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ORIGINAL ARTICLE

Failure to comply with NCCN guidelines for the management of pancreatic cancer compromises outcomes

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Abstract

Introduction: There are little data available regarding compliance with the National Comprehensive Cancer Network (NCCN) guidelines. We investigated variation in the management of pancreatic cancer (PC) among large hospitals in California, USA, specifically to evaluate whether compliance with NCCN guidelines correlates with patient outcomes.

Methods: The California Cancer Registry was used to identify patients treated for PC from 2001 to 2006. Only hospitals with $\geq$ 400 beds were included to limit evaluation to centres possessing resources to provide multimodality care ($n = 50$). Risk-adjusted multivariable models evaluated predictors of adherence to stage-specific NCCN guidelines for PC and mortality.

Results: In all, 3706 patients were treated for PC in large hospitals during the study period. Compliance with NCCN guidelines was only 34.5%. Patients were less likely to get recommended therapy with advanced age and low socioeconomic status (SES). Using multilevel analysis, controlling for patient factors (including demographics and comorbidities), hospital factors (e.g. size, academic affiliation and case volume), compliance with NCCN guidelines was associated with a reduced risk of mortality [odds ratio (OR) for death 0.64 (0.53–0.77, $P < 0.0001$)].

Conclusions: There is relatively poor overall compliance with the NCCN PC guidelines in California's large hospitals. Higher compliance rates are correlated with improved survival. Compliance is an important potential measure of the quality of care.

Keywords

outcomes, pancreatic neoplasia, adenocarcinoma, NCCN, compliance, guidelines

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Introduction

Quality is the new mantra of American medicine and perhaps, in particular, American surgery. In fact, the American College of Surgeons' current slogan is 'Inspiring Quality: Highest Standards, Better Outcomes.'[1] But health care quality has proved challenging to define, much less improve. A variety of quality improvement programmes have been developed in order to meet this need: the National Surgical Quality Improvement Program (NSQIP), the Surgical Care Improvement Project (SCIP), the University Health Consortium Quality and Accountability Program (UHC-QAP) and the Leapfrog Group, among others. Each seeks to address one or more aspects of the three domains of healthcare quality measures: structure, process and outcome.[2] However, it has often proven surprisingly difficult to translate structure or process quality measure to improved outcomes.[3,4] Quality improvement is particularly challenging for complex cancer care, where long-term outcomes result from high-quality care across a spectrum of specialties from radiology to surgery to medical and radiation oncology.[5] For complex cancer operations, individual hospital volume has been the dominant predictor of outcomes.[6] The positive correlation between volume and outcome was demonstrated for operations for pancreatic cancer (PC) more than a decade ago,[7,8] yet there has been only a modest shift towards the use of higher volume centres for care.[9] Thus, assessment of the quality of the

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care of patients with PC must look beyond volume to describe other factors that correlate with optimal outcomes.

In an effort to improve the quality of cancer care, the National Comprehensive Cancer Network (NCCN) began in the 1990s to publish clinical practice guidelines that encompass the diagnosis, treatment and palliation of common cancers based on the best available evidence and expert consensus. These guidelines are updated regularly as new evidence emerges and practice evolves, and are the most widely recognized cancer clinical care guidelines in the United States. While evidence-based practice guidelines are becoming more and more standardized as a means of quality improvement,[10] the effectiveness of guidelines depends not solely on the quality of the guideline but also on dissemination and compliance.[11] Broadly speaking, research into the effect of clinical practice guidelines on patient outcomes is still in its infancy,[12] and only a small number of publications are available that specifically investigate the impact of compliance with NCCN guidelines[13–15]

The aim of the present study was to assess rates of compliance with NCCN guidelines and to analyse the impact of adherence on outcomes. We hypothesized that there is significant variation in the care of patients with PC, and that this variation impacts patient outcomes. To test this hypothesis, we performed a retrospective cohort study examining compliance with the NCCN guidelines for the management of PC in large California hospitals and the effect compliance had on patient.

