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Research Article

Accuracy of the Cancer Functional Assessment Set for Predicting Mortality in Patients With Advanced Cancer Undergoing Chemotherapy and/or Radiotherapy

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Objective: The Cancer Functional Assessment Set (cFAS) is a comprehensive functional tool used to evaluate patients with cancer, and it has the potential to predict mortality with high accuracy. We investigated the accuracy of the cFAS for predicting mortality in hospitalized patients undergoing radiotherapy and/or chemotherapy for advanced cancer, and we calculated a clinically useful cutoff value of the cFAS.
Methods: Patients with advanced cancer undergoing chemotherapy and/or radiotherapy at our hospital were assessed using the cFAS at their admission, and their survival was followed. We plotted receiver operating characteristic (ROC) curves up to 365 days by using mortality data obtained every 30 days after study enrollment.
Results: The areas under the curve (AUCs) were 0.65–0.89 (max. value – min. value within the entire period), and the cutoff value for the cFAS was 66–79 points, calculated using the Youden index. The cutoff value's sensitivity was 0.44–0.80, and its specificity was 0.76–0.93. The AUC showed a decrease after 150 days of follow-up.
Conclusions: The cFAS was able to predict mortality in patients with cancer undergoing chemotherapy and/or radiotherapy with moderate accuracy within approx. 150 days and with low accuracy thereafter up to 365 days.

Keywords: advanced cancer; Cancer Functional Assessment Set; cutoff value; mortality; physical function

1. Introduction

Cancer and associated treatments accelerate patients' muscle loss and decline in physical function [1–4]. This decline in physical function not only reduces cancer patients' activities of daily living and quality of life; it also increases their risk of mortality [5–9]. Various physical assessment scales are thus used as predictors of cancer-related mortality and to help plan cancer patients' rehabilitation and treatment.

The patient's performance status (PS) [10] has traditionally been used to predict mortality in patients with cancer based on an assessment of physical function because the PS is easy to use, although lack of objectivity is a problem [11]. There are many recent reports about the prediction of mortality based on objective assessments of physical function such as grip strength, the timed up and go (TUG) test, a short physical performance battery, and the 6-min walking test (6MWT) [8, 12]. These evaluation scales are easy to administer and are often used in clinical settings. However, since these scales focus on localized assessments (e.g., the hands' grip strength and lower-limb mobility), there is a risk that the evaluation results may vary depending on the body part. A comprehensive functional assessment scale may therefore be effective for assessing the overall physical function of patients with cancer regardless of the impaired body part.

The Cancer Functional Assessment Set (cFAS) is a comprehensive functional assessment scale for patients with cancer that was developed by Miyata et al. [13]. The cFAS consists of various items and includes not only functional aspects such as range of motion and muscle strength but also assessments of the patient's movement, balance, and activity areas. The cFAS also evaluates both impairment and disability as defined by the World Health Organization (WHO) international classification of functioning. The cFAS is suitable for assessing the effects of rehabilitation from a multifaceted perspective, and it has the characteristic of being useful for examining patients with various types of cancer and disabilities.

The Asian Working Group for Cachexia has proposed the following as diagnostic criteria for cachexia: (1) presence of underlying disease, (2) weight loss, (3) subjective symptoms, (4) objective measurements, and (5) biomarkers [14]. The physical function assessment scales are presumed to indirectly reflect cachexia [15], but scales that focus on localized assessments have a limited range of assessment, and there is a possibility of overestimating patients' disorders or missing borderline patients. We hypothesized that the cFAS, which comprehensively assesses patients with cancer, may become a useful tool for predicting mortality that reflects patients' general condition. However, the possibility of predicting mortality by using the cFAS has not been investigated.

There are several methods for evaluating a scale's prediction accuracy. The time-dependent receiver operating characteristic (ROC) curve method is used to calculate prediction accuracy and cutoff values for endpoint events over time [16]. This approach may be beneficial when evaluating the progressive state of cancer. In the present study, we used time-dependent ROCs to evaluate the extent to which the cFAS score predicts the risk of mortality at multiple time points within a 12-month follow-up in patients with advanced cancer who were undergoing chemotherapy and/or radiotherapy and received rehabilitation. We also calculated a clinically useful cutoff value for the cFAS.

