Compliance With Gastric Cancer Guidelines is Associated With Improved Outcomes

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Abstract

Background: Limited data are available on the implementation and effectiveness of NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Gastric Cancer. **Purpose:** We sought to assess rates of compliance with NCCN Guidelines, specifically stage-specific therapy during the initial episode of care, and to determine its impact on outcomes. **Methods:** The California Cancer Registry was used to identify cases of gastric cancer from 2001 to 2006. Logistic regression and Cox proportional hazard models were used to predict guideline compliance and the adjusted hazard ratio for mortality. Patients with TNM staging or summary stage (SS) were also analyzed separately. **Results:** Compliance with NCCN Guidelines occurred in just 45.5% of patients overall. Patients older than 55 years were less likely to receive guideline-compliant care, and compliance was associated with a median survival of 20 versus 7 months for noncompliant care ($P<.001$). Compliant care was also associated with a 55% decreased hazard of mortality ($P<.001$). Further analysis revealed that 50% of patients had complete TNM staging versus an SS, and TNM-staged patients were more likely to receive compliant care (odds ratio, 1.59; $P<.001$). TNM-staged patients receiving compliant care had a median survival of 25.3 months compared with 15.1 months for compliant SS patients. **Conclusions:** Compliance with NCCN Guidelines and stage-specific therapy at presentation for the treatment of patients with gastric cancer was poor, which was a significant finding given that compliant care was associated with a 55% reduction in the hazard of death. Additionally, patients with TNM-staged cancer were more likely to receive compliant care, perhaps a result of having received more intensive therapy. Combined with the improved survival among compliant TNM-staged patients, these differences have meaningful implications for health services research. (J Natl Compr Canc Netw 2015;13:319–325)

Background

Simultaneous to the landmark publication "To Err Is Human: Building a Safer Health System,"[1] the Institute of Medicine released their report entitled "Ensuring Quality Cancer Care" that similarly highlighted increasing concerns regarding the quality and effectiveness of cancer care in the United States.[2] Among the recommendations proposed was the development of guidelines for prevention, diagnosis, treatment, and palliation, and to monitor the quality of cancer care. We have succeeded in many ways with the former. However, the latter remains a challenge, both in defining and measuring the quality of care.[3] Several quality improvement programs have been developed, including the ASCO Quality Oncology Practice Initiative and the National Surgical Quality Improvement Project (NSQIP). In general, each program follows the Donabedian[4,5] paradigm for measuring health care quality with respect to 1 of 3 domains: structure, process, and outcomes. Although limitations exist with each domain,[6] process measures such as guideline compliance offer actionable variables for the provider and are generally linked to quality improvement.

With this backdrop, NCCN developed treatment guidelines for the management of most cancers. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) provide recommendations based on the best evidence available at the time they are derived and on expert consensus. These guidelines are continuously updated and revised to reflect new data and clinical information that may add to or alter current clinical practice standards. The NCCN Guidelines remain among the most widely recognized cancer

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care guidelines in the world. Although the development and evaluation of evidence-based practice guidelines are becoming increasingly standardized,[7] the effectiveness of these guidelines depends on dissemination and compliance.[8] Early research suggests that compliance with guidelines varies dramatically across cancer type and treatment setting.[9–11]

Although multiple quality indicators have been studied for the management of gastric cancer, notably surgical technique and the extent of lymph node dissection,[12–14] limited data exist regarding implementation and effectiveness of clinical guidelines.[15] In this study, we used stage-specific NCCN Guidelines for Gastric Cancer to assess rates of compliance with stage-specific therapy during the initial episode of care and to analyze the impact of adherence on outcomes. We further compared the relationship between the type of staging and compliance, specifically the TNM stage based on the AJCC and the International Union Against Cancer (UICC) classification, versus the summary stage (SS) based on AJCC or SEER stage (eg, patients given a TNM stage of T2N1M0 compared with a corresponding SS of II). We hypothesized that a significant variation in compliance with NCCN Guidelines exists for the treatment of patients with gastric cancer in California, and that low compliance will negatively impact patient outcomes.

