2022. ProtDilat

RCT/endoscopic thx/Stricturing CD

Multicentre, open-label, randomised trial. Adult patients with CD with obstructive symptoms due to fibrotic strictures of <10cm length were randomized to endoscopic balloon dilatation (EDB) or fully covered self-expandable metal stent. (FCSEMS)

*EBD was done with the diameter at the discretion of the endoscopist and a maximum of 2 sessions were allowed within 15-30 days between them. FCSEMS a 20 mm diameter was placed.

<u>Primary endpoints:</u> Efficacy of endoscopic treatment defined by the % of patients free of a new therapeutic intervention at 1 year.

Results: N=80

- At 1 year, 80% EDB vs 51% FCSEMS were free of new therapeutic intervention, OR 3.9 (95%CI 1.4-10.6), p=0.0061.
- There were 2 severe adverse events one on each arm, both bowel perforations.

Conclusion:

EBD is more effective than FCSEMS for Crohn's disease strictures, with a good safety profile for both treatments.

Self-expandable metal stents versus endoscopic balloon dilation for the treatment of strictures in Crohn's disease (ProtDilat study): an open-label, multicentre, randomised trial