2. Methods

2.1. Patients. We conducted a cohort study of patients with advanced cancer who were undergoing chemotherapy and radiation therapy at Tsukuba Medical Center Hospital (Tsukuba, Japan). The physical function of eligible patients was assessed upon their admission, and the patients' survival was followed. The study was approved by the Ethics Committee of Tsukuba Medical Center Hospital (2023-021) and was conducted in accord with the tenets of the Declaration of Helsinki. Written informed consent for study participation was obtained from all of the included patients. This article is based on the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.

The patients were hospitalized between November 2020 and August 2023 and included patients diagnosed with stage III/IV or metastatic cancer who received chemotherapy or radiation therapy and rehabilitation orders. Patients with cognitive dysfunction or problems with language comprehension, patients who had already been included in the study due to readmission, and patients in poor condition due to pain and/or severe fatigue were excluded. Most of the patients received rehabilitation 5 ×/week. There was no standard rehabilitation protocol; a 20- to 60-min session per day was conducted adapted to individual symptoms. All patients received physical therapy, and occupational therapy and speech therapy were added at the discretion of the rehabilitation physician. No outpatient rehabilitation was provided after discharge, and the patients received guidance from physical therapists as needed regarding exercises to do at home. At a patient's readmission during the follow-up period, the order for physical therapy was determined by the patient's physician based on the patient's general condition.

2.2. Measures. All patients underwent the cFAS immediately after hospital admission by the physical therapist in charge. The cFAS is considered objective and simple and does not require any special training [13], and the physical therapist who assessed the patients had > 5 years of experience in cancer rehabilitation. The medical information of the patients including age, sex, body mass index (BMI), current medical history, and past medical history was collected by the corresponding author alone from the patients' medical records. The stage of cancer progression, treatment information, the Charlson Comorbidity Index (CCI) [17], and the stratified Geriatric Nutritional Risk Index (GNRI) [18] were ascertained from the patients' medical history.

The cFAS is a 24-item assessment scale with a maximum score of 102 points; the higher the score, the better the physical function. The scale is broadly divided into the following categories: sit up, stand up, transfer, 50-m walk, stair ascending and descending mobility, grip strength, a manual muscle test (MMT) for the bilateral iliopsoas, a quadriceps, and tibialis anterior muscles' MMT, an abdominal muscles' MMT, bilateral shoulder abduction, ankle dorsiflexion range of motion (ROM), upper- and lower-limb sensory function, one-leg standing with eyes open and standing with eyes closed balance tests, and the patient's level of activity. The assessments of the patients' physical performance and activity were based on the patients' maximum ability within 1 day after the reference date. Grip strength was measured twice while the patient was seated with the elbow extended, and the average value was used. For the assessment of single-leg standing, the stance time was measured twice, and the better result was adopted. An abdominal-muscle MMT was conducted with the patient sitting on a wheelchair or chair, sliding his/her hips forward and leaning the torso backward at a 45° angle against the backrest; the patient's ability to rise from this position was then evaluated. A sensory function evaluation of the patients' upper and lower limbs encompassed superficial, deep, and abnormal sensations, without consideration of the laterality of impairment. If a patient's activities are restricted by a physician due to the presence of bone metastasis or other medical conditions, the relevant category was given the lowest score. In addition, the physical therapist who was

responsible for each patient determined the PS based on the patient's condition at the time of admission.

2.3. Follow-Up Survey. Most of the patients were discharged home and received follow-up outpatient care from each patient's primary clinical department, with repeated chemotherapy and radiotherapy in the hospital as needed. After patients were enrolled, the corresponding author reviewed their medical records every few months to confirm the survival status based on outpatient medical records and death reports from home physicians. The follow-up period ended when a patient's death was confirmed or when 365 days had passed.

2.4. Statistical Analyses. The area under the curve (AUC) is an indicator used to determine a scale's prediction accuracy. We obtained the AUCs by using the survivalROC package in R, and we calculated the time-depended ROC curve and AUC every 30 days. The cutoff value for the cFAS was determined using the Youden index [19] based on the sensitivity and specificity data obtained from our ROC curve calculations. We compared the results by applying the Mann–Whitney U-test or Fisher's exact test, using the calculated major cutoff value of 74 points for the cFAS to clarify the patients' background. Since there were biases in the sample size of each group divided into survival or death, we conducted an internal validity check using the bootstrap validation, which was calculated 2000 times. To assess the impact of the cFAS score and other factors on the prediction of mortality, we conducted an additional analysis at 365 days after assessment. The number of events per variable was set as 10 [20, 21], and we incorporated age, cancer type, and the CCI and GNRI scores into the mortality prediction model along with the cFAS score. We then performed a multivariate Cox proportional hazards regression analysis.