Methods

Study Cohort

All patients admitted with the diagnosis of gastric adenocarcinoma or carcinoma in situ of the stomach to California's general, acute, nonfederal hospitals between 2001 and 2006, inclusive, were identified in the linked database described later. The 2001–2006 study period was specifically chosen because of the relatively few changes in the NCCN Guidelines during this period (see later discussion), and because it provided adequate follow-up time for survival analyses. Only patients with complete TNM staging or SS were included to allow assessment of stage-specific compliance.

Data Sources

The California Cancer Registry (CCR)[16] was used to identify cases of gastric cancer (ICD diagnosis code 151.0–151.9) or carcinoma in situ of the stomach (230.2) diagnosed and treated between 2001 and 2006, inclusive. The CCR contains data collected via a statewide cancer-reporting program mandated by the California Health and Safety Code (sections 103875–103885), and managed by the California Department of Health Services (DHS) in collaboration with the Public Health Institute and 8 regional cancer registries. California state law requires that all hospitals, physicians, and certain other health care providers report every clinical encounter in which cancer is the primary diagnosis, regardless of treatment administered during the encounter. The rate of loss to follow-up in the CCR is low because all clinical encounters related to the treatment of a primary diagnosis of cancer must be reported to the registry, even if primary and subsequent treatments are administered in different hospitals. The registry contains fewer than 3% missing race data and fewer than 3% of records obtained from death certificates. In addition to detailed information about individual tumor characteristics, such as grade, stage, and select molecular marker data, the database also contains socioeconomic data measured at the census block group level, including a validated composite socioeconomic status (SES) score.[17,18]

Data from the CCR were subsequently linked to the California Office of Statewide Health Planning and Development (OSHPD) patient discharge abstracts[19] via a probabilistic linkage method using date of birth in conjunction with social security number. Complete descriptions of each database, and details regarding the linkage, were previously described by our group.[19] The study was approved by both the California Committee for the Protection of Human Subjects and the Stanford University Institutional Review Board.

Compliance

For the purposes of this study, compliance was defined as stage-specific adherence to the 2000 NCCN Guidelines for Gastric Cancer. Gastric cancer staging in the 2000 NCCN Guidelines relied on the 5th edition (1997) of the AJCC and the UICC TNM system.[20] Notably, differences exist between the AJCC 5th edition and the 7th (current) edition, including changes in the primary tumor (T) and regional lymph node (N) classifications. We elected to use data for the years 2001 through 2006 because no major changes were made to the NCCN Guidelines during this period. In broad terms, NCCN Guidelines recommended resection for all patients with

potentially resectable locoregional disease, followed by adjuvant chemoradiation therapy for any patient with stage IB disease or beyond. One exception came with the 2004 guidelines, when patients with T2N0M0 tumors, who were previously recommended to undergo adjuvant chemoradiation therapy after R0 resection, were given the option of observation, depending on tumor characteristics (to view the most recent version of these guidelines, visit NCCN.org). For these patients (T2N0M0), care was considered compliant with or without chemoradiation. To be inclusive given the variety of options available to clinicians and to reflect evolving clinical practice, we defined compliance in relatively permissive terms (Table 1, available online, in this article, at JNCCN.org). For patients with M1 disease according to TNM criteria, care was considered compliant if the patient received chemotherapy (with or without surgery and/or radiation). For patients with stage IV disease according to SS criteria, care was considered compliant if the patient received any treatment modality (surgery and/or radiation and/or chemotherapy), because stage IV included both localized disease (eg, T2N3M0, potentially treated by surgery) and metastatic disease potentially treated by chemotherapy.

The CCR data set includes a data point indicating that chemotherapy was recommended but not administered or the patient declined. These patients were recorded as having received chemotherapy for the purposes of our analysis to give clinicians credit for intent. Surgical procedures were characterized by ICD-9CM codes. Operations assumed to have been performed with curative intent included all partial and total gastrectomies (43.5–43.9). Palliative procedures included 43.1 (gastrostomy), 43.11 (percutaneous endoscopic gastrostomy), 43.19 (other gastrostomy), 44.38 (laparoscopic gastroenterostomy), 44.39 (other gastroenterostomy), and 46.32 (percutaneous endoscopic feeding jejunostomy) that were not associated with a resection.

