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Assessing Compliance with National Comprehensive Cancer Network Guidelines for Elderly Patients with Stage III Colon Cancer: The Fox Chase Cancer Center Partners' Initiative

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Abstract

Background—Fox Chase Cancer Center Partners (FCCCP) performs an annual quality review of affiliate practices based on National Comprehensive Cancer Network (NCCN) guidelines. Given recent treatment advances, we initiated this medical record review in elderly patients with stage III colon cancer to measure compliance with these guidelines.

Methods—Medical records of 124 patients age ≥ 65 diagnosed with stage III colon cancer between 2003 and 2006 were reviewed. Metrics were developed and based on NCCN guidelines for workup and staging, treatment, and gerontology. Documentation was reviewed via paper (13 sites) and electronic record (2 sites).

Results—High compliance with staging and workup guidelines was noted with chest imaging (100%), stage (98%), computed tomography (CT) of the abdomen/pelvis (93%), pathology (91%), and carcinoembryonic antigen (CEA; 91%). Activities of daily living were documented commonly (83%) but colonoscopy less (75%). Age and life expectancy were discussed with the patient in only 49%. Nearly all patients (123 of 124 patients) received adjuvant chemotherapy, with 76 patients (61%) receiving oxaliplatin. Common regimens were FOLFOX (oxaliplatin plus infusional/bolus 5-fluorou-racil and folinic acid) 54%, 5-fluorouracil/leucovorin (5-FU/LV; 19%), and capecitabine (12%). Reasons for excluding oxaliplatin were comorbidity (68%), age (19%), and not specified (13%). Three-quarters of the patients had ≥ 12 lymph nodes sampled and 56% identified the radial margin. Nearly all patients (115 = 93%) received surveillance with history and physical and CEA. Surveillance CT was performed in 78% of the patients.

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Conclusions—A quality review of community oncology practices can assess implementation of treatment advances. Guideline compliance for elderly patients with stage III colon cancer is generally high. Forty percent did not receive oxaliplatin and documentation of life expectancy was infrequent. Further study of oncologist decision making for elderly colon cancer patients is warranted.

Keywords

Colon cancer; Community oncology; Gerontologic oncology; Performance improvement; Quality

Introduction

The standard adjuvant treatment for stage III colon cancer is the 2 drug combination of 5-fluorouracil (5-FU) and oxaliplatin, based on 2 large studies documenting an improvement in recurrence-free survival compared with 5-FU alone.[1,2] In a recent 7-year update of the MOSAIC trial, FOLFOX (oxaliplatin plus infusional/bolus 5-fluorouracil and folinic acid) was also shown to improve overall survival (OS) for patients with stage III colon cancer and high risk stage II disease.[3] However, the combination results in additional toxicity compared with 5-FU monotherapy, primarily consisting of myelosuppression and neuropathy.

It is estimated that by the year 2030, 70% of cancer cases will be diagnosed in those over the age of 65.[4] This older population represents a unique challenge in cancer management. Patients with advanced age often have comorbidities that can increase the risk of treatment complications.[5] Anemia is more common and can complicate cytotoxic therapy.[6] These factors, as well as reduced life expectancy, are considerations for oncologists discussing adjuvant therapy.

One measure of the impact of a "positive" clinical trial is how rapidly the advances become incorporated both in guidelines and in academic and community practice. The Fox Chase Cancer Center Partners (FCCCP) program comprises approximately 23 community cancer programs affiliated with Fox Chase Cancer Center (FCCC).[7] One of its primary missions is to evaluate, support, and improve the quality of care at our community partners.[8] Because of the important improvements in adjuvant therapy for stage III colon cancer and challenges in treating an elderly population, we conducted a 2007 chart review of treatment patterns for elderly patients with stage III colon cancer at 15 medical oncology practices.

Patients and Methods

Audit Development

Using the May 2006 version of the National Comprehensive Cancer Network (NCCN) colon cancer guidelines,[9] an initial list of recommended components of the care of stage III colon cancer was created by FCCC gastrointestinal (GI) medical oncologists. FCCC medical oncologists queried affiliated community oncologists through a formal teleconference to gain consensus on which elements would be most important to every day practice. The results were tabulated in a relational database that was used for specific data capture and a cumulative report. A sample of items is listed in Table 1.