We calculated the necessary sample size using the pROC package in the R software. Calculations were made using an AUC of 0.7, a significance level at 0.05, and 0.8 power, which revealed that a sample size of 24 cases per group was required. Although there were only 15 cases in the 90-day death group, we used bootstrap validation to verify that there was no large deviation from the AUC obtained from the original data, and we thus used the original data as the analysis data. Missing data were imputed by the multiple imputation method using the 'mice' package in R. Twenty datasets were created, and the number of imputation iterations was set to 50. The statistical analyses were conducted using EZR software ver. 1.50 (Saitama Medical Centre, Jichi Medical University, Saitama, Japan) [22], which is a graphical user interface for R (ver. 3.6.3; R Foundation for Statistical Computing, Vienna, Austria).

3. Results

The inclusion criteria were met by 412 patients, and 104 of them were included in the study after the exclusion of duplicate patients and those who could not be contacted during hospitalization, declined to participate, had communication problems, or were in poor general condition (Figure 1). During the follow-up period, there were no instances of dropout, allowing the verification of all patients' mortality status. The missing data rates were relatively high for several cFAS items: handgrip strength, 18.2%; one-leg standing, 13.5%; and trunk muscle strength, 11.5%. There were few missing data for other items.

Most of the patients (73.0%) were male and were ~73 years old (Table 1). The most common type of cancer was lung cancer (82.7%), and most of the patients were at stage IV (70.2%) and had metastases (70.2%). Many patients had an independent daily life with a PS of 0–1 (64.4%). The median cFAS score was 85.5 points (interquartile range [IQR] 74.3–96.8 points), and the distribution of scores had a volume zone in the range of 80–102 points, with the largest number of patients distributed in the 90- to 100-point range (Figure 2). The patient survival rate decreased almost linearly throughout the follow-up period, with 48.1% of the patients dead at the 365-day timepoint (Figure 3).

The AUCs were 0.65–0.89 (max. value – min. value within the entire study period), and the cutoff value for the cFAS calculated using the Youden index was 66–79 points. At this cutoff value, the sensitivity was 0.44–0.80 and the specificity was 0.76–0.93. The AUC showed a decrease after 150 days of follow-up. The AUC for predicting mortality within 365 days after inclusion, calculated from the cFAS, was 0.65–0.89 (max. value – min. value within the study period) (Figures 4, 5(a)). This AUC also showed a decrease after 150 days of follow-up. The cutoff point for determining whether or not a patient was at risk of dying from his or her cancer was 66–79 points. The sensitivity and specificity of the cutoff values calculated using the Youden index were 0.44–0.80 and 0.76–0.93, respectively. When we divided the patients into two groups based on the representative cutoff value of 74 points and compared their backgrounds, we identified significant differences not only in physical function and mortality but also in the GNRI score and the indication for radiation therapy (Table 1). Similarly, different trends in the survival rate were observed between the patient groups that were based on the cutoff value (Figure 3).

The results of the internal validation of the predictive accuracy of cFAS using bootstrap validation are depicted in Figure 5(b). The AUCs at 90, 180, 270, and 365 days' follow-up calculated by bootstrap validation were 0.79 (95% CI: 0.65–0.91), 0.69 (0.56–0.81), 0.66 (0.53–0.77), and 0.66 (0.55–0.76), respectively, and these values were similar to those obtained with the original data. The multivariate survival analysis revealed that the hazard ratios for the cFAS score were significant when analyzed with either a single item (HR 0.96, $p < 0.001$) or multiple selected items (HR 0.98, $p = 0.003$) (Table 2).