Data Analysis

Analyses were performed using SAS 9.3 for Windows (SAS Institute Inc., Cary, NC), and a 2-sided *P* value less than .05 was considered statistically significant. Kaplan-Meier curves were generated for survival by stage of disease and compliance. Hierarchical logistic regression models, adjusted for both patient and hospital level characteristics, predicted the odds of compliant care. Cox proportional hazard models predicted the adjusted hazard ratio for mortality as a function of patient characteristics, including cancer stage, and hospital characteristics. Patient level predictor variables included age, race/ethnicity, gender, type of insurance, and SES. Severity of comorbid illness was defined using the Deyo-modified Charlson comorbidity index for each individual patient.[21,22] Hospital volume was divided into terciles (low, 1–10; medium, 11–20; high, >20) based on the number of annual discharges with a primary diagnosis of gastric cancer during the study period.

Results

During the study period, 14,862 patients were treated for gastric cancer in 398 hospitals. After excluding 4769 patients (32.1%) because of missing staging information, 10,093 patients remained as the study cohort. Of this cohort, 5027 patients (49.8%) had complete TNM staging available, whereas 5066 patients (50.2%) had only SS. Characteristics of the full cohort of 10,093 patients are shown in Table 2 (available online, in this article, at JNCCN.org).

Initial analysis of the entire cohort revealed that care compliant with NCCN Guidelines was delivered to 45.5% of patients overall. In multivariable models, adjusted for patient and hospital factors, we found that patients older than 55 years were less likely to receive compliant care, a trend that worsened for each decade beyond 55 years of age (unpublished data, 2014). Survival differences were compared among patients who received compliant care and those receiving noncompliant care. Patients who received compliant care had a median survival of 19.9 months (95% CI, 18.4–21.6) compared with just 7.3 months (95% CI, 6.8–7.9) for those who received noncompliant care ($P<.001$). This survival difference was consistent across all stages (Figure 1). Cox proportional hazard models revealed that even after controlling for patient and hospital factors, guideline compliance was associated with a 55% decreased hazard of death (hazard ratio [HR], 0.45; $P<.001$).

Because only half of the cohort had complete TNM staging, whereas the remaining patients received a SS alone, the bulk of this analysis was performed comparing these 2 cohorts separately. Baseline differences were found between the groups (Table 3, available online, in this article, at JNCCN.org). Notably, a higher percentage of SS patients were assigned

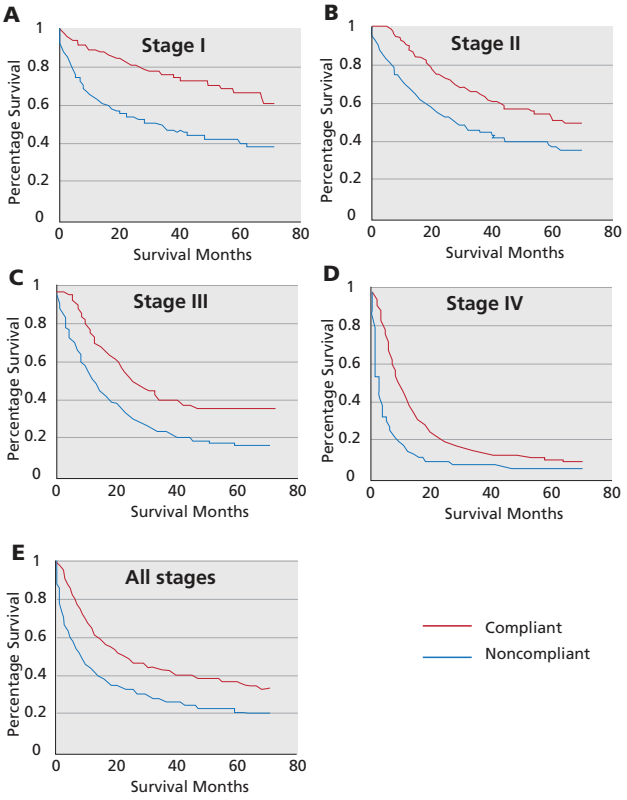

Figure 1 Kaplan-Meier survival curves of patients who received guideline-compliant care versus noncompliant care for stage I (A), stage II (B), stage III (C), stage IV (D), and all stages (E). (*P*<.001 for each survival curve.)

a lower stage; specifically, significantly more patients with stage I disease were in the SS group than in the TNM-staged group (33.1% vs 20.9%; *P*<.001). Additionally, fewer SS patients were treated at an academic center (6.4% vs 9.8%; *P*<.001).

