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Nutritional status of patients with locally advanced pancreatic cancer

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Abstract

Purpose—Nutritional status may influence quality of life and prognosis among pancreatic cancer patients, yet few studies describe measures of nutritional status during treatment. We evaluated the nutritional status of locally advanced pancreatic cancer (LAPC) patients undergoing chemoradiotherapy who received baseline nutritional assessment and counseling.

Methods—Fourteen newly diagnosed LAPC patients enrolled in phase I/II trials of capecitabine with concomitant radiotherapy were assessed for baseline clinical nutrition measures (body mass index, albumin, weight loss, total energy, and protein intake). Participants completed the Anorexia/Cachexia Subscale (A/CS) questionnaire at baseline and during the 6 weeks of treatment. We evaluated associations between baseline characteristics and subsequent A/CS scores with linear regression and changes in A/CS were assessed with the paired *t* test.

Results—We observed a statistically significant increase in mean A/CS between baseline [24.9, standard deviation (SD) = 9.7] and end of treatment (29.9, SD = 6.2). Controlling for baseline A/CS score, only weight loss greater than 5% of body weight over 1 month was associated with A/CS scores at 6 weeks ($\beta = 10.558$, standard error = 3.307, *p* value = 0.009) and mean A/CS scores during the last 3 weeks of treatment ($\beta = 12.739$, standard error = 2.251, *p* value = 0.001).

Conclusions—After 6 weeks of chemoradiotherapy, LAPC patients reported a statistically significant improvement in appetite and weight concerns. Increases in A/CS scores were associated with higher baseline A/CS scores and weight loss of 5% or more during 1 month. Further research is needed to determine the impact of nutritional support during treatment, as improvements in this domain may impact LAPC patients' overall quality of life.

Keywords

Nutritional assessment; Nutritional status; Pancreatic cancer; Supportive care

Introduction

In 2009, an estimated 42,470 individuals were diagnosed with pancreatic cancer in the USA [1]. Individuals with pancreatic cancer often present with locally advanced or metastatic disease, resulting in a 5-year overall survival rate of only 5% [2]. Since the pancreas plays a key role in the production of digestive enzymes and, in turn, the metabolism of nutrients,

nutrition may be an area on which to focus in relation to quality of life and prognosis of individuals with pancreatic cancer.

The pancreas' crucial role in digestion is illustrated by the fact that, at diagnosis, many pancreatic cancer patients have experienced extreme weight loss [8], with cancer cachexia present in approximately 80% of patients [28]. This weight loss is often due to decreased dietary intake stemming from a host of symptoms, including pain or nausea during eating, early satiety, nausea, anxiety, or depression. Research suggests that, among cancer patients, malnutrition can increase the risk of complications related to surgery, as well as adversely affect one's response and tolerance to cancer treatment, quality of life, and overall survival [18]. Weight loss, specifically, has also been associated with both lower response rates to chemotherapy [6, 9, 30] and decreased survival in oncologic patients [5, 9], while weight stabilization among these patients has been associated with improved survival and quality of life [8].

While the experiences of patients, as well as the data related to quality of life and survival for weight loss and malnutrition, point toward the importance of clinical nutrition in pancreatic cancer, there is little research on the nutritional status of pancreatic cancer patients undergoing treatment [13]. Therefore, we described the nutritional status of locally advanced pancreatic cancer (LAPC) patients enrolled in phase I/II trials of capecitabine with concomitant radiotherapy who received nutritional assessment and counseling at baseline and were followed during 6 weeks of treatment using both objective and subjective measures of nutritional status.

