



## Invite comment on Pucciarelli and Spolverato: The fate of the rectum after organ sparing approach to rectal cancer

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The study published in *Technique in Coloproctology* by Arezzo et al. [1] deals with an interesting topic: rectal-sparing approaches, specifically transanal local excision (LE), after neoadjuvant therapy for mid-low locally advanced rectal cancer.

Total mesorectal excision (TME) is widely accepted as the standard surgical treatment after neoadjuvant therapy. Unfortunately, TME is associated with a 26–45% risk of complications, 12–25% risk of sexual and urinary dysfunction, and about 50% risk of impaired bowel function. In addition, TME performed after neoadjuvant therapy almost always includes a stoma either permanent or temporary. About 20% of patients undergoing preoperative chemoradiotherapy achieve a pathologic tumor response and the oncological outcomes of responders are significantly better compared to non-responders. Due to these considerations, there is an increasing interest in rectal-sparing approaches, namely the watch and wait (W&W) and the transanal LE approach that may spare the rectum without affecting the oncological outcomes.

While appealing, the evidence of these approaches is poor, because it relies only on retrospective, single center studies, with a small sample size, and including patients unfit for TME. Moreover, due to the improvement of imaging techniques, the definition of clinical response has been changed over time and there is no standard definition yet. Similarly, there is no consensus on the best time interval between the completion of neoadjuvant therapy and LE.

In recent years, LE after neoadjuvant therapy has been the subject of a few prospective [2–4] and one randomized study [5]. In all these studies, while the oncological outcomes were encouraging and suggested that LE is a feasible option, the non-inferiority of the LE approach compared with TME

failed to be demonstrated [5] and the postoperative complications and difficulties of subsequent radical surgery raised some concern. However, the major drawbacks of LE remain; the expected increase of local recurrence compared with TME and the quite high rate (one-third) of patients requiring a subsequent TME due to residual tumor (radicalization) or recurrence (salvage surgery). Clear advantages of LE over TME are therefore difficult to show, both in terms of oncological outcome [5] and in terms of bowel function and quality of life [4].

In our practice, rectal-sparing approaches in general, and LE in particular, is a reasonable option, provided there is optimal patient selection and a strict follow-up that would guarantee an early diagnosis of local recurrence eventually treated with salvage surgery. A better selection of patients may be obtained by improving the performance of imaging modalities for restaging patients after neoadjuvant therapy and by having more reliable data on risk factors of recurrence. In this context, the study of Arezzo et al. [1] which includes a large number of patients from seven institutions is a useful contribution, as it clearly indicates that a higher risk of local and overall recurrences is associated with ypT3 stage, with a diameter of residual tumor > 10 mm, and with the lack of combined chemotherapy. These findings are largely accepted as valid criteria to include/exclude patients in trials dealing with rectal-sparing treatment after neoadjuvant therapy.

A further conclusion of the study was that survival is associated with pT and not with cT stage. This is not surprising as the effectiveness of imaging in staging patients after neoadjuvant therapy still needs to be improved.

A higher rate of local recurrence after rectal-sparing approaches can be expected compared to standard TME, thus a strict and accurate follow-up, like the one adopted in the RESARCH trial [6] (Fig. 1), would allow an early detection of recurrent tumors, while improving disease-free survival and overall survival. Ongoing trials are trying to determine, if local recurrence impacts on long-term survival

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<i>Follow-up month</i>	3	6	9	12	15	18	21	24	30	36	42	48	54	60
<b>Physical examination, DRE</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>BT + CEA</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Proctoscopy</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Pelvic MRI</b>		X		X		X		X		X		X		X
<b>Chest-abdomen CT</b>				X				X		X		X		X
<b>Colonoscopy</b>				X								X		

**Fig. 1** Follow-up of the RESARCH trial reprinted with permission. *DRE* digital rectal exam, *BT* blood test, *CEA* carcinoembryonic antigen, *MRI* magnetic resonance imaging, *CT* computed tomography

and if the improvement in bowel function and in quality of life after organ-sparing balances the higher risk of local recurrence. To do this, some prospective studies [6], aside from evaluating the traditional oncological outcomes, are evaluating the percentage of organs spared and of definitive stomas.

Organ-sparing approaches are increasingly offered in clinical practice as an alternative to TME after carefully informing patients about the risks and benefits of the approach, however, they still need to be considered as experimental. In the meantime, rectal-sparing approaches should be reserved for selected patients who achieve a good objective endoluminal response after chemoradiation and who are followed up in specialized colorectal centers.

### Compliance with ethical standards

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

**Ethical approval** This article does not contain any studies with human participants performed by any of the authors.

**Informed consent** There is no involvement of patients in this study, thus no informed consent is necessary for the editorial.

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