

for a new device, this approach does not permit proper scientific evaluation of safety and effectiveness. Without careful scrutiny, the data could be misused to gain early and inappropriate regulatory approval, with a risk of subsequent harm to patients.

We declare no competing interests.

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## Complete response after neoadjuvant treatment for rectal cancer

We read the Article by Maxime J M van der Valk and colleagues (June 23, 2018, p 2537)<sup>1</sup> with great interest. 85% overall survival and 94% disease-specific survival was achieved in a highly selected patient group from the watch-and-wait registry; however, no standard selection

criteria were present. The characteristics of the patients, type of data collection, duration of the treatment, specific combination with chemotherapy, and follow-up strategy for those who were enrolled in the watch-and-wait registry appear unclear. We believe in the value of watch-and-wait strategy for some patients who would like to avoid surgery, but the reported outcomes in this study seem too optimistic considering the current evidence-based outcomes in rectal cancer treatment.<sup>2,3</sup>

The initial staging of the disease and the appropriate application of this watch-and-wait strategy can be questioned, especially when 28% of the patients are staged with T1 and T2 and 35% of the patients are staged with N0 disease. This finding questions the justification of giving chemoradiation, putting patients through the toxicity of this physiologically invasive approach with no confirmed benefit. A median follow-up of 3.3 years was reported, yet data collection started as far back as the 1990s. This result is concerning because the authors could have lost many patients' follow-ups, and the results could be skewed when the chart-reviewed follow-up is taken rather than the true last existing follow-up. Although some centres included many patients, other centres had less than ten patients, raising questions about homogeneity of the study population, their experience, and sufficiency for non-operative patients with rectal cancer with management, an experimental treatment strategy with no standardisation.

Considerable amounts of data are missing and could change the view on non-operative management for rectal cancer. Of 880 patients, 159 (18%) patients had unknown clinical T stage, and 133 (15%) patients had unknown clinical N stage. We read only surgical procedures of 148 patients with local regrowth, of 213 patients, and the remaining 65 (31%) patients were said to have been lost to follow-up. Margins status was unknown in 6% of patients

undergoing total mesorectal excision. Regarding the interpretation of the outcomes of recurrence and margin positivity, if those patients had surgery in a standard manner following the neoadjuvant treatment, many of them would be tumour free.

Although this Article promises good outcomes with the watch-and-wait strategy, high-quality randomised trials are needed to define the role of non-operative management for rectal cancer treatment with evidence-based data.

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## Authors' reply

We thank Eren Esen and colleagues for their comments on our study of long-term outcomes of clinical complete responders after neoadjuvant treatment for rectal cancer.<sup>1</sup> They express concern that our results are too optimistic because of selection bias. We acknowledge this limitation in our discussion. However, two recently published meta-analyses,<sup>2,3</sup> including studies with strict inclusion criteria, report similar results regarding local regrowth rates and survival, providing support for our results. Concern was additionally raised about inadequate follow-up, but only 7% of patients