Published in final edited form as:

J Am Coll Surg. 2019 May ; 228(5): 782–791.e2. doi:10.1016/j.jamcollsurg.2019.01.010.

Evaluating Surveillance Patterns after Chemoradiation-Only Compared with Conventional Management for Older Patients with Rectal Cancer

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Abstract

Background—Upfront chemoradiation with omission of surgery (CR-only) is increasingly being used to treat rectal cancer. When CR-only is used with curative intent, intense surveillance is recommended. We hypothesize that in practice few patients treated with CR-only receive intensive post-treatment surveillance.

Study Design—Using SEER-Medicare, all non-metastatic rectal cancer patients (≥ 66 years old) diagnosed from 2004-2012 who received upfront chemoradiation were included. Patients who received CR-only were compared to patients receiving neoadjuvant therapy plus proctectomy. In

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Disclosure Information: Nothing to disclose.

Disclaimer: The ideas and opinions expressed herein are those of the author(s) and endorsement by the National Cancer Institute is not intended nor should be inferred.

Abstract presented at the American College of Surgeons 103rd Annual Clinical Congress, Scientific Forum, San Diego, CA, October 2017.

the 24 months after treatment, markers of surveillance, including carcinoembryonic antigen testing (CEA), endoscopy, and imaging, were compared between groups.

Results—A total of 2,482 individuals met the inclusion criteria: 21% (n=514) had CR-only and 79% had conventional treatment (i.e. chemoradiation plus proctectomy). Only 2.5% and 3.4% of those in the CR-only and conventional treatment groups were in complete compliance with National Comprehensive Cancer Network surveillance guidelines during the first two-years post-treatment ($p<0.01$). The CR-only group was less likely than the conventional treatment group to receive: CEA (aRR:0.57; 95%CI:0.50 to 0.65), endoscopy (aRR:0.76; 95%CI:0.66 to 0.87), and office visits (aRR:0.88; 95%CI:0.84 to 0.92), respectively. However, there were similar rates of cross-sectional imaging between groups (aRR:1.31; 95%CI:0.93 to 1.85).

Conclusions—Adherence to guideline recommended surveillance was poor for all Medicare patients with rectal cancer. Despite recommendations for closer follow-up, patients treated with CR-only were less likely to receive surveillance than those treated with conventional treatment. Efforts should be made to increase adherence to surveillance guidelines for all rectal cancer patients treated with curative intent, but particularly for those with higher risk of recurrence, such as those treated with CR-only.

Precis

Providers should be aware of improvements to post-treatment monitoring, particularly for patients receiving chemoradiation only, because local–regional recurrence rates are expected to be higher. The need for surveillance should be factored into discussions about the risks of the chemoradiation-only approach.

Introduction:

Surgery has always been the cornerstone of curative treatment for rectal cancer, yet omission of surgery for patients who have complete clinical response to neoadjuvant therapy is increasingly accepted.(1–5) Trials evaluating rectal cancer treatment without surgery, also known as watch-and-wait, or nonoperative management (NOM), involve initial treatment with chemoradiation with and without systemic chemotherapy followed by frequent surveillance for patients who have complete clinical response. The goal of surveillance is early diagnosis of treatment failure and recurrence, so salvage therapy, usually surgery, is possible.(5–9) While there is not a standard surveillance schedule, most studies evaluating chemoradiation-only (CR-only) follow patients closely (i.e. at least every three months) according to similar guidelines used for patients treated with traditional management except CR-only patients receive more frequent proctoscopy and pelvic MRI or rectal endoscopic ultrasound. Commonly used surveillance modalities include office visits, serum carcinoembryonic antigen (CEA) measurements, endoscopy, and cross-sectional imaging. (7, 8) (10)

It is clear that use of CR-only is increasing, but our prior work suggests that this may be due more to increasing disparities of care rather than adoption of an innovative treatment paradigm. (2, 11) Patients treated with CR-only as part of an intentional curative-intent treatment plan should be receiving frequent surveillance. Since we believe increased use of CR-only is largely related to increasing disparities of care, we hypothesize that patients

treated with CR-only in a real-world setting may also receive less intensive post-treatment surveillance than patients treated conventionally.