4. Discussion

This study appears to be the first to evaluate the cFAS's ability and accuracy for predicting mortality in patients with advanced cancer undergoing chemotherapy and/or radiotherapy. The results of our analyses demonstrated that the cFAS score can be used to classify the mortality risk within

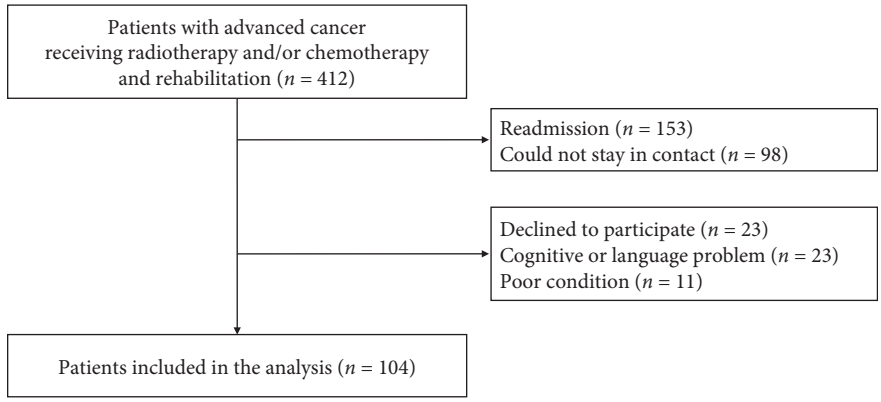

Figure 1: Flow diagram of the study participants.

Table 1: Patient characteristics ($n = 104$).

		Total	cFAS < 74	cFAS ≥ 74	p value
n		104	25	79	
Age, yrs, median [IQR]		73.0 [67.0, 75.3]	73.0 [66.0, 81.0]	72.0 [67.0, 75.0]	0.381
Male, *n* (%)		76 (73.1)	20 (80.0)	56 (70.9)	0.446
Height, *m*, median [IQR]		1.61 [1.60, 1.66]	1.59 [1.56, 1.65]	1.62 [1.56, 1.67]	0.385
Weight, kg, median [IQR]		56.2 [49.2, 65.9]	53.0 [47.3, 61.5]	1.62 [1.56, 1.67]	0.153
BMI, kg/m^2, median [IQR]		21.9 [19.7, 24.5]	20.4 [19.2, 23.4]	22.2 [20.3, 24.6]	0.197
GNRI, *n* (%)	Absent, > 98	54 (51.9)	6 (24.0)	48 (60.8)	0.005*
	Low, 92 to ≤ 98	14 (13.5)	5 (20.0)	9 (11.4)	
	Moderate, 82 to < 92	22 (21.2)	7 (28.0)	15 (19)	
	Major, < 82	14 (13.5)	7 (28.0)	7 (8.9)	
Cancer type, *n* (%)	Lung	86 (82.7)	17 (68.0)	69 (87.3)	0.075
	Urinary	8 (7.7)	4 (16.0)	4 (5.1)	
	GI	7 (6.7)	3 (12.0)	4 (5.1)	
	Other	3 (2.9)	1 (4.0)	2 (2.5)	
Tumor stage, *n* (%)	III	27 (26.0)	3 (12.0)	24 (30.4)	0.091
	IV	73 (70.2)	22 (88.0)	51 (64.6)	
	Unclear	4 (3.8)	0 (0.0)	4 (5.1)	
Metastasis, *n* (%)		73 (70.2)	21 (84.0)	52 (65.8)	0.131
Type of treatment, *n* (%):	Radiation	59 (56.7)	14 (56.0)	45 (57.0)	1
	Chemotherapy	92 (88.5)	20 (80.0)	73 (92.4)	0.128
Chemotherapy treatment lines, *n* (%)	1st	58 (55.8)	13 (52.0)	45 (57.0)	0.182
	2nd	20 (19.2)	4 (16.0)	16 (20.3)	
	3rd	6 (5.8)	0	6 (7.6)	
	4th	13 (12.5)	4 (16.0)	9 (11.4)	
	None	7 (6.7)	4 (16.0)	3 (3.8)	
Indications for radiation therapy, *n* (%)	Radiation alone	1 (1.6)	1 (5.9)	0	0.008*
	Chemoradiotherapy	32 (51.6)	4 (23.5)	28 (62.2)	
	Metastasis site	29 (46.8)	12 (70.6)	17 (37.8)	
CCI, median (IQR)		9.0 [7.0, 11.0]	10.0 [9.0, 11.0]	9.0 [7.0, 11.0]	0.146
ECOG-PS (%)	0	24 (23.1)	0	26 (32.9)	< 0.001*
	1	43 (41.3)	6 (24.0)	42 (53.2)	
	2	13 (12.5)	5 (20.0)	8 (10.1)	
	3	14 (13.5)	11 (44.0)	3 (3.8)	
	4	3 (2.9)	3 (12.0)	0	
cFAS, median (IQR)		85.5 [74.3, 96.8]	63.0 [47.0, 68.0]	92.0 [84.0, 98.5]	< 0.001*