Methods

Study population

Patients were enrolled in phase I and II trials evaluating the effects of capecitabine with concomitant radiotherapy that have been described in detail elsewhere [25, 26]. Briefly, patients eligible for these studies were at least 19 years of age, with histologically confirmed pancreatic adenocarcinoma determined unresectable by surgeons (based on vascular involvement per institution's standards), Eastern Cooperative Oncology Group (ECOG) performance status of 0–2, adequate bone marrow, renal and hepatic function, and the ability to provide informed consent. Exclusion criteria included the presence of distant metastases (including lung and liver); previous chemotherapy, radiotherapy, or chemoradiotherapy for pancreatic cancer; serious, uncontrolled infections, malabsorption syndrome; and lack of physical integrity of the upper gastrointestinal tract.

The trials consisted of two parts. During part A, patients received concurrent radiotherapy with capecitabine (Monday through Friday) during a 6-week period. After finishing part A, patients were assessed for tumor response and/or respectability. During part B, stable and responding patients were treated with capecitabine 2,000 mg/m² p.o. b.i.d. for 14 days every 21 days (one cycle) until evidence of progressive disease, unacceptable toxicity, or patient's preference, with restaging performed every three cycles.

At baseline, a study physician or dietician assessed participants for clinical nutritional status measures including body mass index (BMI), albumin, weight loss, total energy, and protein intake. Participants also completed the self-administered Functional Assessment of Anorexia/Cachexia Treatment (FAACT) questionnaire Anorexia/Cachexia Subscale (A/CS) [24] at baseline and weekly during the 6 weeks of the part A treatment. The A/CS is a validated instrument consisting of 12 Likert scale items that capture the impact of anorexia and cachexia on quality of life by assessing the patient's subjective experience of appetite and weight concerns [24]. Patients responded using the following scale: 0 = not at all, 1 = a

little bit, 2 = somewhat, 3 = quite a bite, 4 = very much. Negatively framed items are reverse scored, such that higher overall scores indicated better or fewer appetite and weight issues.

Statistical analysis

This analysis is limited to 14 of the 35 patients enrolled in the phase I and II trials who completed the 6-week part A treatment and had the relevant baseline data and A/CS 6-week data. Patient characteristics were described with simple descriptive statistics and Pearson correlation coefficients were calculated to explore the relationships between the objective measures of nutritional status, as well as A/CS scores. Changes in the A/CS scores between baseline and end of treatment (week 6) were assessed with the paired *t* test. We evaluated associations between baseline characteristics and A/CS scores (week 6—end of treatment; mean of weeks 4, 5, and 6) with linear regression adjusting for the baseline A/CS score. Finally, we derived the most parsimonious model predicting the follow-up A/CS scores using backward elimination. Statistically significant characteristics from the minimally adjusted model were placed in a model and removed one at a time, such that only variables significant at the 0.05 level were retained in the final multivariate model. To ensure that there was no negative confounding or other statistically significant characteristics, all other variables were placed into the multivariate adjusted model one at a time and retained only if significant at the 0.05 level. All analyses were performed using SAS, version 9.1.3 (SAS, Cary, NC, USA).

Results

The average age of participants was 61.3 years, and just over 70% of the sample was female (Table 1). Participants were predominantly White and all had a stage III tumor. The mean BMI was 29.2 and half of the participants had lost greater than 10% of their body weight over the past 6 months, while 42.9% had recent weight loss greater than 15% of body weight. Patients had a mean total energy intake of 1,754 kcal/day, with a mean protein intake of 66.6 g/day and average serum albumin of 3.7 (g/dl). Both age and BMI were significantly negatively correlated with each other ($r = -0.60$), while protein intake and caloric intake, as well as baseline and 6-week A/CS scores were significantly positively correlated ($r = 0.88$ and $r = 0.53$, respectively) (Table 2).