Methods:

Data

We conducted a retrospective analysis of Medicare beneficiaries residing in Surveillance, Epidemiology, and End Results (SEER) regions using SEER-Medicare data.(12)

Cohort

We included patients diagnosed with non-metastatic rectal adenocarcinoma (C209) between 2004 and 2012. During our study period, SEER did not separate clinical and pathological staging data and registries prioritized the reporting of only the least advanced stage of disease. Therefore, we included individuals with stage 0 rectal cancer who received radiation +/- chemotherapy as this stage of disease likely represents a tumor response to treatment. We required that patients have a month of diagnosis, be age ≥ 66 years old at diagnosis, were not diagnosed at death or autopsy, were continuously enrolled in fee-for-service Medicare Parts A (hospital) and B (outpatient) for 12 months prior to diagnosis (for identification of comorbidities) through the end of the surveillance period (i.e. 24 months after the end of initial treatment), and who had no previous cancers (Figure 1). Individuals that exited fee-for-service Medicare during the surveillance period due to death or change in coverage (e.g., enrollment in managed care) were excluded.

Among this sample, we included patients who received radiation with or without chemotherapy starting within 6 months of diagnosis and before surgery. Next, individuals were classified as receiving surgery if they had a claim for proctectomy within 90 days of their last observed radiation or chemotherapy claim in the initial treatment cycle. Those without a proctectomy claim in the 90-day post-chemoradiation treatment-window were classified as receiving CR-only. Individuals that had a local excision surgery without claims for proctectomy during the 90-day post-chemoradiation treatment-window were excluded from both groups, as the purpose of the local excision could not be determined (i.e. diagnostic biopsy or definitive treatment).

Study Variables

Age, gender, race, marital status, cancer stage, and month/year of diagnosis were extracted from the SEER registry data. Comorbidities were determined by applying the Klabunde modification of the Charlson Comorbidity Index to inpatient, outpatient, and professional Medicare claims occurring 12 months prior to diagnosis.(13) Additionally, we measured disability status using the Davidoff Disability Status model, a validated claims-based predictive proxy measure for performance status. (14)

Surveillance Period and Markers

We defined surveillance starting 90 days after the last chemotherapy or radiation date in the initial treatment cycle for both groups. Prior work has anchored the start of surveillance on the date of surgery,(15–17) however this becomes challenging when an individual does not

receive surgery. We sought equipoise by starting 90-days from the last chemotherapy claim without a break in treatment greater than 90 days. (17) The surveillance period included two years of follow-up.

The National Comprehensive Cancer Network (NCCN) Guideline Surveillance for Rectal Cancer after Surgical Resection was used to compare adequate follow-up between groups. (10) The NCCN recommends colonoscopy within 1 year of resection for non-metastatic rectal cancer. They further recommend routine follow-up office visits, cross-sectional imaging, and carcinoembryonic antigen (CEA) testing at least every 6 months for the first two years, Table 1. Receipt of surveillance was measured using procedure codes for the following services: endoscopy, CEA testing, office visits, and cross-sectional imaging.(18) Duplicated claims for the same procedure on the same date of service were excluded such that each test was counted only once. In addition to colonoscopy, we also included endoscopic ultrasound and flexible sigmoidoscopy in the endoscopy surveillance category. For cross-sectional imaging, computed tomography scanning (CT) of the chest, abdomen and pelvis is recommended by the NCCN guidelines, however for the purposes of this study magnetic resonance imaging (MRI) and positron emission tomography-CT (CT-PET) imaging were included. Any combination of imaging modalities that included the chest, abdomen and pelvis were considered compliant with guideline recommendations.

Visits to physicians were evaluated in total and by specialty using the Medicare Health Care Financing Administration specialty claims codes. We categorized physician specialty as primary care (PCP: included general practitioner, family practice, internal medicine, geriatrician), medical oncologist (medical oncology, hematology/oncology), radiation oncologist, gastroenterologist, and surgeon (general surgeon, surgical oncologist, colorectal surgeon). We evaluated both any visit to any physician and visits to a specific specialist in the 2-year surveillance period. We did not require an associated rectal cancer diagnosis code with office visits to avoid undercounting health care encounters. Office visits associated with chemotherapy administration were excluded from surveillance visit counts only; imaging and CEA testing performed on the same day were not excluded.

Outcomes

Outcome measures were developed corresponding to NCCN guidelines for rectal cancer patients receiving conventional treatment.¹⁴ We compared each surveillance type separately and as a whole (i.e. complete surveillance compliance) by treatment group. Additionally, we sought to identify factors associated with poor adherence to surveillance guidelines.