Abbreviations: BMI, body mass index; CCI, Charlson Comorbidity Index; cFAS, Cancer Functional Assessment Set; ECOG-PS, Eastern Cooperative Oncology Group-Performance Status; GI: gastrointestinal; GNRI: Geriatric Nutritional Risk Index.
* $p < 0.05$.

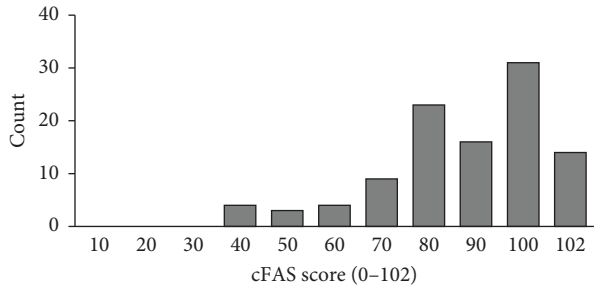

Figure 2: Distribution of the patients' Cancer Functional Assessment Set (cFAS) scores.

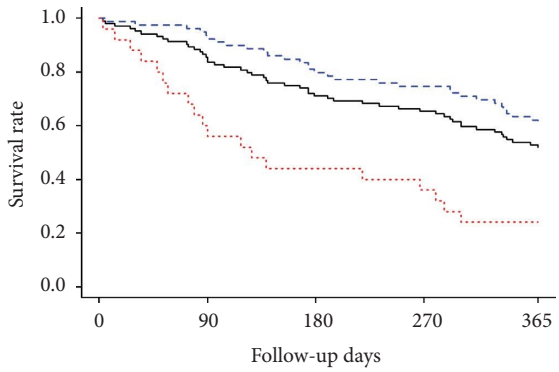

Figure 3: Changes in the survival rate of patients with cancer during the follow-up period. Black solid line: the entire patient series. During the 365-day follow-up period, 48.1% of the patients died. The numbers of death were as follows: 90 days, n = 15; 180 days, n = 30; 270 days, n = 36; and 365 days, n = 50. Blue dashed line: the patients with cFAS scores ≥ 74 points. Red dotted line: the patients with cFAS scores < 74 points.

365 days with moderate accuracy and later low accuracy in patients with advanced cancer who are undergoing chemotherapy and/or radiotherapy. Our findings revealed that the cFAS showed high specificity in predicting mortality and can be considered effective for identifying patients at a high mortality risk.

4.1. Classification by the ROC Curve. The accuracy of using the AUC in the ROC curves was verified using the Fischer et al. classification [23], and our present study showed that the accuracy of the cFAS in predicting mortality was moderate within 150 days and low after 180 days. Although few studies have examined the prediction of mortality in patients with cancer based on a physical function assessment alone, the AUC that we obtained herein is not largely different from those in recent reports, such as 0.78 for the TUG test [24] and 0.61 for grip strength [25]. Investigations that included multiple factors in their evaluation of the risk of mortality have been more accurate, with AUCs around 0.7–0.9 [25–28].

The pathogenesis of cancer is extremely complex, and many factors are involved in the risk of mortality. We conducted the present analyses as an attempt to predict

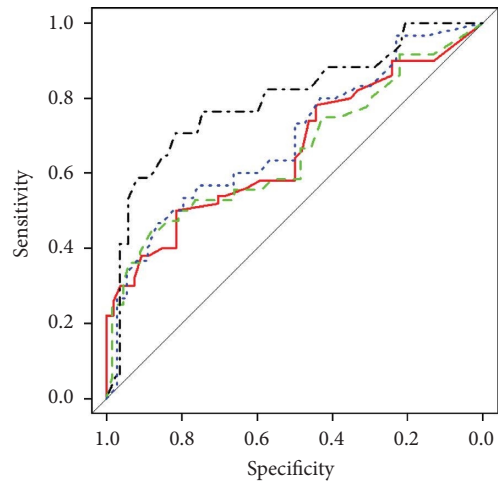

Figure 4: The ROC curve for the prediction of patient mortality using the cFAS for each timepoint from study enrollment. Black dot-dashed line: 90 days. Blue dashed line: 180 days. Green dotted line: 270 days. Red solid line: 365 days.