Although compliance for those staged according to TNM criteria was 51.2%, those staged using SS criteria received compliant care just 39.7% of the time, with an odds ratio (OR) for compliance of 1.59 (95% CI, 1.47–1.72; *P*<.001). The percentages of TNM-staged and SS patients receiving compliant care for each stage are shown in Figure 2. Largely contributing to this difference in compliance between TNM-staged and SS patients is the rate of surgery. A greater percentage of patients with TNM staging underwent surgery (76.8% vs 42.7%; *P*<.001; OR for surgery, 4.45; 95% CI, 4.08–4.85; *P*<.001). Logistic regression analysis was performed, demonstrating that increasing age was associated with worse compliance, a trend that existed for both TNM-staged and SS patients. Higher Charlson score was associated reduced compliance, whereas patients treated at mid- and high-volume centers were associated with delivery of compliant care. Academic affiliation did not impact compliance. Additional predictors of compliance for both groups are shown in Table 4 (available online, in this article, at JNCCN.org).

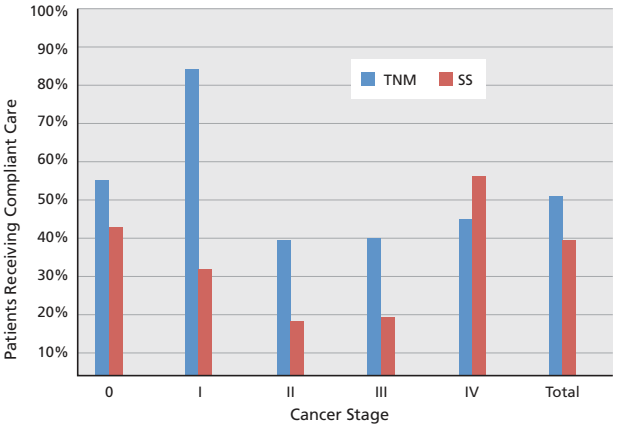

Figure 2 Percentage of patients with gastric cancer receiving care that was compliant with NCCN Clinical Practice Guidelines in Oncology (Version 1.2000)[20] according to cancer stage and staging system used (TNM stage vs summary stage [SS]).

Survival differences were also examined. Median survival was similar for TNM-staged versus SS patients (10.1 vs 10.9 months; *P*=.69). However, TNM-staged patients receiving compliant care had a median overall survival of 25.3 months (95% CI, 22.9–28.2), whereas SS patients receiving compliant care had a median overall survival of 15.1 months (95% CI, 13.5–16.5). Interestingly, TNM-staged patients receiving noncompliant care had worse unadjusted survival compared with SS patients (Figure 3). On Cox proportional hazard modeling, compliant care was associated with a reduction in mortality for both groups; however, the reduction was even greater for patients staged based on SS criteria (HR, 0.34; 0.32–0.37; *P*<.001) compared with those with complete TNM staging (HR, 0.58; 0.53–0.62; *P*<.001). Patients who received their care at mid- and high-volume centers had a reduced hazard of mortality, a trend that held for both staging groups. Additional characteristics predictive of mortality are shown in Table 5 (available online, in this article, at JNCCN.org).