Methods

Sources of data

The California Cancer Registry (CCR)[16] data were linked to the California Office of Statewide Health Planning and Development (OSHPD) patient discharge abstracts. This dataset was subsequently linked to hospital characteristics from the publicly available California Hospital Annual Financial Datafile (HAFD).[17]

The CCR contains data collected via a state-wide cancer-reporting programme 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 eight regional cancer registries.[16] California state law requires that all hospitals, physicians and certain other health care providers report every clinical encounter where cancer is the primary diagnosis regardless of treatment administered during the encounter. All relevant clinical, radiological and pathological data are reported, which decreases the loss to follow-up rate for patients who complete treatment within the state, 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 the individual tumours, with grade, stage and select molecular marker data, the database also contains census block group level sociodemographic data, including a validated composite socioeconomic status (SES) score.[18,19]

The California OSHPD patient discharge database compiles data for all discharges from more than 400 general, acute, non-federal hospitals in the state. In addition to the principal diagnosis (reason for admission) and the principal procedure, coded using the International Classification of Diseases-9th Clinical Modification (ICD-9-CM), the database also contains coding for up to 24 additional diagnoses (secondary diagnoses) and up to 19 additional procedures performed during the index hospitalization. California is one of only two databases, nationwide, to historically require all secondary diagnoses to be entered with concomitant coding for whether the condition was present on admission (CPOA). CPOA coding allows for distinction between co-morbidities and hospital acquired conditions (i.e. complications), and therefore facilitates risk adjustment of outcomes in multivariable models. The database also contains demographic information including age at diagnosis, gender and insurance status. Hospital volume can be derived based on the total number of discharges for a particular diagnosis aggregated at the hospital level.

Data from the CCR are linked to OSHPD data using a probabilistic linkage method employing day, month and year of birth in conjunction with the patient's social security number. The linkage was performed by the staff at the CCR then stripped of linking variables before disclosure to the investigators. OSHPD-assigned unique hospital identifiers were then used to link the CCR-OSHPD data to California Hospital Annual Financial Data (HAFD). The HAFD contains hospital level characteristics such as geographic location, Medicaid utilization rate, hospital ownership and teaching hospital status as designated by the state.

The study was approved by the California Committee for the Protection of Human Subjects (CPHS), the California Cancer Registry and the Stanford University Institutional Review Board.

Study cohort

All patients admitted with the diagnosis of pancreatic adenocarcinoma (principal diagnosis code 157.0–157.3, 157.8) to California's general, acute, non-federal hospitals between 2001 and 2006, inclusive, were identified in the linked database described above. In order to limit the analysis to larger hospitals which would likely possess the personnel and resources to deliver multidisciplinary care, we only included hospitals with more than 400 beds. Fifty-two hospitals were identified with $\geq$ 400 beds; two were excluded because they are rehabilitation facilities. Eight academic hospitals were identified by affiliation with a medical school, whereas 'teaching hospitals' are designated in the dataset by affiliation with resident training ($n = 19$).

Compliance

In order to assess compliance during the years 2001–6, we started with the 2000 NCCN guidelines.[20] Of note, cancer stage in the 2000 NCCN guidelines relied on the 5th edition (1997) of the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC) TNM system.[21] The prin-

ciple difference between the AJCC 5th edition and the subsequent 6th and 7th (current) editions is the definition of T3 and T4 tumors:

5th edition: T3 Tumour extends into any of the following: duodenum, bile duct and peripancreatic tissues

T4 Tumour extends directly into any of the following: stomach, spleen, colon and adjacent large vessels

6/7th editions: T3 Tumour extends beyond the pancreas but without involvement of the celiac axis or superior mesenteric artery

T4 Tumour involves the celiac axis or superior mesenteric artery (unresectable)

Thus, in the newer editions, T4 tumours are explicitly unresectable by consensus definitions of resectability,[22] while a small number of patients staged as T4 (and thus Stage VIa) according to the 5th edition would have tumours that would have been deemed resectable by experienced pancreatic surgeons (e.g. requiring portal vein resection/reconstruction or en-bloc resection of adjacent stomach, adrenal, etc.). However, appropriate resection of an adjacent portal vein or adjacent organs applies to a very small number patients on a population basis and thus, for our analysis, we assumed that T4 (and thus all stage IV) tumours were unresectable.

