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Could the STELLAR Study Change the Rectal Cancer Treatment Algorithm?

TO THE EDITOR:

Jin et al[1] have recently reported on the STELLAR trial in the *Journal of Clinical Oncology*. Despite the results of this study supporting the intensification of neoadjuvant therapy in the treatment of locally advanced rectal cancer, we think that experimental therapy (after short-term radiotherapy, four cycles of capecitabine + oxaliplatin chemotherapy before surgery) is not convincing enough to replace standard therapy and cannot change oncology practice because of some limitations.

First, although it was stated in the study design that patients in the standard treatment arm should receive six courses of adjuvant chemotherapy, only 57% of patients started adjuvant therapy. The fact that approximately half of the patients in the standard treatment arm have never received adjuvant chemotherapy will limit the interpretation and applicability of the study results. In addition, only 82 of the patients who started adjuvant therapy were able to complete the planned therapy, which represents 23% of patients in the standard patient arm. In another TNT study, PRODIGE-23, it was found that 79% of the patients in the standard treatment arm started adjuvant therapy and 40% completed at least 80% of the planned adjuvant therapy.[2] Comparing the survival results of the patients who started adjuvant therapy in the control group with the survival results of the experimental group may provide more objective interpretations about the study results. In other words, the survival results of per protocol analysis would be better to compare the effectiveness of the experimental arm.

A second concern is the time from initiation of neoadjuvant therapy to surgery. Although it is feared that a prolonged period of time after initiation of neoadjuvant radiotherapy may increase surgical complications, the RAPIDO study showed that surgical complications did not increase even in patients who were operated after approximately 25 weeks.[3] In the STELLAR study, the time from the start of neoadjuvant radiotherapy to surgery was reported as 21 weeks (range, 4-64) in the experimental arm and 14 weeks (range, 10-57) in the standard treatment arm. However, when the range values were evaluated, it was determined that some patients in the experimental arm had surgery 64 weeks after the initiation of radiotherapy and 54 weeks later in the standard arm. Similarly, in the experimental arm that required four capecitabine + oxaliplatin administrations after short-term radiotherapy, it was reported that there were patients who were operated in the fourth week from the start of radiotherapy. These results in range values do not match the protocol. The minimum and maximum values in range period would be clarified.

We congratulate the authors for this study evaluating total neoadjuvant therapy in locally advanced rectal cancer, which has been a hot topic in recent years. It is likely that future studies will not recommend a one-size-fits-all treatment approach, and treatment regimens are expected to be individualized according to different risk groups. With new studies to be conducted in different risk groups, we can expect the use of TNT in oncology practice to become standard.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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