Author's Response to Letter to the Editor

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While simulation methods have their strengths, they have important non-real-world limitations. Many assumptions in the analysis that Metze and Adam refer to in their letter to the editor lack some clinical face validity. The authors base their simulation models on a modest number of select cases (upper rectum and sigmoid colon), a total of 6 cases of T1 lesions and 34 cases for T2 lesions [1]. All patients were node positive and they modeled that nodes were randomly selected from 23 nodes for the T1 lesions and 17 for the T2 lesions.

First, the authors included only node-positive cases, which can bias the findings. The time and effort needed to identify nodes is not trivial. As such, it is possible that additional nodes are not looked for after one or more abnormal nodes are found. So, the true number of positive nodes in a specimen is often unknown. Secondly, lymph nodes are typically not collected in a random fashion. There is a higher likelihood that positive nodes will be in close proximity to the tumor and follow the blood supply drainage. Abnormal nodes are usually identified first. The authors found a linear relationship in the likelihood of identifying positive nodes by modeling random selection of nodes. As all patients had one or two positive nodes, it is intuitive that the ability to identify node positivity will follow a linear relationship with the number examined. Lastly, these modest sample sizes are subject to inherent biases, lack statistical power, and may not generalize to other practices or to the population.

In our article, we analyzed over 3,500 colon cancer patients with T1 lesions and 7,700 with T2. All patients were node negative, which allowed us to examine the relationship between the number of nodes examined and the impact on survival. Patients who are not truly node negative will be understaged and may not have received chemotherapy. As Surveillance, Epidemiology, and End Results (SEER) currently does not have data on receipt of chemotherapy, it will be important in the future to compare survival rates for the potentially understaged patients who did not receive chemotherapy. We were careful not to suggest that our work establishes the ideal number that should be examined for these lesions. Rather we posed the question of whether patients with these early tumors who have <12 lymph nodes examined are really unstaged and if this should equate to poor quality of care. We would argue that measures of quality should be associated with outcomes.

Reference

1. Leibl S, Tsybrovskyy O, Denk H. How many lymph nodes are necessary to stage early and advanced adenocarcinoma of the sigmoid colon and upper rectum? *Virchows Arch.* 2003;443(2): 133–138.

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