Patients were considered compliant with guidelines if during the two year surveillance period, they had all of the following: 1) 2 physician visits per year, 2) 2 CEA tests per year, 3) 1 colonoscopy, and 4) 2 cross-sectional imaging studies per year, Table 1.

Analyses

Bivariate analyses were performed to identify the factors associated with different treatment approaches: CR-only or CR plus surgery (i.e. conventional therapy). Multivariable logistic regression was used to assess associations between the CR-only and the patient-level covariates. Generalized estimating equations with log links and binomial/Poisson

distributions were used to test associations and estimate risks for receiving surveillance as recommended by the NCCN guidelines.(19, 20) We controlled for the following variables: age, race, gender, comorbidity, disability, marital status, cancer stage, year of diagnosis, SEER geographic region, urban versus rural residence, and census-reported zip code level measures of median household income, poverty level, and education.

Sensitivity Analyses

For sensitivity analyses, we sought to control for variability in the timing of surveillance studies and competing health priorities as they relate to cancer surveillance rates. First, we adjusted the frequency of surveillance guidelines to consider patients who met modified guidelines if year-1 surveillance requirements were met within 24 months, Table 1.

Second, we performed a subset analysis of only patients ages 66-74 years old. We also performed a sensitivity analysis using propensity score matching, to ensure that treatment groups were balanced in terms of baseline characteristics that may have influenced surveillance outcomes, eTable 1.

Results:

There were 2,482 individuals who met the inclusion criteria for the study, Figure 1. The majority of patients, 1,968 (79%), were treated with conventional treatment, and 514 individuals (21%) were treated with radiation +/- chemotherapy-only (CR-only) for their initial treatment, Table 2. There was a 4% average annual increase in CR-only over our study period (aRR 1.04; 95%CI: 1.005 to 1.07; p=0.02).

Individuals who were older, had increased comorbidities, single/divorced, and African-American had higher rates of CR-only, Table 2. The CR-only group was less likely than the conventional treatment group to have an office visit with a surgeon before the start of surveillance, 65% vs. 90%, p <0.01. Although CR-only was more common among African-Americans, there were no differences in pre-surveillance office visits to a surgeon by race (results not shown).

During the first and second surveillance years, 26% (n=134) of the CR-only group later had evidence of a surgery in the surveillance period, while only 1.6% (n=31) of the conventional treatment group required additional surgery. The mean time to surgery for the CR-only patients was 283 ±159 days. Additional chemotherapy was received by 31% and 66% in the first year, and 25% and 29% in the second year, respectively, in the CR-only and conventional treatment groups. Radiation was given to 9% and 11% in the first year, and 7% and 6% in the second year, respectively to the CR-only and conventional treatment groups. Results for adherence to surveillance guidelines were not significantly changed when the patients receiving additional therapy were excluded.

Both the CR-only and conventional treatment groups had poor adherence to the NCCN surveillance guidelines. Only 2.5% of the CR-only group and 3.4% of the conventional treatment group met all the recommended NCCN guidelines, respectively, p <0.01. Adherence to the following individual guidelines was lower for the CR-only group

compared to the conventional treatment group: CEA (aRR:0.57; 95%CI:0.50 to 0.65), endoscopy (aRR:0.76; 95%CI:0.67 to 0.87), and office visits (aRR:0.88; 95%CI:0.84 to 0.92), respectively. However, there were similar rates of cross-sectional imaging between groups (aRR:1.31; 95%CI:0.93 to 1.85), Figure 2. Patient factors associated with poor adherence to guidelines were older age and increased disability.

CR-only patients were more likely than the conventional treatment group to receive transrectal ultrasound (TRUS), 8.2 vs. 1.5%, $p<0.01$, Table 3. There were similar rates of pelvic MRI between the CR-only and conventional treatment groups; 5.5% vs 5.2%, $p=0.81$. Of note, though not generally supported by evidence-based guidelines, approximately one-third of patients received a PET-CT during the surveillance period.(21)

Office visits were used as a surrogate marker of history and physical exams during the surveillance period. When all office visits were included, 79.2% and 91.5% of patients met guidelines (i.e., 2 office visits/year). The CR-only group was less likely to have at least one visit with a surgeon compared to the conventional treatment group, 62% vs. 80%, $p<0.01$.