The NCCN guidelines do allow variation in care and evolve over time. For example, while adjuvant treatment of resected PC is standard, neoadjuvant care is explicitly mentioned as an acceptable alternative. In addition, the allowable chemotherapy and radiotherapy has evolved. The 2000 guidelines recommend gemcitabine for unresectable disease[23] and 5FU-based chemoradiation for all resected tumours (beyond Tis) based on the GITSG data.[24] However, subsequent modifications have included alternative regimens (e.g. adjuvant gemcitabine based on CONKO-1[25]). 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 the chemotherapy for our analysis to give the treating facility credit for the recommendation. While radiation was not required for compliant care at any stage, chemoradiation was considered compliant if administered in an adjuvant or neoadjuvant setting or with palliative intent in stage IV disease. Four patients were coded as having received radiation but no chemotherapy of any kind. We assumed that these patients had received 5FU concomitantly with the radiation (but this was omitted in the coding), and coded them as having received chemoradiation for our analysis. Surgical procedures were characterized by ICD-9 codes. Operations assumed to have been performed with curative intent included all pancreatectomies: 52.5 (52.51-3, 52.59), 52.6, 52.7. Palliative procedures included 51.87 (endoscopic biliary stent), percutaneous biliary drains (51.98), gastroenterostomy (44.38, 44.39), gastrostomy (43.11, 44.32), biliary anastomoses (51.36, 51.39) and nerve block (04.49) that were not associated with a resection. In order to be inclusive given the variety of options available to clinicians and to reflect evolving clinical practice, we defined compliance in very permissive terms:

Stage	NCCN-based definition of compliant treatment
O	Surgery
I	Surgery + chemotherapy or chemoradiation (adjuvant or neoadjuvant)
II	Surgery + chemotherapy or chemoradiation (adjuvant or neoadjuvant)
III	Surgery + chemotherapy or chemoradiation (adjuvant or neoadjuvant)
IV	Chemotherapy ± palliative procedures ± palliative radiotherapy

Data analysis

Analyses were performed using SAS 9.2 for Windows (SAS Institute Inc., Cary, NC, USA), and a two-sided $P < 0.05$ was considered statistically significant. Kaplan–Meier curves were generated to survival based on stage, compliance, academic volume and annual hospital volume. Multivariable and multilevel logistic regression analyses were used to calculate the adjusted OR predicting compliance (individual patient receipt of compliant care) and mortality as a function of patient characteristics and hospital characteristics (because compliance was defined by stage, it was excluded from the modelling). The same multivariable modelling was then used to calculate the adjusted OR for mortality as a function of patient characteristics, cancer stage and hospital characteristics. Patient level predictor variables included age, race/ethnicity, gender, type of insurance and socioeconomic level. Severity of co-morbid illness was defined using the Deyo-modified Charlson comorbidity index[26,27] for each individual patient. Hospital characteristics evaluated for the study included annual PC volume, teaching status and academic affiliation. Case volume was divided into terciles (low 1–15; medium 16–25; high > 25) based on the number of annual discharges with a primary diagnosis of PC during the study period. All other hospital variables were defined in the HAFD.

Results

During the study period, 17 970 patients were treated for PC in 397 hospitals. Of these, 5690 (32%) were treated in the 50 hospitals that had 400 or more beds. After excluding 1984 patients with missing staging information, 3706 patients remained as the study cohort (Table 1). The stage distribution was as follows: 17 Stage 0 (0.5%), 291 stage I (7.9%), 952 stage II (25.7%), 395 stage 3 (10.7%) and 2051 stage IV (55.3%). The 5-year survival for the entire cohort was 23%.

Care that was compliant with the NCCN guidelines was delivered to just 34.5% of patients overall, breaking down into 88.2% of Stage 0, 18.6% Stage I, 33.8% Stage II, 20.8% Stage III and 39.4% Stage IV. Among the 50 large hospitals in California, compliance ranged from 5% to 57%. Figure 1 shows the distribution of compliance of all 50 hospitals according to rank (highest

