SURGERY FOR RECTAL ENDOMETRIOSIS: THE TECHNIQUE OR THE INDICATION, THAT IS THE QUESTION Paolo Vercellini, M.D.a,b Greta Sergenti, M.D.a Edgardo Somigliana, M.D.a,b Form ^a Gynecology Unit, Fondazione IRCCS Ca' Granda – Ospedale Maggiore Policlinico and ^b Department of Clinical Sciences and Community Health, Università degli Studi, Milano, Italy Keywords: endometriosis; surgery; pelvic pain; infertility; medical treatment Word Count: 1493 Correspondence: Paolo Vercellini, M.D. Department of Clinical Sciences and Community Health, Università degli Studi di Milano and Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Via Commenda, 12 - 20122 Milan, Italy Tel: +39.02.55032318; fax: +39.02.50320264; e-mail: paolo.vercellini@unimi.it

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Obviously, the skill of the surgeon is relevant to the final outcome, but even the most talented surgeon should think before recommending surgery, "Why do I do what I do?" *

*Garcia-Velasco JA, Arici A, Fertil Steril 2004;81:1206

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Bafort and co-workers report the results of a retrospective study conducted on 232 women who underwent surgery for endometriosis including excisional procedures on the rectal ampulla (1). This anatomical clarification is important, as it excludes the lesions infiltrating the rectosigmoid junction, i.e., those that most frequently cause subocclusive symptoms.

Generally, endometriosis infiltrating the anterior rectal wall is part of a larger lesion involving the Douglas pouch and often infiltrating the posterior vaginal fornix. Indeed, almost half of the patients in Bafort et al. study underwent segmental vaginal resection. These lesions very rarely cause bowel lumen obstruction. Therefore, the decision to undertake elective excision of part of the rectal ampulla is dictated by other, non-life-threating clinical conditions, such as intractable dysmenorrhea, severe deep dyspareunia, and catamenial dyschezia.

The primary study objective was to compare the incidence of postoperative complications in women undergoing rectal shaving or disk excision (conservative surgery group) and in those undergoing segmental rectal resection. Overall, 10% of patients (23/232) experienced Clavien-Dindo type-3 or -4 complications, including bowel leakage and rectovaginal fistula formation. This is consistent with the available evidence (2). Postoperative severe complications were more frequent in the rectal resection group than in the conservative surgery group. However, statistical significance vanished after correction for between-group differences in baseline clinical characteristics, or when considering only subjects undergoing first-line surgery. However, given the limited number of patients included in this latter subgroup analysis (n=108), the 95% CI of the OR estimate was very large (from 0.77 to 51.43), and a type II error cannot be excluded.

More importantly, the frequency of Clavien-Dindo type-3 or -4 complications observed in patients undergoing repetitive surgery was more than double (14%) than that observed in patients undergoing first-line surgery (6%). This justifies the probably most important take-home message of this study, that is, candidates for complex pelvic surgery for deep endometriosis must be referred to centers of expertise, where adequately executed procedures should limit the risk of re-operative interventions for persistent lesions, with the associated increased likelihood of severe morbidity. This recommendation is also ethically relevant, as the diagnosis of rectal and vaginal endometriosis at physical examination combined with ultrasonography and, in selected cases, with MRI, is feasible and accurate (1,2). Thus, these lesions should not be missed preoperatively.

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Women undergoing conservative surgery or segmental resection experienced similar symptom and lesion recurrence rates, the secondary study outcome.

Given the methodological drawbacks inherent to the retrospective nature of their study, the authors used a propensity score model, an appreciable biometric approach aimed at limiting confounding. In fact, women who underwent segmental resection reported severe symptoms more frequently and had larger rectal nodules and higher endometriosis classification scores compared to women who underwent conservative surgery.

This suggests that the type of procedure performed might have been influenced by both, preoperative clinical, and intra-operative anatomical variables. In other words, if the type of surgery adopted in individual cases was not an unrestricted a priori choice, but was a somewhat obligatory approach dictated by more complex conditions, the demonstration of a difference in complication rate seems to lose part of its practical importance, because surgeons could have not behaved otherwise anyway. If this was the case, even sophisticated statistical techniques may reveal of limited aid in disentangling the impact of different surgical techniques per se, that is, independently of baseline patient characteristics.

The vast majority of women underwent surgery for pain and infertility. Over two-thirds of participants were infertile, two-thirds complained of dyschezia, and about half of deep dyspareunia.