cancer patients' life prognoses by using only the cFAS score without the inclusion of many factors, and the results of a multivariate Cox proportional hazards regression analysis also demonstrated that the cancer patients' cFAS score is a potential independent prognostic factor. Notably, simpler assessment scales may be more useful than complex models in clinical settings. The value of the present study is that it demonstrates the potential of using the cFAS alone to predict mortality. Although the cFAS did not show a clear advantage over other tests [24, 25] as we initially predicted, we believe that the cFAS alone can be used as a clinically simple prognostic tool on its own.

4.2. Cutoff Value. The cutoff value for predicting mortality using the cFAS was 66–79 points, with the variation depending on each timepoint. However, since the cutoff value did not show any particular trend over time and was 73–75 points at most of the timepoints, we suspect that the variation was due to the cutoff being set simply based on the maximum value of the Youden index. In fact, the maximum value of the Youden index at the time when the cutoff value varied (i.e., at 60, 120, 150, and 365 days) was very close to the index value of 73–75 points, and thus these scores seem useful as clinical cutoff points.

The specificity of the cutoff value was also high compared to other studies that reported cutoff values in physical function assessments [24, 25, 29], which suggests that the cFAS is good at identifying patients at high risk of mortality. The goals of rehabilitation for patients with cancer vary depending on the patient's life prognosis [30]. Patients with advanced cancer who are undergoing chemotherapy or radiation, such as the patients in this study, are in a border area between the 'maintenance rehabilitation period' and the "palliative rehabilitation period." If it is possible to easily predict life expectancy using the cFAS, therapists may be able to quickly change the rehabilitation plans and goals.

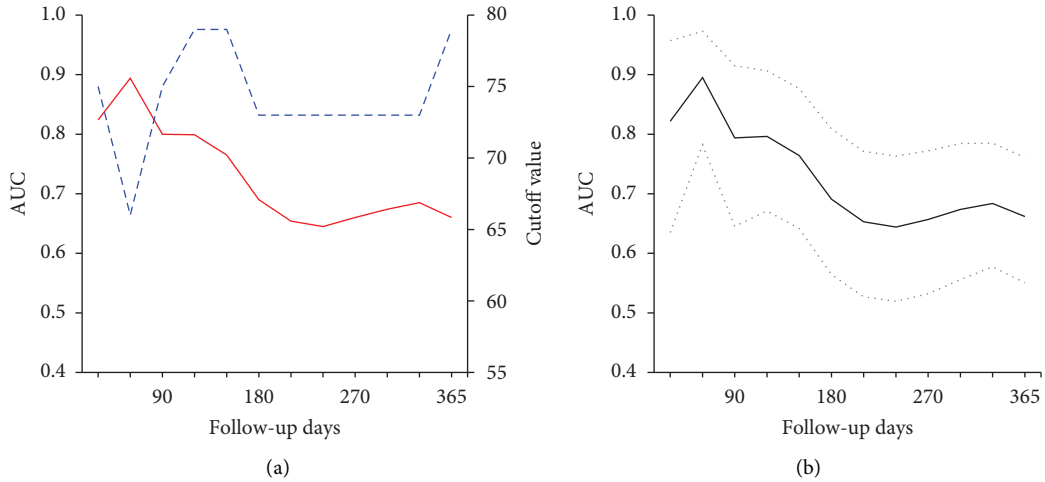

Figure 5: Changes in the AUC and the cutoff value. (a) *Red solid line:* the original AUC data. *Blue dashed line:* the cutoff value. (b) The bootstrap validation data. *Black solid line:* the estimated value of the AUC using the bootstrap method. *Gray dotted line:* the 95% confidence interval.

Table 2: Results of the multivariable survival analysis.

	HR (95% CI)	*p* value
cFAS univariate analysis		
cFAS	0.96 (0.95–0.98)	< 0.001*
Analysis based on five selected items		
cFAS	0.98 (0.70–0.99)	0.003*
Age	0.91 (0.90–0.96)	0.001*
Cancer type	1.47 (1.04–2.07)	0.03*
CCI	1.40 (1.16–1.71)	0.001*
GNRI	1.66 (1.27–2.12)	< 0.001*

*$p < 0.05$.

