rates of excellent preparation (BBPS ≥8) overall (76.1% vs 64.8%, p=0.0025) and in most colon segments across subgroups.
- Compliance was higher with oral sulphate solution (92.4% vs 85.1%, p=0.0024) and investigator satisfaction was greater (p=0.0003); safety and tolerability were similar between treatments, with one serious adverse event (acute proctitis) related to oral sulphate solution.

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