Table 1 Study cohort

Characteristics	*n* (%)	%
Pancreatic cancer patients		
Treated at large hospitals (≥ 400 beds)	5690	
Excluded for lack of adequate staging	1984	
Study cohort	3706	
Sex		
Male	1876	50.6%
Female	1830	49.4%
Race		
White	2484	67%
Black	319	8.6%
Hispanic	524	14.1%
Asian/Pacific Islander	379	10.2%
Insurance		
Private	1366	36.9%
Medicare	1721	46.5%
Medicaid	303	8.2%
Uninsured	107	2.9%
Unknown	209	5.6%
Treatment hospital		
Academic	971	26.2%
Non-academic	2735	73.8%
Teaching	1849	49.9%
Non-teaching	1857	50.1%
Stage		
0	17	0.5%
I	291	7.9%
II	952	25.7%
III	395	10.7%
IV	2051	55.3%

compliance on left). The red bars indicate case volume, demonstrating that several of the higher volume hospitals nonetheless had poor compliance.

Of patients with stage I–III cancer just 28% received compliant care (surgery and chemotherapy or chemoradiation), 27% received no treatment or palliative intervention only, 21% underwent resection but received no adjuvant or neoadjuvant therapy and 24% received chemotherapy or chemoradiation for their localized pancreatic disease. Patients with stage IV disease received compliant care in 39% of cases; however, more than half (52%) received no treatment or palliative intervention only, and 9% underwent a formal pancreatectomy (+/– adjuvant therapy) in spite of having advanced disease.

A multilevel logistic regression analysis was performed to predict compliant care (Table 2). After adjusting for patient and hospital factors, we found that patients older than 65 were less likely to get compliant care, as were patients of Hispanic origin and those of lower SES. Charlson's co-morbidity score was not uniformly associated with receipt of compliant care. While patients with Charlson scores of 1 or 2 (vs. 0) were less likely to get compliant care, patients with higher co-morbidity scores (Charlson 3, 41% of all patients) were more likely to receive compliant care. Thus, co-morbidities as measured by the Charlson composite score did not appear to be a strong predictor of the care provided. Although patients at academic and teaching hospitals were not more likely to receive compliant care on multilevel analysis, high-volume centres were more likely to deliver NCCN compliant care than mid- and low-volume centres.

Patients who received compliant care had reduced unadjusted mortality compared with those who received non-compliant care (Fig. 2a), with a median survival of 8.8 [95% confidence interval (CI): 8.3–9.4] months vs. 3.9 months (95% CI: 3.6–4.4) ($P \leq 0.0001$). This effect was more pronounced for Stages I–III than Stage IV (Fig. 2b). Survival was also better at academic centres than non-academic centres [median 4.0 (3.8–4.3) vs. 8.1 (7.2–9.0), $P < 0.0001$] and at high-volume centres > 25 cases/years compared with mid- and low-volume centres [median 7.2 (6.5–7.7), 3.9 (3.5–4.3) and 3.0 (2.7–3.4) respectively, $P < 0.0001$, comparing high to mid and low]. Of note, a similar magnitude survival benefit was seen for compliant care in an analysis of the nearly 18 000 patients treated for PC (irrespective of hospital size), although the survival curves for both compliant and non-compliant care patients were poorer in the hospitals with < 400 beds (data not shown).

Table 3 shows the multilevel logistic regression analysis for predictors of mortality. In spite of controlling for patient demographics, co-morbidities and cancer stage, guideline compliance was associated with a 36% decreased odds of mortality (OR = 0.64 95% CI 0.53–0.77, $P < 0.0001$). Patient factors predictive of mortality included age greater than 65 years, a low SES and advancing cancer stage. Care at academic centres was associated with a decreased risk of mortality (OR 0.66; 95% CI 0.51–0.84; $P < 0.005$). Similarly, patients who received care at high-volume centres had significantly decreased mortality. In fact, patients who received care at low- and mid-volume centres had a significantly increased odds of mortality (3.2 and 2.5, respectively, see Table 2). Given the important effect that volume had on survival, it is important to note that patients who received compliant care had improved survival irrespective of the volume of the institution where they were treated (Fig. 3).