Discussion

Gastric cancer remains a formidable disease, with more than 20,000 new cases diagnosed annually and

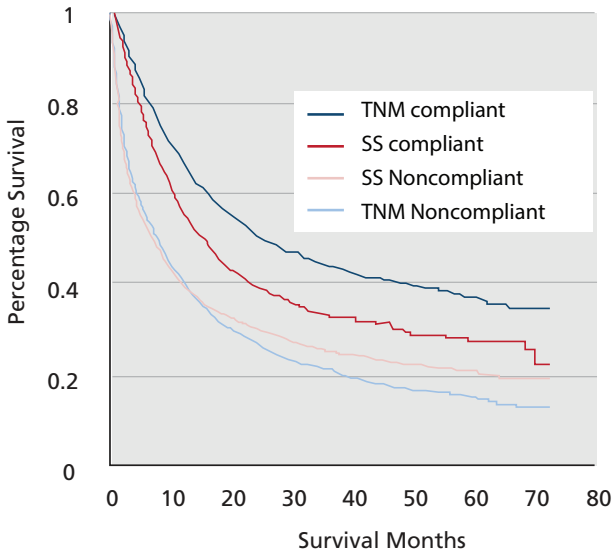

Figure 3 Kaplan-Meier survival curves of TNM-staged and summary staged (SS) patients who received guideline-compliant care versus noncompliant care for all stages ($P<.001$).

more than 10,000 cancer-related deaths per year in the United States.[23] Level 1 evidence has shown that multimodality therapy to include chemotherapy and/or radiation, combined with curative resection, can increase disease-free and overall survivals.[24,25] Despite this, limited data are available regarding the delivery of care that is compliant with clinical practice guidelines for gastric cancer.

In this study, we show that overall compliance with NCCN Guidelines in California for the treatment of gastric cancer was relatively poor, with less than half of all patients receiving compliant, stage-specific care at presentation. Patients with stage II and III gastric cancer were least likely to receive compliant care. Older age was the most significant predictor of noncompliant care, with progressively worsening compliance for every decade older than 55 years. This has great significance given that most patients diagnosed with gastric cancer were older than 65 years. The importance of compliance with NCCN Guidelines is in the fact that compliant care was associated with improved survival across all stages and with a 55% reduction in the hazard of mortality. This result is consistent with those of other published reports showing that compliance with complex cancer care guidelines is associated with improved outcomes, whether for the management of pancreatic cancer, melanoma, or ovarian cancer.[19,26,27]

The association between guideline compliance and improved outcomes is an important one, given the increased emphasis on outcomes-drive practice in our health care system. The Centers for Medicare & Medicaid Services already use value-based purchasing, and more specifically, "pay for performance," as a means for providing economic incentives for providing high-quality care.[28,29] Although the effectiveness of financial incentives to improve the quality of care remains to be seen, these have garnered significant support and will likely expand over time (both in scope and number of metrics).[30]

Currently, the cancer care delivery system is lacking when it comes to pay for performance or public reporting metrics, likely owing to the complex nature of cancer care, including the multimodal treatment options across multiple medical specialties.[31] That said, as part of the 2010 health care reform (Patient Protection and Affordable Care Act), the Department of Health and Human Services will begin collecting data from cancer centers for several quality measures already endorsed by the National Quality Forum (NQF).[32] As part of the law, subsequent pay for performance initiatives will begin pilot testing at free-standing cancer centers in 2016, with subsequent expansion in 2018.[32,33] Although questions remain as to which quality measures will be used, process measures such as guideline compliance offer actionable yet mutable measures linked directly to quality improvement.[6] Furthermore, several process measures for cancer care quality are already endorsed by the NQF.[34] In showing that reduced compliance with NCCN Guidelines affects outcomes, namely mortality, we offer an actionable measure that clinicians, hospitals, and payers may use in monitoring the quality of care being delivered.

A new finding highlighted in this study is the discrepancy between compliance and mortality rates for patients assigned a complete TNM stage versus SS. We found that compliance rates were significantly better for TNM-staged patients compared with those with SS alone. This suggests that SS patients may have undergone less-intensive therapy. One possible explanation is that TNM-staged patients are more likely to have staging based on pathology specimens, whereas SS patients are more often staged clinically (ie, via imaging) without pathologic data. This is supported by the difference in the rate of surgery between the groups, with patients staged according to TNM criteria having a greater than 4-fold increase in the odds of undergoing surgery. Unfortunately, the

current data set did not allow us to directly assess the reasons for the difference in the rate of surgery between the groups. Additionally, an apparent stage migration was seen in SS patients, evidenced by the higher proportion of patients with stage I disease among SS patients compared with TNM-staged patients. This finding is consistent with the suggestion that SS patients may have undergone less-intensive therapy, leading to clinical rather than pathologic staging. CT has previously been shown to have limited specificity in identifying lymph node metastases,[35] and there is a well-documented nodal stage up-migration associated with performing a formal D2 lymphadenectomy.[36]