At baseline, the average A/CS score was 24.9 ± 9.7 , and at the end of the 6-week treatment, with a mean increase of 5.0 ± 8.3 points, the mean A/CS score was 29.9 ± 6.2 (p value for paired *t* test = 0.042). In a model adjusting only for baseline A/CS scores, weight loss greater than 5% of body weight over 1 month was statistically significantly, associated with A/CS scores at the end of the 6-week treatment ($\beta = 10.558$, standard error = 3.307, p value = 0.009) (Table 3). A similar association was observed for weight loss greater than 5% of body weight over 1 month and mean A/CS score during weeks 4, 5, and 6 of treatment ($\beta = 12.739$, standard error = 2.251, p value = 0.001). There was also a borderline statistically significant inverse association with protein intake ($\beta = -0.080$, standard error = 0.037, p value = 0.053) and mean A/CS score during weeks 4, 5, and 6; however, this association was no longer statistically significant when adjusted for weight loss over 1 month (p value = 0.528).

The final multivariate model predicting follow-up A/CS scores included only baseline A/CS and weight loss greater than 5% of body weight over 1 month (Table 4). Other sociodemographic and clinical measures were not associated with follow-up A/CS scores. For every one unit increase in baseline A/CS score, there was a corresponding 0.463 and 0.555 increase in A/CS scores at 6 weeks and over the last 3 weeks of treatment, respectively. In addition, individuals who had weight loss greater than 5% of body weight

over 1 month had a 10.558 and 12.739 increase, respectively, in AC/S scores at week 6 and over the last 3 weeks compared to those who did not report this weight loss.

As mentioned earlier the nutritional support was provided during the study at baseline by a study physician and dietician at baseline and the dietician alone (physician involved if necessary) during follow-up visits. Participants also completed the self-administered FAACT questionnaire A/CS at baseline and weekly during the 6 weeks of the part A treatment. Nutritional support was composed of guidance on diet, maintaining calorie intake during chemoradiation, and use of supplements if indicated. Only one person needed TPN towards the end of 6 weeks, while another patient had a feeding tube placed during week 4 due to uncontrolled nausea. Three patients received low doses of oral megestrol.

Overall satisfaction about the nutritional support and the self-administered FAACT questionnaire A/CS was not collected formally, but was discussed with the patients. Based on the study summary, most patients (>80%) appreciated the A/CS as well as involvement of a dietician, and 90% agreed that only 1–2 min were needed to complete the assessment.

Discussion

In this sample of LAPC patients, the mean baseline BMI of 29.2 was just shy of the definition for obesity, yet nutritional status was compromised, with many reporting weight loss up to 15% of body weight and just over 20% consuming less than 1,500 kcals per day. After 6 weeks of chemoradiotherapy and baseline nutritional assessment and counseling, these patients reported a statistically significant improvement in appetite and weight-specific concerns on the AC/S. Higher baseline A/CS score and weight loss greater than 5% of body weight over 1 month were predictive of higher A/CS scores at the end of treatment and during the final 3 weeks of treatment.

Weight loss and cachexia are of particular concern in patients with pancreatic cancer [28]. This was illustrated in our population by the high percentage of individuals reporting recent weight loss. Another study of 20 unresectable pancreatic cancer patients who were not receiving chemotherapy or radiation found that participants had lost 15% of body weight on average at the time of diagnosis, and this weight loss continued, such that at the time of death, individuals had lost approximately 25% of body weight, marked by loss of both skeletal muscle and fat [31]. Another study of 24 patients with unresectable pancreatic cancer observed an average weight loss 20% at diagnosis [16]. A large European study of 1,000 cancer outpatients reported that nutritional risk, as measured with the Nutritional Risk Screening instrument, was highest among patients with pancreatic and esophageal cancer, with more than half of these two groups of patients reporting weight loss of greater than 10% of body weight [7]. Additionally, another study that focused on pre- and post-operative weight among 26 patients with resectable tumors observed a decrease in BMI from baseline (pre-operative) to discharge from surgery, as well as from baseline to 3 months [12].

Pancreatic cancer and nutrition are closely intertwined, simply due to the organ having digestive functions. In addition to the physical symptoms patients experience that can make eating difficult and painful, weight loss in those with pancreatic cancer may be partly explained by their elevated resting metabolic rate compared to age- and sex-matched controls [11]. Not only is nutritional status relevant directly to weight loss, but more importantly, malnutrition and weight loss have been shown to play a role in patients' response to chemotherapy, overall survival, and quality of life [5, 6, 8, 9, 18, 21, 30].