Discussion

Overall compliance with NCCN guidelines in California's large hospitals was relatively poor, with just over a third of patients receiving compliant care. The importance of this lies in the fact that compliant care, when controlled for patient and hospital factors, was associated with almost a 40% reduction in the risk of mortality. Improved survival for patients receiving compliant care

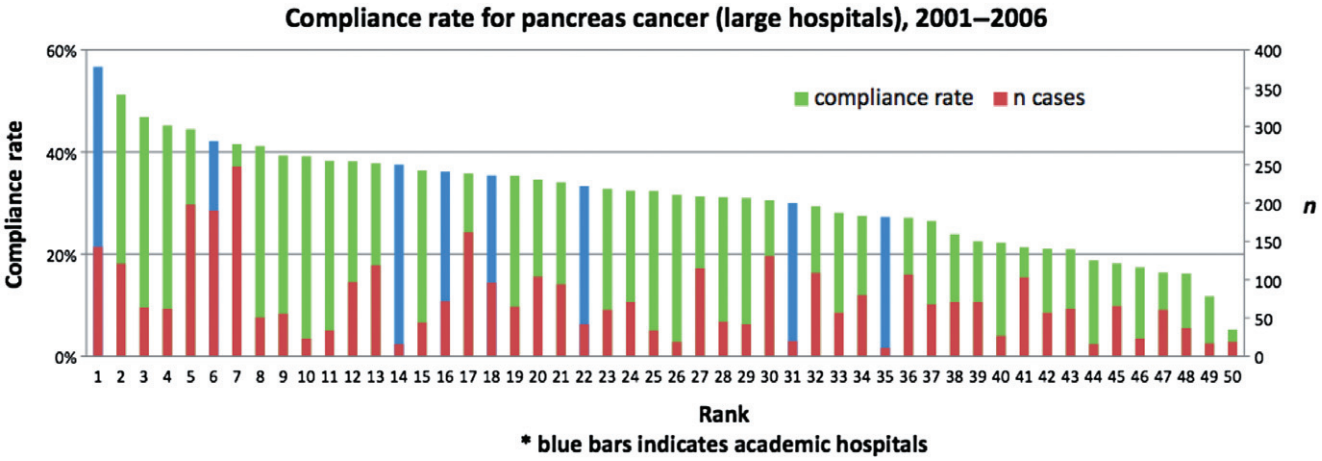

Figure 1 Compliance rate (green bars) for the 50 large California hospitals, with highest compliance to the left. Blue bars indicate academic hospitals. The red bars indicate annual case volume

Table 2 Multilevel logistic regression model predicting guideline compliance (pancreas cancer, large and academic hospitals, California 2001–2006)

Variable	Odds ratio	95% confidence interval	*P-value*
Patient factors			
Female (vs. male)	**1.01**	0.87–1.16	0.933
Age 45–54 years (vs. < 45)	**0.95**	0.64–1.42	0.804
Age 55–64 years (vs. < 45)	**0.74**	0.51–1.10	0.136
Age 65–74 years (vs. < 45)	**0.68**	0.46–0.99	0.045*
Age 75–84 years (vs. < 45)	**0.30**	0.20–0.44	<0.0001*
Age > 85years (vs. < 45)	**0.10**	0.06–0.16	<0.0001*
Black (vs. white)	**0.94**	0.72–1.22	0.632
Hispanic (vs. white)	**0.78**	0.62–0.98	0.036*
Asian/Pasific Islander (vs. white)	**0.94**	0.74–1.19	0.585
Charlson 1 (vs. 0)	**0.99**	0.79–1.23	0.904
Charlson 2 (vs. 0)	**0.64**	0.45–0.92	0.015*
Charlson 3 (vs. 0)	**1.23**	1.05–1.45	0.011*
Income quintile 1 (lowest) vs. 5 (highest)	**0.61**	0.47–0.80	<0.0001*
Income quintile 2 vs. 5	**0.61**	0.48–0.78	<0.0001*
Income quintile 3 vs. 5	**0.65**	0.52–0.80	<0.0001*
Income quintile 4 vs. 5	**0.80**	0.66–0.98	0.032*
Hospital factors			
Academic	**1.18**	0.85–1.62	0.324
Teaching	**0.99**	0.76–1.29	0.946
Low volume (1–15; vs. high)	**0.72**	0.57–0.92	0.007*
Mid volume (16–25; vs. high)	**0.82**	0.67–1.00	0.050*

Multivariable model was constructed with demographic factors and co-morbidities.
*Indicates significant *P*-values.

was seen for all stage of cancer, at both academic and non-academic hospitals, and in high to low case-volume settings.

