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Editorial

Non-Surgical Treatment of Localized Rectal Cancer Is an Experimental Option[☆]



El tratamiento no quirúrgico del cáncer de recto localizado es una opción experimental

Many factors have contributed to a fundamental change in the natural history of rectal cancer. The introduction of total mesorectal excision, the use of pelvic magnetic resonance imaging for the initial staging, the administration of preoperative chemoradiotherapy in patients with risk factors for locoregional recurrence and the integration of decisions made by multidisciplinary teams have undoubtedly led to this change in paradigm. Locoregional control is optimal and local recurrence rates do not surpass 5% in most national registries. ²

Furthermore, 12%–16% of patients with locally advanced tumors treated with neoadjuvant chemotherapy achieve a complete pathologic response. This phenomenon consists of the disappearance of all tumor remains in the rectal wall and in the adjacent lymph nodes. Although a minor observation, patients in whom treatment induces this situation have excellent prognoses, with an estimated 10-year relapse-free survival rate of more than 90%.³

A logical question derived from the former observation is whether radical surgery is always necessary in patients who reach complete pathologic remission, and to which point this situation can be defined without recurring to the histopathological study of the resected specimen. In addition to the pioneering studies by Habr-Gama et al.,4 in recent years several researchers have reported retrospective patient series that, after having obtained complete clinical remission, have opted for a non-surgical treatment option, thus avoiding a radical approach (with its associated morbidity and mortality) under the hypothesis that it is not necessary in most patients.5-8 All the series confirm prolonged control of the disease during observation in patients who presented complete clinical remission after neoadjuvant chemoradiotherapy. The reported percentages, however, varied greatly among the different series. Local recurrences, most of which were endoluminal, occurred in 5%–50% of cases in the first 2 or 3 years, but most cases were rescued with surgical resection.

In this issue of Cirugía Española, a similar series is published in which 30 patients, who reached complete clinical remission after treatment with conventional chemoradiotherapy, were followed up in an expectant observational program without surgery. Only 4 presented local recurrences in the first year, and all were rescued with radical surgical resections or local excisions. None presented recurrence after surgery. The authors concluded that this non-surgical approach is feasible and the oncologic results are satisfactory in a population of selected patients.

Despite the apparently satisfactory results, however, this "watch-and-wait" approach has not been evaluated in the most appropriate manner to generate the most solid scientific evidence. Several authors have argued that there are only retrospective series, with heterogenous selection and evaluation criteria, in which it is difficult to control all the biases that could intervene in the assessment of the results. The selection criteria defining clinical remission are imprecise. The follow-up criteria are variable, as is the compliance with these criteria.

The omission of surgery can have short-term advantages, although the effect that it may have on oncologic results requires long-term observation. However, the ideal situation for a conservative organ treatment to be able to be evaluated in a randomized prospective study versus radical surgical treatment (in which oncological, functional and quality-of-life results of both strategies can be evaluated) is unlikely. Neither physicians nor patients would accept a clinical trial model with such disparate therapeutic options.

The objective of neoadjuvant treatment in patients with locally advanced rectal cancer is to provide for surgical

DOIs of original article: http://dx.doi.org/10.1016/j.ciresp.2016.03.003, http://dx.doi.org/10.1016/j.ciresp.2015.12.007

^{*} Please cite this article as: Roselló S, Cervantes A. El tratamiento no quirúrgico del cáncer de recto localizado es una opción experimental. Cir Esp. 2016;94:311–312.

resection with free distal and circumferential margins, minimizing the risk of locoregional recurrence. Different strategies have been developed to increase the effect of this treatment and thus increase the rate of complete pathologic response. Intensifying neoadjuvant chemotherapy before or after radiotherapy, adding oxaliplatin or increasing the number of cycles can be valid approaches. Postponing evaluation to simply allow for a delayed effect of chemoradiotherapy that induces better remission is another strategy to consider.

The higher the rate of clinical remissions observed, the more necessary it will be to consider conservative treatment without surgery. Its application will require a context of clinical research where close, detailed observation is crucial. The definition of criteria to guarantee that the conservative approach is safe and does not put oncologic results at risk is of fundamental importance. Likewise, it is important to determine an adequate follow-up for the early detection of local recurrences that would provide for their curative management. It seems possible to extend the application of neoadjuvant treatment to less advanced cases with the main objective of obtaining more complete remissions, which may allow for an organ-preserving strategy in tumors of the lower third of the rectum.¹³

Thus, conservative treatment of locally advanced rectal cancer with a "watch-and-wait" approach after complete clinical remission induced by neoadjuvant treatment must not currently be considered routine clinical practice. This approach should be viewed as a possible option and a strategy to be further researched by motivated multidisciplinary expert groups who are aware of the uncertainties that arise with its implementation. Therefore, it is essential to develop clinical research protocols with long-term objectives and to standardize selection criteria as well as treatment and follow-up procedures in order to effectively respond to any fundamental questions that may arise. ^{14,15} It is only through more and higher quality research that another possible change in the paradigm for locoregional rectal cancer treatment can be established.

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2173-5077/

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