Sensitivity Analyses

Using modified surveillance requirements (i.e. the first year surveillance requirements could be met over a two-year period), there were higher rates of compliance for both groups. However, the CR-only group still had lower rates for surveillance markers except imaging: CEA (aRR:0.70; 95%CI:0.65 to 0.76), endoscopy (aRR:0.77; 95%CI:0.70 to 0.84), office visits (aRR:0.94; 95%CI:0.92 to 0.97), and imaging (aRR:0.96; 95%CI:0.84 to 1.10), respectively. Furthermore, only 14.4% and 24.6% of the CR-only and conventional treatment groups met all the modified requirements even under this extended timeframe for assessing surveillance completion, $p < 0.01$.

To address competing health priorities, we, first, performed a subset analysis with only patients ages 66 - 74 years old and, second, used propensity score matching to restrict to clinically similar patients based on our measured covariates. With the younger population-only, there were no significant changes to our initial results. CR-only group had lower rates for surveillance markers except imaging: CEA (aRR:0.57; 95%CI:0.48 to 0.68), endoscopy (aRR:0.81; 95%CI:0.69 to 0.96), office visits (aRR:0.90; 95%CI:0.84 to 0.95), and imaging (aRR:1.13; 95%CI:0.74 to 1.72), respectively. In our propensity score matching analysis 34 patients in the CR-only group were unable to be matched, of which the overwhelming majority were older (85% were aged 85+ at the time of their cancer diagnosis) and had higher levels of comorbidity (32% had 2+ comorbidities versus 14% in the CR-only cohort overall). However, despite excluding these patients from the analysis cohort, our study results remained unchanged, eTable 1.

Discussion:

Adherence to guideline recommended surveillance was poor for all Medicare patients with rectal cancer. Only a small fraction of our cohort met all NCCN guidelines for the two-year surveillance period. While our primary goal was to assess surveillance differences between

those receiving conventional therapy and CR-only, follow-up care for both groups was indistinguishably poor.

When evaluating treatment and surveillance patterns by patient-level characteristics, there were a few clear patterns. Rates of CR-only are increasing with time, which is consistent with prior work.(2) Black patients were more likely to have surgery omitted, yet surveillance patterns were not different by race. Older patients, those with increased comorbidities, and those identified as single/divorced were more likely to receive CR-only treatment and less likely to receive surveillance. Yet, competing health priorities likely did not fully explain the omission of surgery and surveillance, as this study required patients survive the entire two-year surveillance period, and propensity score matching excluded the most elderly and unwell in the CR-only group. Lastly, >96% of our cohort was seen by a provider during our surveillance period, so it is unlikely they were completely lost to follow-up.

Prior studies evaluating surveillance guidelines after colorectal cancer treatment have shown low rates of adherence, albeit not as low as our study which is most likely reflective of our stricter guidelines. Vargas et al. reported overall guideline compliance of 25% with CEA adherence rates of 29%.(15) Other studies have shown similar results with overall surveillance after colorectal cancer treatment less than 50%.(18) (16, 22) Various professional societies recommend slightly different surveillance schedules; however, it is universally agreed upon that cross-sectional imaging, CEA and office visits should be performed at least once per year and a colonoscopy should be performed within one year of surgery.(21) Even when our cohort was allowed to complete the first-year surveillance guidelines over the first two-year follow-up period, only 25% of the conventional group and 14% of the CR-only group were compliant.

For CR-only patients, the role of TRUS and pelvis MRI should be critical since there is a particularly high risk of locoregional failure, up to 25% in the first two year.(5) However, only 10% of CR-only patients received either TRUS or MRI in our cohort. Conversely, 34% of our cohort received a PET/CT scan during the surveillance period, which has been shown to increase costs without improving outcomes.(23)

Prior work has sought to determine explanations for the variations in care for colorectal patients using SEER-Medicare. Popescu et al. found between-physician variation explained less than 20% of the differences and after controlling for between-physician differences, median household income explained only 13% and within-physician differences by race/ethnicity were less than 2%. The majority of residual within-physician disparities in proper care were thought to be due to differences in patient-provider communications, patient preferences and treatment adherence, or unmeasured clinical severity.(24) Our data do not provide the granularity to fully understand why surveillance after rectal cancer treatment is substandard.

We sought to evaluate provider and hospital-level factors associated with treatment and surveillance. Prior similar investigations generally assigned patients to a surgeon and facility where their index surgery was performed.(25) However, we were not able to do this as many individuals not receiving surgery did not see a surgeon and/or were not treated at a hospital.