Case Selection and Audit Implementation

Participating medical oncologists or their staff identified patients seen in their office aged 65 years of age or older with a diagnosis and resection for stage III colon cancer from July 2003 to July 2006. July 2003 was selected as the start date as this immediately followed the original presentation of the MOSAIC trial at American Society of Clinical Oncology (ASCO) meeting in 2003. The quality assurance study included 15 private practice medical

oncology offices in New Jersey and Pennsylvania in 2007. Two practices were hospital-based with the remaining freestand-ing facilities. Participation of partner practices was encouraged but optional. A senior project manager who is a registered nurse and certified in oncology from FCCC, reviewed medical records via paper chart copy in 13 sites and electronic medical record in 2 sites. Documentation was considered "compliant" if the event was noted in the chart and if applicable within the timeframe recommended by NCCN guidelines. Results were reviewed with a GI medical oncologist at FCCC in cases of question or discrepancy. In general, a project manager spent 1 full day at each office practice with an estimated 30 minutes per paper chart.

Results

Documentation of Initial Workup and Staging

Table 2 lists compliance with documentation of initial workup and staging. Nearly all patients had adequate stage documentation on the chart (ie, "stage III"). Similarly, nearly all had the actual pathology report on the chart. Lower compliance was noted with documentation of a colonoscopy having been performed in general, and of reaching the cecum in particular. Most patients also had adequate initial staging imaging and carcinoembryonic antigen (CEA) measurements performed.

Adjuvant Treatment

Table 3 summarizes the adjuvant therapy received by patients. Nearly all patients received adjuvant therapy. Approximately half of the patients received FOLFOX with 61% of the regimens containing oxaliplatin. Of those who did not receive oxaliplatin, the vast majority of charts contained documentation regarding the reason. Most commonly cited were comorbidities, with age specifically mentioned in only 19% of patients. One third of the patients received a single agent fluoropyrimidine. The average number of cycles that oncologists planned to administer was 12. However, at least 10 cycles were completed only 40% of the time.

Other Metrics

Table 4 lists compliance with other measured metrics. At least 12 lymph nodes were retrieved in approximately three fourths of the patients. Nearly all patients had history and physical and CEA surveillance per NCCN guidelines (history and physical and CEA every 3 months for 2 years, then every 6 months for 5 years). Yearly computed tomography (CT) scans were performed during surveillance in nearly 80% of patients. Although 83% of patients had their activities of daily living (ADL) evaluated, life expectancy was discussed with less than half of the patients.

Discussion

Our chart review of elderly patients with stage III colon cancer suggests that the vast majority of elderly patients seen in a medical oncology practice receive adjuvant therapy for stage III colon cancer. However, nearly 40% did not receive oxaliplatin and discussion of life expectancy was limited.

There has been increasing attention on the oncologic care of elderly patients with colorectal cancer.[10] The elderly have historically been underrepresented in cancer clinical trials, with those over the age of 65 comprising one quarter to one third of the cohorts.[11,12] Despite their smaller numbers, the elderly have generally been found to derive similar benefit as younger patients in pooled analysis of older adjuvant studies containing only 5-FU as the treatment arm.[13] More recently, a pooled analysis of trials documented that the elderly and younger

patients obtained similar benefit with FOLFOX compared with 5-FU, although myelosuppression was more common in the elderly.[14] However, this analysis contained only 1 adjuvant trial. In contrast, an analysis from the ACCENT database pooling 6 adjuvant trials reported no benefit for either disease-free survival or OS for the addition of either irinotecan or oxaliplatin to a fluoropyrimi-dine in patients older than 70.[15]

Outside of a clinical trial, administration of adjuvant therapy in elderly patients with stage III cancer has been variable. Schrag et al[16] performed a Surveillance, Epidemiology, and End Results (SEER) database analysis and noted that just over half of patients over the age of 65 received chemotherapy within 3 months of diagnosis. Similarly, Ayanian et al[17] noted decreasing rates of adjuvant therapy administration with increasing age in an analysis of the California Cancer Registry. The higher adjuvant therapy receipt rate in our study may reflect a growing awareness of the elderly patient's ability to tolerate FOLFOX. It also may reflect the fact that an "elderly" audit should ideally include patients above higher age thresholds (ie, 70 or 75 years old). We chose this cutoff based on practical considerations to include an adequate sample size for our audit. The high rate of adjuvant therapy may also represent a selection bias, in that we sampled charts of patients referred to a medical oncology office. However, only 60% of patients received FOLFOX. Our analysis argues against age bias, as only a small minority of charts reported age as a factor in decision making. However, medical oncologists who were actually using age as treatment criteria may have been reluctant to document this on the chart. Comorbidities were most commonly cited.