Physician compliance with the NCCN guidelines for the management of PC can vary for a number of reasons. These factors can perhaps be divided into three broad categories: the hospital/clinical environment, the patient factors and the doctor. The first of these centres around the availability of infrastructure and clinical resources. This includes everything from equipment

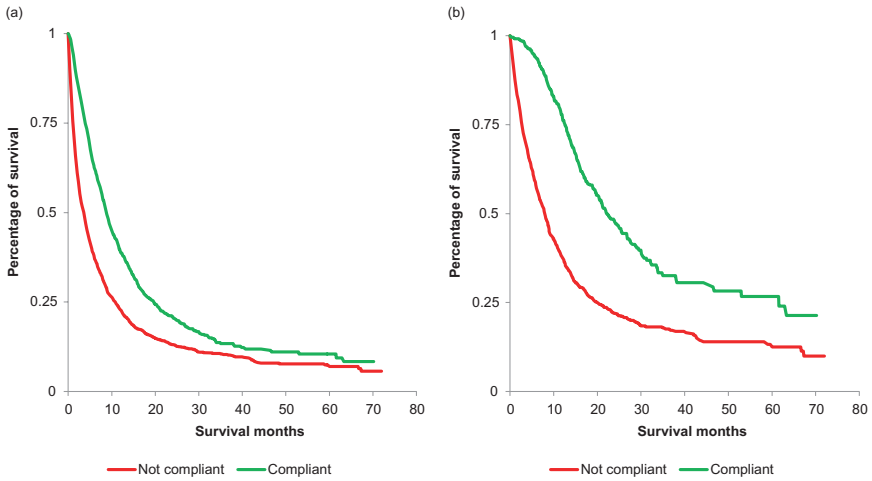

Figure 2 Kaplan–Meier curve comparing survival of those who received compliant care (green line) vs. non-compliant care (red line) for all stages (a) and excluding stage IV (b). ($P < 0.001$ for both)

Table 3 Multilevel logistic regression model predicting of mortality (pancreas cancer treated in large and academic hospitals, California 2001–2006)

Variable	Odds ratio	95% confidence interval	*P-value*
Compliance	**0.64**	**0.53–0.77**	**<0.0001***
Patient factors			
Female (vs. male)	**0.888**	0.75–1.06	0.182
Age 45–54years (vs. < 45)	**1.342**	0.84–2.15	0.221
Age 55–64 years (vs. < 45)	**1.728**	1.10–2.71	0.017
Age 65–74 years (vs. < 45)	**2.227**	1.42–3.49	<0.0001*
Age 75–84 years (vs. < 45)	**2.521**	1.60–3.97	<0.0001*
Age > 85years (vs. < 45)	**5.001**	2.84–8.81	<0.0001*
Black (vs. white)	**1.049**	0.75–1.46	0.777
Hispanic (vs. white)	**1.078**	0.82–1.41	0.585
Asian/pacific islander (vs. white)	**0.810**	0.61–1.07	0.140
Charlson 1 (vs. 0)	**0.659**	0.52–0.84	0.001*
Charlson 2 (vs. 0)	**0.834**	0.57–1.21	0.343
Charlson 3 (vs. 0)	**1.499**	1.22–1.83	<0.0001*
Cancer stage			
Stage 0 (vs. I)	**0.25**	0.07–0.95	0.041*
Stage II (vs. I)	**1.62**	1.22–2.17	0.001*
Stage III (vs. I)	**2.77**	1.96–3.92	<0.0001*
Stage IV (vs. I)	**7.84**	5.84–10.52	<0.0001*
Hospital factors			
Academic	**0.66**	0.51–0.84	<0.0001*
Teaching	**0.84**	0.67–1.06	0.144
Low volume (1–15; vs. high)	**3.210**	2.39–4.31	<0.0001*
Mid volume (16–25; vs. high)	**2.505**	1.97–3.18	<0.0001*

*Indicates significant *P*-values.