Hopefully an ongoing clinical trial (NCT02217865) will provide better understanding of patient preferences and patterns of care regarding surveillance after colorectal cancer treatment.(26) There are limitations to our study. Our study period is relatively old compared to CR-only treatment.(1) Initial publications began in 2004, which coincides with the start of our study, however publications have grown exponentially since that time.(27)

It is unclear from claims data if individuals have a complete clinical response or if there were other reasons, besides intent, that patients forgo surgery. First, SEER does not include both clinical and pathological staging; thus, it is not possible to know if a patient had a clinical complete response. Furthermore, we do not know the location of the rectal cancer. Patients with low-rectal cancers, perhaps more frequently, chose chemoradiation-only when offered an abdominoperineal resection instead of a low anterior resection. Secondly, in 2004, only the innovators and very early adopters may have intentionally treated patients with chemoradiation-only. Accordingly, the 15% of patients that did not undergo surgery in 2004 could represent the baseline rate of elderly Medicaid patients unfit for surgery. It is acceptable to limit the use of surveillance if chemoradiation-only was chosen as a palliative alternative. These explanations cannot be determined within SEER-Medicare data; however, we attempted to control for factors as best as possible by requiring survival during the treatment and surveillance period.

Additionally, we would not suspect more patients to be more unfit for surgery over time. Third, cancer recurrence is not recorded in SEER; accordingly it is impossible to know if surveillance patterns led to detection of recurrence and a change in management. In any case, the lack of guideline-coordinate surveillance for the majority of our cohort cannot be justified by the lack of granularity in the data.

There are limitations regarding chemotherapy and radiation. Because oral chemotherapy (in this case, capecitabine) has been shown to be under-captured in claims,(28) we allowed patients who appeared to receive radiation without chemotherapy to remain in the sample. Ten percent of our sample had radiation without chemotherapy. Likewise, we did not try to determine if an individual completed a full-course of radiation, however the median number of claims, 31, was the same for both groups.

The long-term goal of this research is to improve outcomes for individuals with rectal cancer by optimizing care received from diagnosis through post-treatment surveillance. Specifically, we aim to better understand how new innovative treatment paradigms (i.e. CR-only) are implemented and perform in general practice. Avoiding surgery is an appealing approach to the treatment of rectal cancer as it preserves the rectum and avoids the morbidity of a large surgical procedure. However, appropriate surveillance is critical in the setting of CR-only to reduce the risk of poor outcomes through early identification and salvage treatment of recurrence.

Conclusions:

As the prevalence of rectal cancer survivors continue to grow, providers should be aware of the room to improve post-treatment monitoring, particularly for patients receiving CR-only

since local regional recurrence rates are expected to be higher. Conversely, the role of PET-CT in routine surveillance for non-metastatic rectal cancer is unwarranted (21), yet one-third of this cohort received it. Physician education may be an important step to improving surveillance for rectal cancer. Lastly, the need for intensive surveillance should be discussed and factored in to discussions about the risks and benefits of the CR-only approach.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgment:

The authors acknowledge the efforts of the National Cancer Institute; the Office of Research, Development and Information, CMS; Information Management Services, Inc.; and the Surveillance, Epidemiology, and End Results (SEER) Program tumor registries in the creation of the SEER-Medicare database.

Support: Funding for this project was supported by the North Carolina Translational and Clinical Sciences Institute via the National Center for Advancing Translational Sciences, NIH (grant award no. UL1TR001111). Dr Cole was partially supported by a National Research Service Award Pre-Doctoral/Post-Doctoral Traineeship from the AHRQ sponsored by The Cecil G Sheps Center for Health Services Research, University of North Carolina (UNC) at Chapel Hill, grant no. T32-HS000032. The database infrastructure used for this project was funded by Department of Epidemiology, UNC Gillings School of Global Public Health; the Cecil G Sheps Center for Health Services Research, UNC; the CER Strategic Initiative of UNC's Clinical & Translational Science Award (UL1TR001111); and the UNC School of Medicine.

Disclosures outside the scope of this work: Dr Cole is an employee of Truven Health Analytics, an IBM Company. Dr Sanoff has received research funding from Novartis, Bayer, and Merck.

