

New ASTRO clinical practice statement updates treatment standard for rectal cancer

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The American Society for Radiation Oncology (ASTRO) recently issued a new clinical practice statement, "Appropriate Customization of Radiation Therapy for Stage II and III Rectal Cancer: An ASTRO Clinical Practice Statement Using the RAND/UCLA Appropriateness Method." An executive summary of the guideline was published in the May-June 2016 issue of *Practical Radiation Oncology (PRO)*, ASTRO's clinical practice journal, and the full guideline is available as an open-access online article in *PRO*.

The clinical practice statement, which was developed by a multidisciplinary expert working group, outlines recommendations to customize neoadjuvant and adjuvant [radiation therapy](#) for patients with moderately advanced rectal cancer based on their risk of recurrence. The statement also examines non-operative therapies for patients who are medically inoperable or refuse abdominoperineal resection, taking into account the emerging technologies available for this subset of patients.

The standard of care for all patients with stage II-III rectal cancer has been a combined multi-modality approach of chemotherapy, radiation therapy (RT) and surgery, as established in a 1990 consensus statement from the National Cancer Institute (NCI). This standard, however, is based on data collected in the 1970s and 1980s, when both RT and chemotherapy were necessary to reduce the high risk of local recurrence following less sophisticated forms of surgery. Advancements in [treatment options](#) over the past three decades—including more refined surgical techniques, more effective systemic agents and more focal and

shorter-course RT options—have drastically lowered recurrence rates, creating situations where one or more modalities may be omitted and the side effects of treatment may be reduced.

"This statement provides practicing physicians with an idea of how to employ alternative treatment options for rectal cancer patients, such as short-course radiation therapy or non-operative management approaches. It also lets us identify patients who may be more amenable to different treatment sequencing options, rather than grouping everyone with stage II and III [rectal cancer](#) together for a single standard tri-modal treatment approach. There are cases where we can achieve the same survival benefit with less treatment," said Karyn A. Goodman, MD, an associate professor of [radiation oncology](#) at the University of Colorado and lead author of the practice statement's executive summary.

The guideline was developed through the RAND/UCLA Appropriateness Method, where members of an independent, multidisciplinary expert panel rate the appropriateness of different treatment approaches for different clinical scenarios based on a systematic review of published research. Experts in oncology, gastroenterology and internal medicine rated more than 200 unique scenarios combining risk factors that influence treatment decisions with potentially appropriate treatment modalities. Panelists individually scored each scenario on a nine-point scale that assessed the anticipated benefit versus harm for an average patient in that situation. Ratings from the 10-member panel were aggregated into three categories for the Clinical Practice Statement; therapeutic options were labeled as Appropriate for median panel ratings of seven to nine without disagreement, May Be Appropriate for median ratings of four to six or if there was disagreement, and Rarely Appropriate for median ratings of one to three without disagreement.

Scenarios and treatment recommendations were grouped into four

sections, including (1) neoadjuvant and (2) adjuvant therapies used in conjunction with rectal surgery as well as non-operative management approaches for (3) medically inoperable patients and (4) patients who refuse radical rectal surgery.

For neoadjuvant therapy, panelists rated five treatment options, stratified by three patient characteristics: risk classification based on disease stage (intermediate-risk, moderately-high-risk or high-risk disease), distance from the tumor to the anal verge and distance from the tumor to the mesorectal fascia.

Neoadjuvant chemoradiation was rated Appropriate for all scenarios, while neoadjuvant brachytherapy alone was rated Rarely Appropriate across all scenarios. Neoadjuvant chemotherapy alone was rated May Be Appropriate for intermediate- and moderately-high-risk patients with non-threatened mesorectal fascia and Rarely Appropriate for the other scenarios. Forgoing neoadjuvant therapy was rated potentially appropriate only for cases with higher tumors situated far from the mesorectal fascia, where there would be no concern for positive margins following surgery.

Goodman explained the importance of radiation in treatment sequencing for tumors situated closer to the anal verge. "Tumors that sit lower in the rectum are in a more narrow part of the pelvis and therefore tend to have a higher risk of positive margins. Lower tumors also have a somewhat higher rate of lymph node metastasis. In these cases, radiation therapy is particularly important to help reduce the risk of local recurrence following surgery by shrinking the tumor, which helps surgeons resect more cleanly, and by eliminating micro-metastatic disease that may remain in pelvic lymph nodes not removed during surgery," she said.

Neoadjuvant short-course radiation therapy (i.e., 25 Gy across five fractions) was rated Appropriate for many intermediate- and moderately-

high-risk cases with non-threatened mesorectal margins and May Be Appropriate for other scenarios. While short-course radiation is the standard of care for moderately-advanced cases in many Northern European countries, it is rarely used in the U.S., said Goodman, yet she sees this option as gaining traction domestically, as evidenced in part by the recommendations of this panel.

For adjuvant therapy, panelists assessed two treatment options, chemotherapy alone and chemoradiation plus four or more months of chemotherapy, stratified by three patient characteristics: circumferential resection margin, distance from the anal verge and risk classification based on total postsurgical nodal count.

Adjuvant chemoradiation therapy (CRT) plus chemotherapy was rated Appropriate for all patients with positive margins and for patients with negative margins but higher risk classification and/or lower tumors. Adjuvant chemotherapy alone was rated Appropriate only for patients with negative margins, moderately-high-risk disease and higher tumors; it was rated May Be Appropriate for all other scenarios.

For medically inoperable cases (e.g., elderly patients who are not strong surgical candidates), panelists considered five non-operative treatment sequences, stratified by three patient characteristics: performance status based on Eastern Cooperative Oncology Group score, presence or absence of local symptoms and distance from the anal verge.

Chemoradiation was rated Appropriate for medically inoperable patients with good performance status and May Be Appropriate for those with poor performance status. External beam radiotherapy (EBRT) alone and chemotherapy alone were rated May Be Appropriate for all scenarios. Brachytherapy alone and brachytherapy combined with CRT were rated potentially appropriate for lower tumors but rarely appropriate for higher tumors.

The guidelines also assess definitive non-operative treatment for patients who experience a pathologic complete response following neoadjuvant chemoradiation and want to avoid radical surgery, particularly those with low-lying tumors who are at higher risk for a permanent colostomy. Panelists considered three treatment options, including standard-dose chemoradiation alone, chemoradiation plus brachytherapy boost and chemoradiation plus EBRT boost. Each approach was rated Appropriate for scenarios where patients refuse standard therapy.

The panel also considered the appropriateness of using intensity-modulated radiation therapy (IMRT) in place of three-dimensional conformal radiation therapy (3-D CRT) in neoadjuvant and adjuvant settings. IMRT is an advanced RT technique that delivers more focal radiation doses and spares more radiosensitive healthy tissue than with 3-D CRT. For each of the three [treatment](#) scenarios (neoadjuvant RT alone, neoadjuvant chemoradiation, adjuvant chemoradiation), panelists rated IMRT as May Be Appropriate, noting both upsides, such as reduced toxicity, as well as downsides, such as the higher financial costs, of using the technique.

More information: Karyn A. Goodman et al, Appropriate customization of radiation therapy for stage II and III rectal cancer: Executive summary of an ASTRO Clinical Practice Statement using the RAND/UCLA Appropriateness Method, *Practical Radiation Oncology* (2016). [DOI: 10.1016/j.prro.2015.11.014](https://doi.org/10.1016/j.prro.2015.11.014)

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