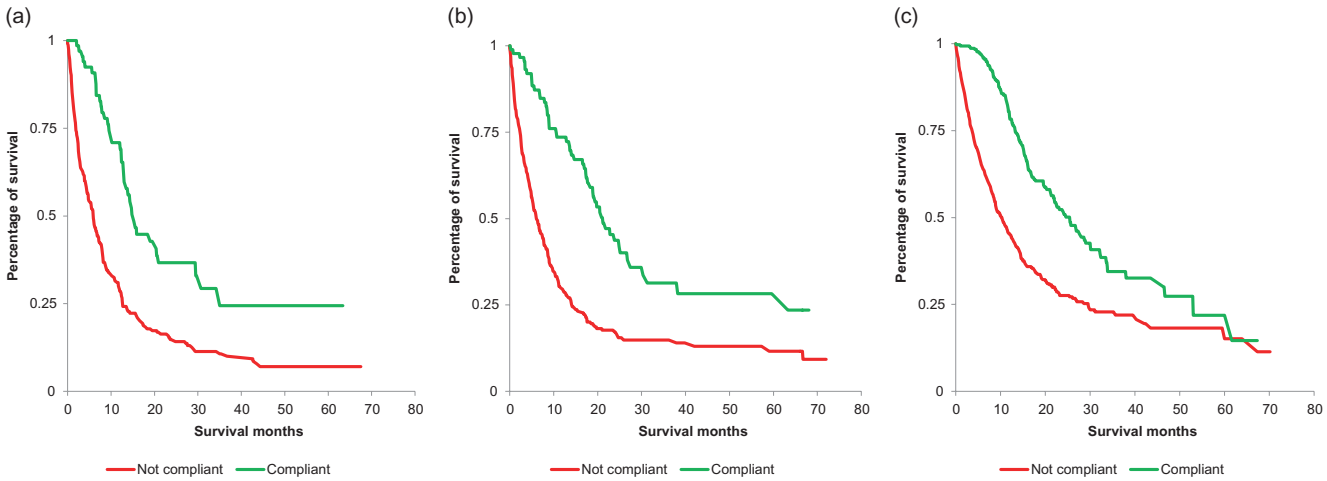

Figure 3 Kaplan–Meier curves comparing survival of stages I–III patients who received compliant care (green line) vs. non-compliant care (red line) at (from left to right) low- (1–15), medium- (16–25) and high- (>25) volume centres. Improved survival is seen for compliant care in every setting. ($P < 0.001$ for all)

(high-quality cross-sectional imaging and linear accelerator for radiation) to hospital services (beds, operating rooms and nursing) to medical expertise (medical and radiation oncology, and pancreatic surgery). All of these may contribute to variation in the care delivered, although the impact of each has not been well characterized. In order to try to limit the effect of this infrastructure element, we limited our analysis to traditional full-service hospitals with greater than 400 beds. Physicians working in the 50 hospitals in California that make up our list should have access (within their own facility or very nearby) to the means to provide multimodality care for PC. In addition, certainly the experience and knowledge of the physician (or more often team of physicians) caring for a patient also contributes to the likelihood of providing compliant care. In the present study, it was not found that academic or teaching hospitals were more likely to be compliant on multilevel analysis. However, higher volume centres were more likely to give compliant care. This is consistent with accumulating evidence for a variety of cancers that higher volume hospitals and cancer centres are more compliant with treatment guidelines than lower volume centres.[28–30]

The second factor in the variable delivery of compliant care is the patient him or herself. We found that older patients were less likely to get compliant care, which is possibly partly (although probably not exclusively) related to frailty associated with age. We also found that Hispanic and lower SES patients were less likely to get compliant care. Variations in cancer care based on ethnicity and SES are well documented in previous studies.[31,32] Certainly, the overall health of the patient is probably a principle consideration in decisions surrounding a newly diagnosed PC. Surprisingly, the Charlson score was not uniformly a predictor of compliant care. While Charlson 1 and 2 patients were less likely to get compliant care (compared with patients with a Charlson of 0), Charlson 3 patients were more likely to get compliant care. This finding requires further investigation, but suggests that pre-existing comorbidities are not the main barrier to care. The acute health (or ill health) of the patient would also certainly be a factor in care decisions.