Even among the reports of cutoff values for physical function assessments that predict mortality in patients with cancer, there are few studies that describe cutoff values and sensitivity and specificity values calculated for patients with cancer [24, 29]. In some studies, the cutoff value is substituted according to the diagnostic criteria for sarcopenia [31] or the reference values for healthy elderly people [32] in order to predict prognoses, but it is unclear whether it is appropriate to substitute the general condition of patients with advanced cancer, in whom cachexia is strongly progressing and causes functional decline. Caution should thus be used when interpreting cutoff values, as the muscle wasting caused by aging in healthy people (age-related sarcopenia) has a different pathogenesis from the muscle wasting caused by cancer cachexia [33].

Although some research groups have reported physical functional cutoff values for patients with cancer [24, 29], there are still very few data, and our present investigation could provide valuable data as a study that identified cutoff values for patients with advanced cancer. The study's sample size was somewhat small, but since there was no major difference in the results of the bootstrap validation, it is likely that the cutoff value can be generalized at least to patients with advanced lung cancer undergoing radiation and chemotherapy.

4.3. The Study Population. The most characteristic feature of this study's patients was that many of them had lung cancer. Since lung cancer is one of the cancer types with a low 5-year survival rate in Japanese people [34], the findings of our mortality prediction analysis must be interpreted with this in mind. In addition, we included a large number of patients who were elderly and had metastatic lesions, which may have affected the mortality rate. Although the patient backgrounds in earlier studies have varied, metastasis [26, 35], older age [26, 35], gender [26], and malnutrition [25, 27] have been reported as high-risk factors for mortality. Our comparison of the present patients' backgrounds by stratifying them based on their cFAS scores revealed that the distribution of indications for radiation therapy differed significantly. We had limited the study's patient population to those at a particular stage of cancer and controlled for a certain degree of disease progression; however, the result concerning the distribution of indications for radiation therapy suggests that there may have been differences in the patients' disease status that could have influenced treatment that were not captured in the data we collected.

4.4. Study Limitations. This study has several limitations. The population that we assessed had a high proportion of lung cancer, and thus the data may not be generalizable to other types of cancer. The accuracy of the mortality prediction classification and the cutoff point may change if the characteristics of the disease are different. Second, we were not able to standardize the timing of the cFAS measurements with the patients' treatment progression. The participants included patients who were evaluated during their first session of chemotherapy or radiation treatment as well as those who had already undergone repeated treatments, and there was thus a mix of patients with different treatment progressions. Indeed, our analyses revealed variations in the chemotherapy treatment lines and the indications for radiation therapy. The progress of treatment may affect a patient's prognosis, and ideally, patients should have been enrolled in the study at the time of their initial treatment;

however, at the time of initial treatment (when cachexia is not often advanced), rehabilitation orders are not necessarily given, and it was thus difficult for us to control. The data from this study can be considered clinical data in terms of prediction, which includes various aspects of treatment progress. The cFAS may be able to provide more accurate predictions in patient groups with more controlled treatment stages. Finally, the sample size used in the multivariate survival analysis was limited, and we could not include all factors that could potentially have an impact. There may thus be factors that strongly influence mortality that were not included in the analyses.

5. Conclusion

The results of this study revealed that the cFAS score at admission for patients with advanced cancer undergoing chemotherapy and/or radiation therapy may be able to predict patients' mortality risk within 365 days, with low-to-moderate accuracy. The estimated cutoff value for predicting mortality within 365 days was approx. 73–75 points.

Data Availability Statement

The data to support the findings of this study are available upon reasonable request.

Ethics Statement

The study was approved by the Ethics Committee of Tsukuba Medical Center Hospital (2023-021) and was conducted in accord with the tenets of the Declaration of Helsinki. Written informed consent for study participation was obtained from all of the included patients.

Disclosure

All authors read and approved the final manuscript.

Conflicts of Interest

The authors declare no conflicts of interest.

Author Contributions

All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by Kenta Kawamura and Atsushi Tsukamoto. The first draft of the manuscript was written by Kenta Kawamura, and all authors commented on previous versions of the manuscript.

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