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CORRESPONDENCE

Recalled stapler device, high complication rate, non validated scoring system and misquote from the STARR surgeons

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Dear Sir,

We read with great interest the prospective cohort study by Giarratano et al. [1] recently published in this journal. The authors reported the outcomes of 262 consecutive patients undergoing stapled transanal rectal resection (STARR) for obstructed defecation syndrome (ODS) and radiologically proven rectocele. The authors advocate STARR as a safe, effective, and minimally invasive technique.

As a prelude to three United Kingdom National Institute for Health Research-funded randomised controlled trials (RCTs) on non-drug therapies for chronic constipation (i.e. bowel retraining, anal irrigation, and laparoscopic ventral mesh rectopexy for internal rectal prolapse), the CapaCiTY (Chronic Constipation Treatment PathwaY) Working Group, along with a broad consensus group derived from the Association of Coloproctology of Great Britain and Ireland (ACPGBI) affiliated Pelvic Floor Society, and European Society of Coloproctology (ESCP) have seized the opportunity to assess the literature available on the surgical treatment of chronic constipation [2–7]. This process (praised as an "impressive authoritative comprehensive compendium") [8] led to a series of graded practice recommendations in order to facilitate the often challenging decision making relating to the care of such patients [9]. Rectal excisional procedure represented one of the five main surgical options scrutinised (the others being colonic resection [3], rectal suspension [4], reinforcement of the rectovaginal septum [6], and sacral nerve stimulation [7]) with a total of 47 studies identified, providing data on outcomes in a total of 8340 patients [5]. Of these, five were RCTs (three 1b and two 2b) and 42 were observational studies.

Over a half of patients included in the study by Giarratano et al. ($n = 149$, 57%) underwent STARR using the PPH03 device, which is no longer licenced for this use due to concerns that the staple line height is insufficient for the thickness of the resected and anastomosed tissue. The author found an overall morbidity rate of 23%. Although not reaching statistical significance, this was higher in patients undergoing STARR using the PPH01 compared to PPH03 device (i.e. 27% vs. 20%, respectively). With the exception of the study by Jayne et al., where the 36% morbidity rate was admittedly overinflated by the inclusion of the symptom 'defecatory urgency' (in many cases probably not a de novo symptom but present in 39.9% of patients preoperatively), the re-assessed rate of perioperative complications from the meta-analysis of 1b/2b studies included in our previous systematic review was 14.0% (95% confidence interval 9.0–19.0%). As a matter of fact, the morbidity rate in the 2b study by Giarratano et al. is not negligible or in line with the mean values of our meta-analysis.

Furthermore, Giarratano et al. stated that we 'did not comment on functional results' in our recent systematic review, which is not even referenced in their manuscript. Undoubtedly, this statement reflects a perfunctory reading of the article, since we reported in great detail the functional outcomes of rectal excisional procedures, with stratified results per procedure in Table 6 [5].

Reliance on proving efficacy using global satisfaction rating and unvalidated scoring systems is not satisfactory and greater emphasis should be placed in future studies on the use of disease-specific and generic quality of life scoring instruments.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This study did not require ethical approval.

Informed consent Informed consent was not required for this study.

References

1. Giarratano G, Toscana C, Toscana E, Shalaby M, Sileri P (2019) Stapled transanal rectal resection for the treatment of rectocele associated with obstructed defecation syndrome: a large series of 262 consecutive patients. Tech Coloproctol 23(3):231–237
2. Knowles CH, Grossi U, Horrocks EJ, Pares D, Vollebregt PF, Chapman M, Brown SR, Mercer-Jones M, Williams AB, Hooper RJ, Stevens N, Mason J, Group NCW, Pelvic Floor S (2017) Surgery for constipation: systematic review and clinical guidance: paper 1: introduction and methods. Colorectal Dis 19(Suppl 3):5–16
3. Knowles CH, Grossi U, Chapman M, Mason J, Group NCW, Pelvic Floor S (2017) Surgery for constipation: systematic review and practice recommendations: results I: colonic resection. Colorectal Dis 19(Suppl 3):17–36
4. Grossi U, Knowles CH, Mason J, Lacy-Colson J, Brown SR, Group NCW, Pelvic Floor S (2017) Surgery for constipation: systematic review and practice recommendations: results II: hitching procedures for the rectum (rectal suspension). Colorectal Dis 19(Suppl 3):37–48
5. Mercer-Jones M, Grossi U, Pares D, Vollebregt PF, Mason J, Knowles CH, Group NCW, Pelvic Floor S (2017) Surgery for constipation: systematic review and practice recommendations: results III: rectal wall excisional procedures (rectal excision). Colorectal Dis 19(Suppl 3):49–72
6. Grossi U, Horrocks EJ, Mason J, Knowles CH, Williams AB, Group NCW, Pelvic Floor S (2017) Surgery for constipation: systematic review and practice recommendations: results IV: recto-vaginal reinforcement procedures. Colorectal Dis 19(Suppl 3):73–91
7. Pilkington SA, Emmett C, Knowles CH, Mason J, Yiannakou Y, Group NCW, Pelvic Floor S (2017) Surgery for constipation: systematic review and practice recommendations: results V: sacral nerve stimulation. Colorectal Dis 19(Suppl 3):92–100
8. Smart NJ, Wexner S (2017) Surgery for constipation: systematic review and clinical guidance. Colorectal Dis 19(Suppl 3):3–4
9. Knowles CH, Grossi U, Horrocks EJ, Pares D, Vollebregt PF, Chapman M, Brown S, Mercer-Jones M, Williams AB, Yiannakou Y, Hooper RJ, Stevens N, Mason J, Group NCW, Pelvic Floor S, European Society of C (2017) Surgery for constipation: systematic review and practice recommendations: graded practice and future research recommendations. Colorectal Dis 19(Suppl 3):101–113