The third factor in the variation in care is the doctor. Physicians are notoriously resistant at following guidelines across the entire spectrum of medical practice.[33–35] Specifically for PC, the poor overall prognosis for the bulk of patients with PC, combined with the high complications rates historically associated with pancreatic surgery,[30] may lead some physicians to therapeutic nihilism. Previous authors have demonstrated that a high percentage of patients with early stage PC do not undergo surgery.[36] Physicians frequently cite individual patient needs and situational complexity in non-compliance with clinical practice guidelines.[33] There is complexity to the multimodality care of patients with PC, and certainly care must at times be tailored to the tumour and patient. However, we sought to define compliance in broad terms to avoid debates like those between adjuvant vs. neoadjuvant, specific chemotherapy regimens or chemotherapy vs. chemoradiation. Thus, within our definition of compliance, certainly wide variation in practice would be permissible. However, in spite of a low bar, compliance was poor.

The present study is limited by the very nature of the database. The nature of a retrospective analysis of secondary data limits our ability to attribute causality. Specifically, in this study, the 'true' stage of patients who did not undergo surgery (and hence are staged based on radiographic data alone) is less certain. However, the Kaplan–Meier survival curves by stage in this cohort (despite only a minority undergoing surgery) are entirely typical (data not shown). In addition, the radiographical staging is in fact the basis of clinical care decisions (and thus should be the data underlying the offer of compliant care). Certainly a portion of patients with PC will have such a poor performance status on presentation that

compliant care, based on their radiographical staging alone, is not feasible because of their poor performance status. This data set does not allow us to tease out the impact this element has on the delivery of compliant care. The CCR does not include a measure of acute performance status (e.g. Karnofsky score). However, we found a wide variation in compliance across hospitals, although patients with similar staged cancer would presumably present suffering similar sequelae from their tumours. Furthermore, while there are data confirming that performance status impacts short-term outcomes in pancreas surgery,[37,38] and thus undoubtedly does influence the decision regarding surgical resection, the poor compliance for even those patients who are clinically Stage I or II suggests that it was not generally the ill health of the patients that was the barrier. Performance status does also impact survival for stage IV disease.[39] However, for these patients, the NCCN guidelines explicitly recommend Gemcitabine chemotherapy for both good and poor performance status patients as a Category 1 recommendation because of the proven palliative benefit.[20] Thus, given the strong correlation we have demonstrated between compliance and patient level outcomes, the lack of a Karnofsky performance measure is likely to represent a small deficiency in the current analysis.

Patient preferences may affect adherence with guidelines.[40] Although this element cannot be directly assessed with respect to surgical intervention with our data, we have accounted for this with respect to delivery of chemotherapy. The CCR database does include a variable noting that chemotherapy was recommended but not delivered or refused. These patients were coded for our analysis as having received chemotherapy, so that facilities were not penalized if patients declined chemotherapy.

The development of quality indicators for PC care has proved extraordinarily challenging.[41] In spite of interest in identifying a new 'yardstick,' the principle measures of quality in PC have, for some time, been surgical case volume and peri-operative mortality.[42,43] Our data does confirm a clear relationship between case volume and outcomes. While volume has been a principle indicator of quality for all complex surgery, it remains problematic. The definition of high volume in the literature varies widely,[44] and patients are not clearly migrating to higher volume centres.[9] Programmes such as NSQIP and UHC-QAP target another quality metric, post-operative morbidity and mortality complications. While post-operative complications certainly impact long-term survival in PC,[45] the mere avoidance of complications falls far short of assessing the multimodality care of the PC patient. Furthermore, a minority of patients with PC go to surgery, so these outcome measures do not apply. In contrast, compliance with the NCCN clinical practice guidelines possibly offer a process and appropriateness measure that is associated with improved outcomes. Clearly, the NCCN guidelines are not designed at present to be a quality indicator. They represent a consensus approach to care pathways to be offered to patients. Quality measures typically imply that non-compliance is an indicator of poor care. Arguably, for a portion of the patients in our cohort, the choice against surgery or chemotherapy was absolutely appropriate. However, there is little doubt that a gap remains in care. We believe that motivating physicians to provide compliant care (or explain why compliant care was not appropriate/offered/accepted in individual cases) would improve the overall care of patients with PC.

In conclusion, the present study showed a poor rate of compliance with NCCN guidelines for PC in California's large hospitals. Compliance was correlated with decreased mortality. Measures should be taken to improve compliance in the care of these patients.

Conflicts of interest

None declared.

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