Moreover, the difference between TNM-staged and SS patients is highlighted by the Kaplan-Meier curves showing survival differences between compliant and noncompliant care for the 2 staging groups. Although guideline-compliant TNM patients had improved survival (compared with guideline-compliant SS patients), noncompliant TNM-staged patients actually had the worst overall survival. In other words, the 2 curves for TNM-staged patients show greater separation. In addition, multivariable logistic regression analysis revealed that the reduction in mortality for patients receiving compliant care was even greater for SS patients compared with TNM-staged patients. It is somewhat difficult to interpret this difference, given the now established differences between TNM-staged and SS patients, including the apparent stage migration in SS patients.

These differences have significant implications for future studies relying on cancer registries. Staging, of course, is not performed at the initial encounter, but rather is extracted from the chart based on the imaging and pathology data, and from the impressions of the clinicians treating the patients. Our data suggest that it is not safe to assume for the purposes of database research that patients with gastric cancer staged as T2N1M0 are the same as those listed as stage II, because the former has had true pathologic staging, whereas the latter may not. To our knowledge, this is the first study to show that patients assigned a TNM stage and those assigned a SS are not, in fact, the same. Although whether this finding is applicable to other cancers remains to be seen, future studies relying on cancer registries should acknowledge this potential confounder.

A few limitations of this study should be noted. First, it is a retrospective analysis, and therefore we cannot and do not intend to attribute causality. Nonetheless, the strength of the correlations we have exposed suggests that improving compliance may have a positive impact on survival. Also, more than 30% of patients in the cancer registry had to be excluded from analysis because of missing or incomplete staging information. Although this represents a significant proportion of the total cohort, it is consistent with other literature relying on similar registries.[37]

Additionally, any attempt to evaluate compliance with treatment guidelines is limited by the inevitable changes and evolving practices that occur over time. The 2001–2006 study period was specifically chosen given the few changes in the NCCN Guidelines during this period, and compliance was defined in permissive terms. However, results from the MAGIC trial[38] were first reported in mid-2005 and later published in 2006, presenting the possibility that a subset of clinical oncologists adopted perioperative chemotherapy before the end of 2006. However, this is unlikely to have significantly impacted the results given the small number of patients it would have probably affected.

Furthermore, although surgery is a key component and included in our compliance definition for all (including M1 disease, for which palliative operations are included), the data are limited by the lack of individual patient performance status as a means of measuring whether a patient is considered medically unfit for surgery. In fact, NCCN Guidelines for the study period include categorizing the patient as medically fit versus medically unfit during the initial clinical evaluation, a distinction that is not possible given the current data set. Although higher Charlson score was associated with reduced compliance, there are limitations to using this as a surrogate for medically unfit patients, because the latter distinction is more complex and includes factors such as performance status.

Finally, patient preference may affect adherence with guidelines.[39] Although it is difficult to assess patient preference with regard to surgical intervention, we have accounted for this with respect to chemotherapy. The CCR database does include a variable noting that chemotherapy was recommended but not delivered (or refused). For the purposes of this study, these patients were coded as having received chemotherapy, and therefore as having received compliant

care. Thus, it is imaginable that the outcomes measure (mortality) can be confounded as a result of coding these patients as having received compliant care.

Conclusions

Using the NCCN Guidelines for the treatment of patients with gastric cancer, our data suggest that compliance with stage-specific therapy during the initial episode of care is associated with improved survival, and patients staged using complete TNM criteria were more likely to receive guideline-compliant care than those staged using SS alone. Further studies are needed to elucidate whether these differences exist for other cancers, and to determine the full implications these differences may have on health services research.

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