We observed that those who had weight loss greater than 5% over 1 month had greater improvements in appetite and weight concerns at the end of the 6-week treatment. In general, those with weight loss had lower baseline A/CS scores compared to those who had

not lost weight. Therefore, these patients may have been more likely to benefit from counseling pertaining to nutrition and would have had the greatest potential for improvement. Although weight loss is a significant problem, it may also serve to motivate individuals to seek ways to improve their experience with eating.

Several studies have evaluated oral or parenteral nutrition among patients with pancreatic cancer and observed improvement in weight loss and appetite [3, 10, 20]. One study found that, even with improvements in weight loss and appetite, there was no corresponding improvement in functional capacity as measured by the Karnofsky Performance Status [10], a finding supported by reviews of nutritional supplementation for anorexia and cachexia [4, 15]. A study that included a total of eight patients (five with pancreatic cancer) noted improvements in nutritional status with counseling and oral nutritional supplement, as measured by the Subjective Global Assessment and Patient Scored Subjective Global Assessment, but chemotherapy regimens among these patients were not standardized [3]. Finally, in a pilot study of 32 ambulant patients with inoperable pancreatic cancer, parental nutrition was associated with at least a temporary benefit in nutritional status [20].

We found that the baseline nutritional assessment and counseling implemented in these two clinical trials was easy to employ and administer, making it translatable to a diverse array of clinical settings. Although among a different population, head and neck cancer patients, there is evidence that starting nutritional counseling early, when nutritional status is only marginally compromised, may be beneficial for final outcomes [22, 23]. Research suggests that clinicians are interested in clinical nutrition, but this interest does not often translate into practice [14, 17]. One study found that clinical nutrition was more of a focus for physicians and nurses when they had greater access to clinical dietitians [27]. Nutritional status is an important component of pancreatic cancer and recommendations for understanding nutritional needs of these patients include assessing body composition, physiologic function, micronutrient status, recent dietary habits, and weight change [13].

This study had several strengths, including the longitudinal design, standardized treatment regimen for patients, and measures of nutritional status encompassing both self-report from patients and objective clinical measures. We are not aware of other studies of pancreatic cancer patients that have used the A/CS, but in validity testing of this instrument, it appears to assess domains very specific to anorexia and cachexia that are not covered in other quality-of-life instruments [24]. Given the prevalence of these two issues in pancreatic cancer, it was well suited to capture patients' experience of these problems. Limitations included a relatively small sample, and given the non-randomized design, we are unable to evaluate if improvement in nutritional status improvements were due to factors other than the baseline nutritional assessment and counseling. For example, several chemotherapy trials that did not include nutritional interventions have reported improvements in quality of life, functional capacity, and weight, so treatment alone may contribute to improvements in various areas [19, 29].

In conclusion, among LAPC patients who received a nutritional assessment and counseling delivered by clinicians at the start of clinical trials for capecitabine with concomitant radiotherapy, we observed an improvement in concerns related to weight and appetite between baseline and the end of the 6-week treatment. Additional studies in larger populations are needed to see if this trajectory is replicated in other LAPC patients undergoing treatment. Randomized designs should be implemented to evaluate the effect of early nutritional assessment and counseling on nutritional status. Future research should also focus on the impact of improvements in nutritional status on LAPC patients' overall quality of life and survival.

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Table 1

Means and proportions of selected baseline characteristics of patients with locally advanced, unresectable pancreatic cancer (n=14).