References:

1. Habr-Gama A, Perez RO, Nadalin W, et al. Operative versus nonoperative treatment for stage 0 distal rectal cancer following chemoradiation therapy: long-term results. *Ann Surg* 2004;240:711–717–discussion 717–718. [PubMed: 15383798]
2. Ellis CT, Samuel CA, Stitzenberg KB. National trends in nonoperative management of rectal adenocarcinoma. *J Clin Oncol* 2016;34:1644–1651. [PubMed: 27022115]
3. Maas M, Beets-Tan RGH, Lambregts DMJ, et al. Wait-and-see policy for clinical complete responders after chemoradiation for rectal cancer. *J Clin Oncol* 2011;29:4633–4640. [PubMed: 22067400]
4. Appelt AL, Ploen J, Harling H, et al. High-dose chemoradiotherapy and watchful waiting for distal rectal cancer: a prospective observational study. *Lancet Oncol* 2015;16:919–927. [PubMed: 26156652]
5. van der Valk MJM, Hilling DE, Bastiaannet E, et al. Long-term outcomes of clinical complete responders after neoadjuvant treatment for rectal cancer in the International Watch & Wait Database (IWWD): an international multicentre registry study. *Lancet* 2018;391:2537–2545. [PubMed: 29976470]
6. Maas M, Nelemans PJ, Valentini V, et al. Long-term outcome in patients with a pathological complete response after chemoradiation for rectal cancer: a pooled analysis of individual patient data. *Lancet Oncology* 2010;11:835–844. [PubMed: 20692872]
7. Torok JA, Palta M, Willett CG, Czito BG. Nonoperative management of rectal cancer. 7 ed. *Cancer* 7 ed. 7 ed.; 2016;122:34–41. [PubMed: 26599064]
8. Habr-Gama A, Gama-Rodrigues J, Juliao GP Sao, et al. Local recurrence after complete clinical response and watch and wait in rectal cancer after neoadjuvant chemoradiation: impact of salvage therapy on local disease control. *Int J Radiat Oncol Biol Phys* 2014;88:822–828. [PubMed: 24495589]

9. Glynne-Jones R, Hughes R. Complete response after chemoradiotherapy in rectal cancer (watch-and-wait): have we cracked the code? *Clin Oncol* 2016;28:152–160.
10. National Comprehensive Cancer Network. Rectal Cancer Version 1.2018 Available at: <https://www.nccn.org>. Accessed May 4, 2018.
11. Ellis CT, Sanoff H, Stitzenberg KB. Inferior survival rates after chemoradiation for rectal cancer without surgery—reply. *JAMA Oncol* 2017;3:859–861.
12. National Cancer Institute. SEER-Medicare Linked Database. Available at: <http://appliedresearch.cancer.gov/seermedicare>. Accessed July 24, 2017.
13. Klabunde CN, Legler JM, Warren JL, et al. A refined comorbidity measurement algorithm for claims-based studies of breast, prostate, colorectal, and lung cancer patients. *Ann Epidemiol* 2007;17:584–590. [PubMed: 17531502]
14. Davidoff AJ, Gardner LD, Zuckerman IH, et al. Validation of disability status, a claims-based measure of functional status for cancer treatment and outcomes studies. *Med Care* 2014;52:500–510. [PubMed: 24638118]
15. Vargas GM, Sheffield KM, Parmar AD, et al. Physician follow-up and observation of guidelines in the post treatment surveillance of colorectal cancer. *Surgery* 2013;154:244–255. [PubMed: 23889952]
16. Cooper GS, Kou TD, Reynolds HL. Receipt of guideline-recommended follow-up in older colorectal cancer survivors : a population-based analysis. *Cancer* 2008;113:2029–2037. [PubMed: 18780338]
17. Snyder RA, Hu C-Y, Cuddy A, et al. Association between intensity of posttreatment surveillance testing and detection of recurrence in patients with colorectal cancer. *JAMA* 2018;319:2104–12. [PubMed: 29800181]
18. Brawarsky P, Neville BA, Fitzmaurice GM, et al. Surveillance after resection for colorectal cancer. *Cancer* 2012;119:1235–1242. [PubMed: 23184361]
19. Zou G A modified poisson regression approach to prospective studies with binary data. *Am J Epidemiol* 2004;159:702–706. [PubMed: 15033648]
20. Spiegelman D Easy SAS calculations for risk or prevalence ratios and differences. *Am J Epidemiol* 2005;162:199–200. [PubMed: 15987728]
21. Steele SR, Chang GJ, Hendren S, et al. Practice guideline for the surveillance of patients after curative treatment of colon and rectal cancer. *Dis Colon Rectum* 2015;58:713–725. [PubMed: 26163950]
22. Carpentier MY, Vernon SW, Bartholomew LK, et al. Receipt of recommended surveillance among colorectal cancer survivors: a systematic review. *J Cancer Surviv* 2013;7:464–483. [PubMed: 23677524]
23. Sobhani I, Itti E, Luciani A, et al. Colorectal cancer (CRC) monitoring by 6-monthly 18FDG-PET/CT: an open-label multicentre randomised trial. *Ann Oncol* 2018;29:931–937. [PubMed: 29365058]
24. Popescu I, Schrag D, Ang A, Wong M. Racial/ethnic and socioeconomic differences in colorectal and breast cancer treatment quality: the role of physician-level variations in care. *Med Care* 2016;54:780–788. [PubMed: 27326547]
25. Charlton ME, Hrabec JE, Wright KB, et al. Hospital characteristics associated with stage II/III rectal cancer guideline concordant care: analysis of Surveillance, Epidemiology and End Results-Medicare Data. *J Gastrointest Surg* 2016;20:1002–1011. [PubMed: 26658793]
26. Patient-Centered, Risk-Stratified Surveillance After Curative Resection of Colorectal Cancer. [Internet]. 2014 Available at: <https://www.pcori.org/research-results/2013/patient-centered-risk-stratified-surveillance-after-curative-resection>.
27. Sammour T, Price BA, Krause KJ, Chang GJ. Nonoperative management or “watch and wait” for rectal cancer with complete clinical response after neoadjuvant chemoradiotherapy: a critical appraisal. *Ann Surg Oncol* 2017;24:1904–1915. [PubMed: 28324284]
28. Lund JL, Sturmer T, Harlan LC, et al. Identifying specific chemotherapeutic agents in Medicare data. *Med Care* 2013;51:e27–e34. [PubMed: 22080337]

