

Letter to the Editor: "Endoscopic treatment of Crohn-related strictures with a self-expandable stent compared with balloon dilation: A prospective, randomized, controlled study"



Carta al editor: "Endoscopic treatment of Crohn-related strictures with a self-expandable stent compared with balloon dilation: A prospective, randomized, controlled study"

Dear Editor,

We read with great interest the article recently published by Per Hedenström and Per-Ove Stotzer.¹ The study compares the efficacy of self-expandable metal stent (SEMS) with endoscopic balloon dilation (EBD), for strictures in Crohn's Disease (CD). The study clearly has important methodological shortcomings that makes difficult to draw firm conclusions. Firstly, when a study of these characteristics is performed, the sample size calculation is critical. In this case, the sample size calculation was made aiming to find differences in the clinical success, but the expected outcomes are not specified. In addition, the primary outcome was not the clinical success but the technical success. A low number of patients were required ($n=28$) but the total number of patients finally analyzed were only 12, clearly insufficient to demonstrate any differences. Secondly, during the study, the protocol was modified, and an EBD was performed prior to stent placement in 4 of 7 patients, being only 3 patients treated with stenting alone. This clearly affect the results of the SEMS treatment due to it is impossible to know what it was the responsible of the effects either for clinical and technical success and for adverse events. With these results it is impossible to make conclusions in any sense and less to say that patients with CD may benefit from treatment with SEMS rather than EBD. The overall success rate obtained in meta-analyses assessing the efficacy of EBD range from 58% to 80.8%.² Regarding stent placement, the efficacy reported in the literature range from 51.3% to 58.7%,^{3,4} with one of these studies being a randomized multicenter clinical trial designed by the authors of this letter comparing the use of stents versus EBD in the treatment of strictures of CD patients.⁴ The results of this clinical trial with 80 patients, showed that EBD is more effective (80.5% vs 51.3%) than fully covered SEMS with an equally good safety profile.⁴ Despite we appreciate the effort, value and the difficulty to carry out a study of these characteristics, this paper has a low quality that implies a confusing conclusion.

In summary, based on current literature, EBD should be the preferred endoscopic treatment for CD strictures.

Authors' contribution

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Conflicts of interest

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References

1. Hedenström P, Stotzer PO. Endoscopic treatment of Crohn-related strictures with a self-expandable stent compared with balloon dilation: a prospective, randomised, controlled study. *BMJ Open Gastroenterol.* 2021;8:e000612.
2. Bettenworth D, Gustavsson A, Atreja A, Lopez R, Tysk C, Van Assche G, et al. A pooled analysis of efficacy, safety, and long-term outcome of endoscopic balloon dilation therapy for patients with stricturing Crohn's disease. *Inflamm Bowel Dis.* 2017;23:133–42.
3. Das R, Singh R, Din S, Lund J, Krishnamoorthy R, Hearing S, et al. Therapeutic resolution of focal, predominantly anastomotic Crohn's disease strictures using removable stents: outcomes from a single-center case series in the United Kingdom. *Gastrointest Endosc.* 2020;92:344–52.
4. Loras C, Andújar X, Gornals JB, Sanchiz V, Brullet E, Sicilia B, et al. 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. *Lancet Gastroenterol Hepatol.* 2022. S2468-1253(21)00386-1.

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