Characteristics	N (%) or mean $\pm$ SD
Age, mean $\pm$ SD	61.3 $\pm$ 9.8
Gender, n (%)	
Male	4 (28.6)
Female	10 (71.4)
Ethnicity, n (%)	
White	10 (71.4)
African American	4 (28.6)
Tumor Stage, n (%)	
III	15 (100.0)
Study Group, n (%)	
Group 1	7 (50.0)
Group 2	7 (50.0)
Body mass index (kg/m ²), mean $\pm$ SD	29.2 $\pm$ 6.9
Spontaneous weight loss > 5% over one month, n (%)	2 (14.3)
Spontaneous weight loss > 10% over 6 months, n (%)	7 (50.0)
Spontaneous total recent weight loss > 15%, n (%)	6 (42.9)
Total energy intake (kcal/day), mean $\pm$ SD	1754 $\pm$ 698
Total energy intake < 1500 kcal/day, n (%)	3 (21.4)
Protein intake (g/day), mean $\pm$ SD	66.6 $\pm$ 34.9
Albumin (g/dl), mean $\pm$ SD	3.7 $\pm$ 0.4
Albumin less than 3.0 g/dl, n (%)	1 (7.1)

SD: Standard Deviation; ECOG: Eastern cooperative oncology group

Correlations between baseline characteristics and FAACT anorexia/cachexia (A/C) subscale scores at baseline and after six weeks of combined treatment (n=14).

Table 2

	Age	Albumin	BMI	Total Energy	Protein	Baseline A/C	Six Week A/C
Age	1.0	0.21	-0.60*	0.01	0.07	0.23	0.41
Albumin	-	1.0	-0.34	0.35	0.23	0.24	0.47
BMI	-	-	1.0	-0.34	-0.34	0.29	0.08
Total energy	-	-	-	1.0	0.88*	0.20	-0.15
Protein	-	-	-	-	1.0	0.04	-0.28
Baseline A/C	-	-	-	-	-	1.0	0.53*
Six Week A/C	-	-	-	-	-	-	1.0

* Statistically significant at 0.05 level.

Table 3

Associations* between baseline characteristics and follow-up FAACT anorexia/cachexia subscale (A/CS) scores (n=14).

Characteristic	Six Week FAACT A/CS Score		Mean of Weeks 4, 5 and 6 FAACT A/CS Score	
	β (SE)	p-value	β (SE)	p-value
Age	0.190 (0.154)	0.245	0.064 (0.159)	0.692
Gender				
Female	Reference	-	Reference	-
Male	-3.300 (3.380)	0.350	-5.058 (3.058)	0.126
Ethnicity				
White	Reference	-	Reference	-
African American	2.384 (3.396)	0.497	1.036 (3.352)	0.763
Study Group				
Group 1	Reference	-	Reference	-
Group 2	1.256 (3.034)	0.687	3.171 (2.801)	0.283
Body mass index (kg/m ²)	-0.064 (0.256)	0.807	0.219 (0.239)	0.381
Weight loss > 5% over one month	10.558 (3.307)	0.009	12.739 (2.251)	0.001
Weight loss > 10% over 6 months	-0.986 (3.732)	0.797	0.892 (3.621)	0.810
Total recent weight loss > 15%	-2.341 (3.371)	0.502	1.226 (3.320)	0.719
Total energy intake (kcal/day)	-0.002 (0.002)	0.313	-0.004 (0.002)	0.065
Protein intake (g/day)	-0.053 (0.042)	0.240	-0.080 (0.037)	0.053
Albumin (gm/dl)	5.910 (4.113)	0.182	0.624 (4.372)	0.889

* Adjusted for baseline FAACT A/C subscale score.

Table 4

Multivariate model predicting follow-up FAACT anorexia/cachexia subscale (A/CS) scores (n=14).

Characteristic	Six Week FAACT A/CS Score		Mean of Weeks 4, 5 and 6 FAACT A/CS Score	
	β (SE)	p-value	β (SE)	p-value
Baseline A/CS	0.463 (0.124)	0.003	0.555 (0.085)	<0.001
Weight loss > 5% over one month	10.558 (3.307)	0.009	12.739 (2.251)	0.001