

The fragility of randomised controlled trials on prophylactic mesh for prevention of parastomal hernia

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Introduction

- **Prophylactic mesh** during stoma formation has been demonstrated to **reduce parastomal hernia incidence**
- Nevertheless, supporting evidence is of **limited quality** and there is lack of universal consensus
- We conducted a systematic review utilising the **fragility** or **reverse fragility index** to assess the **robustness** of **randomised controlled trials** (RCTs) evaluating the use of prophylactic mesh for the prevention of parastomal hernia

Methods

1. Systematic review per PRISMA
2. PROSPERO registration (CRD42025642457)
3. Search: Medline, Embase, CENTRAL

Intervention = mesh
Control = no mesh

4. Formal narrative synthesis of data
5. Risk-of-Bias 2 assessment
6. FI or RFI calculation

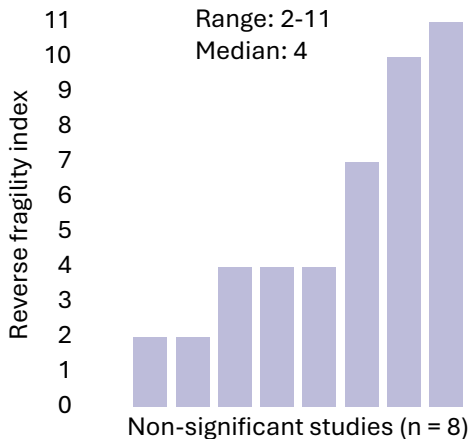
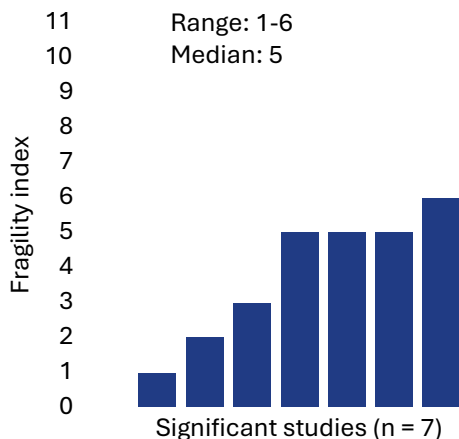
Minimum number of patients that would need a different outcome to:

Fragility index (FI) = lose statistical significance

Reverse fragility index (RFI) = gain statistical significance

Results

15 RCTs including 1187 patients	Overall parastomal hernia incidence 0-93.8%
End colostomies (majority), loop colostomy or end ileostomy	Mesh positions: intraperitoneal, preperitoneal, retromuscular
Approaches: open, laparoscopic, robotic	Mesh types: biologic in 2 RCTs



Conclusions

- Majority of RCTs were fragile, regardless of significant or non-significant primary outcome
- It remains unclear as to whether mesh prophylaxis effectively prevents parastomal hernia
- Higher quality RCTs are urgently required to inform best clinical practice