Figure 1.
Study inclusion and exclusion criteria.

Figure 2.
Adjusted risk ratio of guideline surveillance for chemoradiation -only compared to conventional therapy.

Table 1.

Guidelines for Surveillance after Curative Resection for Rectal Cancer: National Comprehensive Cancer Network and Modified Guidelines

Guideline, year	CEA	Office visits [*]	Lower Endoscopy [*]	Imaging (chest/abdomen/pelvis) [*]
NCCN guideline surveillance for rectal cancer after surgical resection				
1	2×	2×	1×	2×
2	2×	2×	0	2×
Modified guideline surveillance				
Within 2-y period	2×	2×	1×	2×

^{*} All outpatient office visits, types of endoscopic evaluation, and cross-sectional imaging were included.

NCCN, National Comprehensive Cancer Network.

Table 2.

Characteristics of Medicare Recipients with Nonmetastatic Rectal Cancer

Characteristic	All patients	Chemoradiation-only	Conventional treatment	p Value
Overall, n	2,482	514	1,968	
Sex, %				0.27
Male	56.8	19.9	80.1	
Female	43.2	21.7	78.3	
Race, %				0.001
White	84.3	20.2	79.8	
Black	6.7	31.3	68.7	
Other	9.0	17.4	82.6	
Age group, %				<0.0001
65 to 74 y	58.1	15.9	84.1	
75 to 84 y	35.8	22.6	77.4	
85 plus y	6.1	55.0	45.0	
Charlson score, %				0.002
0	65.4	19.1	80.9	
1	23.9	21.8	78.3	
2+	10.7	28.2	71.8	
Marital status, %				<0.0001
Married/partnered	57.7	16.8	83.2	
Divorced/widowed/separated	30.3	25.2	74.8	
Single	8.4	29.7	70.3	
Unmarried/unknown	3.5	24.1	75.9	
Stage of disease, %				<0.0001
0	2.2	44.4	55.6	
1	24.7	29.4	70.6	
2	38.0	20.4	79.6	
3	35.2	13.5	86.5	
Metro group, %				0.90