Because the comorbidities were the most commonly cited reason for excluding oxaliplatin therapy, a more formal functional assessment of the elderly patient would be of high value both in general oncologic care and in evaluating adjuvant therapy for stage III colon cancer in particular.[18] In our assessment, although a reference to basic ADLs was noted, a formal functional assessment was rarely performed. Functional assessment tools including the Katz index[19] and the Lawton scale[20] were provided as handouts to participating practices to support appropriate documentation and assessment changes. These tools can be used to support the practitioner in assessing the capabilities of the gerontologic patient to tolerate standard doses or courses of chemotherapeutic or radiation treatment. It would also be useful for future reviews to take into account patient-related factors. Patient decision making may be much different for older patients, as their tradeoffs between length and quality of life may diverge from younger patients.[21] Withholding of oxaliplatin may thus be completely appropriate for older patients based on preference but this will require further evaluation.

A commonly evaluated quality measure for colorectal cancer is the number of lymph nodes retrieved at resection. We have recently shown that a targeted educational initiative throughout our partner community affiliates is associated with increased nodal yield for colon cancer surgery.[22] In the current smaller experience, nearly three fourths of samples had at least 12 lymph nodes. This compares quite favorably to older reports at community sites, and may reflect increased attention to quality measures at the participating sites.[23] This is particularly notable in view of the fact that elderly patients tend to have fewer lymph nodes retrieved at surgery.[24]

In summary, a quality audit for elderly patients with stage III colon cancer throughout a large community cancer affiliate program demonstrated a high rate of adjuvant therapy administration. Although nearly 40% of the patients did not receive oxaliplatin, the vast majority had appropriate documentation of reasoning. Comorbidi-ties rather than age were the overwhelming reasons cited in the charts. Withholding oxaliplatin therapy may be completely appropriate based on patient preference and life expectancy. Further evaluation of the impact of targeted support for functional status and life expectancy assessment and

documentation is warranted. In addition, we plan to study the relationship between guideline compliance and patient outcome measures.

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Table 1

Sampling of Audit Items

Patient Identification
TNM Staging on Chart?
Diagnostic:
Pathology/biopsy, colonoscopy, CBC, chemistry profile, CEA, abdominal/pelvic CT, CXR (Chest CT OK)
Colonoscopy/sigmoidoscopy on chart?
Did colonoscopy reach to level of cecum?
Pathology report on chart?
Was lymph node dissection ≥ 12 lymph nodes?
Number positive nodes
Number total nodes
Final margin status (≤ 1mm, 1–2mm, ≥ 2 mm)
Radial margin status identified?
Type of Adjuvant Treatment and Number of Cycles:
1) 5-FU bolus with leucovorin (Roswell Park regimen)
2) 5-FU bolus with leucovorin (Mayo Clinic Regimen)
3) Infusional 5-FU (De Gramont Regimen)
4) Capecitabine
5) FOLFOX (oxaliplatin, infusional 5-fluorouracil, bolus 5-FU, leucovorin)
6) FLOX (oxaliplatin, bolus 5-FU, leucovorin)
7) CAPOX (capecitabine plus oxaliplatin)
8) Irinotecan
9) FOLFIRI (infusional 5-FU, irinotecan, leucovorin)
10) IFL (irinotecan, bolus 5-FU, leucovorin):
11) Other
Start of Therapy_____
Stop Date Therapy_____
If Oxaliplatin Not Used, Reason Given?
1) Age
2) Comorbidities
3) Preexisting neuropathy
4) Patient preference
5) Performance status
6) Other (specify)_____
Comorbidities documented? Yes/no and which?
Assessment of Life Expectancy Documented Before Initiating Adjuvant Therapy?
Activities of Daily Living Documented Pretreatment?
Surveillance Documented?
Should Include from Point of Last Treatment:

a. ≤ Q 3 months ± 1 month = H&P for 2 years then ± every 6 months ± 1 month for 5 years.
b. CEA ≤ every 3 months ± 1 month for 2 years then ± every 6 months ± 1 month up to 5 years.
c. CT performed during surveillance?
d. Reason for CT documented?

Table 2

Compliance with Documentation of Initial Workup and Staging

Metric	Compliance (%)
Chest Imaging	100
Staging	98
CT Abdomen/pelvis	93
CEA	91
Pathology Report	91
Colonoscopy	75
Colonoscopy Reaches Cecum	58

Table 3

Common Adjuvant Regimens and Reasons for Excluding Oxaliplatin

Regimen	Frequency (%)
Any	99
Contained Oxaliplatin	61
FOLFOX	54
5-FU/LV	19
Capecitabine	12
FLOX/CapOx	5
Infusional 5-FU/capecitabine Alone	2
Why No Oxaliplatin?	
Comorbidity	68
Age	19

Table 4

Other Metrics

Metric Pathology	**Compliance (%)**
≥ 12 lymph nodes	74
Identify radial margin	61
Surveillance	
H+P/CEA	93
CT	78
Gerontologic	
ADL	83
Discuss life expectancy	49