More than one patient out of four experienced pain symptoms recurrence. The pregnancy rate was 63% (26/41) in women who sought a natural conception, and 69% (70/102) in those who underwent ART after surgery. What would have been the reproductive performance of these latter women had they undergone directly IVF? It seems extremely difficult to discriminate between the specific fertility-enhancing effect of colorectal lesion removal, and that of excision of all other pelvic lesions, both in women seeking a natural conception and in those undergoing IVF postoperatively. Moreover, the performance of successful rectal surgery could be considered as a general indicator of great technical capabilities. This, and not excision of rectal endometriosis per se, might explain the very high postoperative pregnancy rates observed by Bafort and co-workers.

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The debate on the best technique to excise rectal endometriosis is still ongoing (3), and tradeoffs between safety and long-term efficacy of different degrees of radicality are not fully clarified. More in general, in surgical studies great emphasis is given to technical details regarding the different procedures, and less so to the quality of the evidence on which those procedures are indicated. This is unexpected, as colorectal surgery with opening of the bowel lumen is among the riskiest interventions that may be performed in women with endometriosis.

The authors correctly list some indisputable surgical indications, including bowel stenosis causing sub-occlusion, presence of severe pain symptoms in women seeking a natural conception, inefficacy of, or intolerance and contraindications to medical treatments, and patient preference for surgery instead of hormonal therapies. In all other clinical conditions, women must be allowed to understand the uncertainties regarding the benefits of rectal surgery, as they have the right to choose based on their priorities, not our opinions.

Unfortunately, most of the available data are derived from retrospective cohort studies. This impedes a precise estimate of the magnitude of the effect of the different techniques. Therefore, when only the potential harms are known, it is difficult to delineate a therapeutic balance to inform patient decisions. In particular, the incremental benefit of excising rectal lesions in addition to other endometriotic pelvic lesions in diverse clinical conditions is currently scarcely defined. In this

regard, comparative effectiveness research should be conducted on patient populations selected on the basis of a specific main complaint. As an example, to understand how beneficial is rectal endometriosis excision on deep dyspareunia, only participants with moderate to severe pain at intercourse as their main symptom should be selected. The same is true for other pain symptoms and infertility, because trying to assess multiple secondary outcomes on an unselected study population may lead to scarcely reliable results.

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The importance of a sound methodological approach to assess the purported benefits of radical excision of rectal endometriosis cannot be overlooked. Surgical indications must be based on robust evidence, especially when dealing with a benign chronic disease not endangering life, and in case of major differences in potential harms between treatment options (4). Knowing or not knowing if a complex procedure was justified by convincing data is very different, especially when severe postoperative complications eventually ensues.

On one hand, when endometriosis infiltrates the rectal ampulla below the rectosigmoid junction, bowel occlusion is exceedingly rare. On the other hand, suppressive hormonal treatments are successful in relieving pain in at least two-thirds of symptomatic women with rectal endometriosis (5), and IVF is an effective alternative to surgery in infertile women (4). In addition, the rate of postoperative complications observed in Bafort et al. series reflects the performance of a multidisciplinary group of very experienced and technically capable pelvic surgeons. The generalizability of these findings may be limited, and the outcomes in the hands of less talented surgeons could reveal substantially less favorable.

The extent of acceptance of additional potential severe morbidity associated with rectal surgery seems highly variable among individual women. This may be partly due to the selfselection of patients who choose a center of expertise based on the alignment of their personal preferences with the locally favored therapeutic approach. However, it may not be excluded that the type of information provided to women greatly influences their final choice. If this is true, the completeness and correctness of the counselling process, including the uncertainties on the potential benefits of rectal surgery, is of utmost importance, as one out of ten patients undergoing resection will suffer a moderate/severe complication. The implications of postoperative morbidity seem different in case of inadvertent versus deliberate elective opening of the bowel lumen. Moreover, based also on the results of the present study, women undergoing repeat surgery must be made aware preoperatively of the particularly increased risk of complications.

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Bafort and co-workers appropriately insist also on adequate information regarding the practical and psychological consequences of a diverting ileostomy, which seems to be increasingly performed by some authoritative surgical groups, but that may not be easily accepted by young women with benign disease.

Finally, after 30 years, probably the time has come to contemplate whether the timehonored, but somewhat arbitrary definition of deep endometriosis as lesions infiltrating ≥ 5 mm beneath the peritoneum, should be abandoned. The criterion adopted by the authors to diagnose deep rectal endometriosis, i.e., infiltration of the muscularis layer, seems easily reproducible and more accurately reflects lesion pathogenesis (2).

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