Characteristic	All patients	Chemoradiation-only	Conventional treatment	p Value
Urban	87.4	20.8	79.3	
Less urban/rural	12.6	20.5	79.6	
Region, %				0.81
Northeast	21.7	21.9	78.1	
South	26.6	20.5	79.6	
North Central	11.4	19.1	80.9	
West	40.3	20.7	79.3	
Radiation without chemotherapy, %	10.4	20.8	7.7	<0.0001
Median household income, % *				0.62
1 st (< \$33,700)	19.7	23.1	76.9	
2 nd (\$33,700 - < \$45,100)	22.6	20.1	79.9	
3 rd (\$45,100 - < \$60,500)	24.7	21.0	79.0	
4 th (\$60,500)	32.2	19.4	80.6	
Missing	0.7	22.2	77.8	
Below poverty, % *				0.04
<5.0	28.4	17.6	82.4	
5.0-9.9	27.3	19.2	80.8	
10.0-19.9	26.3	23.4	76.6	
20.0	17.3	23.3	76.7	
Missing	0.7	22.2	77.8	
Non-high school graduate, % *				0.60
10.0	31.7	19.2	80.8	
10.01-25.0	43.8	20.7	79.3	
25.01-50.0	21.6	22.4	77.6	
>50.0	2.3	25.0	75.0	
Missing	0.7	22.2	77.8	
Diagnosis date, %				0.02
2004	9.2	14.4	85.6	
2005	11.9	19.7	80.3	

Characteristic	All patients	Chemoradiation-only	Conventional treatment	p Value
2006	11.6	18.0	82.0	
2007	12.4	22.7	77.3	
2008	11.5	16.5	83.5	
2009	12.0	22.9	77.1	
2010	12.5	22.5	77.5	
2011	12.6	25.9	74.1	
2012	6.3	22.4	77.6	
National Cancer Institute Center designation, %				0.098
None	86.1	21.3	78.7	
Clinical	2.9	22.2	77.8	
Comprehensive	11.0	15.8	84.3	
Poor predicted disability status, % [‡]	4.3	7.0	3.6	<0.001
Survival time, d				
Mean	2307.19	2010.25	2384.74	
Median	2140.50	1785.50	2251.00	

* Census-level data.

[‡] Using the Davidoff Disability Status model, a validated claims-based predictive proxy measure for performance status.

Surveillance Activities among Medicare Recipients Treated with Chemoradiation-Only Compared to Conventional Management

Table 3.

Surveillance	All patients	Chemoradiation only	Conventional treatment	p Value
Overall, n	2,482	514	1,968	
Surveillance, across all activities, %				<0.0001
Any surveillance	56.9	69.1	53.8	
NCCN compliance	3.2	2.5	3.4	
Modified compliance	22.5	14.4	24.6	
CEA during 2-y surveillance period, %				
Any surveillance, 1 CEA	88.0	70.0	92.6	<0.0001
NCCN compliance, 2+ CEA/y	56.9	33.1	63.2	<0.0001
Modified compliance, 2 CEA/2 y	79.9	57.4	85.8	<0.0001
Endoscopy during 2-y surveillance period, %	65.8	49.8	69.9	<0.0001
Transrectal ultrasound, 1	2.86	8.17	1.47	<0.0001
Colonoscopy, 1	64.6	46.3	69.4	<0.0001
NCCN compliance, 1 within year one	43.9	33.5	46.7	<0.0001
Modified compliance, 1/two-year period	65.8	49.8	69.9	<0.0001
Imaging during 2-y surveillance period, %	63.5	55.1	65.8	<0.0001
Chest X-ray	82.7	77.4	84.1	0.0004
CT abdomen	52.3	42.4	54.9	<0.0001
CT pelvis	74.2	66.5	76.2	<0.0001
MRI abdomen	4.1	3.3	4.3	0.3035
MRI pelvis	5.2	5.5	5.2	0.8105
PET/CT	33.8	31.3	34.5	0.1750
NCCN compliance, 2/y	8.1	8.6	8.0	0.6946
Modified compliance, 2/two-year period	31.1	23.9	33.0	0.0004
Outpatient office visits during 2-y surveillance period, %				
Primary care physician	82.4	78.6	83.4	0.0112
Gastroenterologist	30.0	28.6	30.4	0.4312
Surgeon	76.5	61.9	80.3	<0.0001

Surveillance	All patients	Chemoradiation only	Conventional treatment	p Value
Radiation oncologist	28.6	30.5	28.2	0.2850
Medical oncologist	80.3	67.7	83.6	<0.0001
NCCN compliance, 2 visits/y	89.0	79.2	91.5	<0.0001
Modified compliance, 2/two-y period	97.5	93.4	98.6	<0.0001