# Palliative Rehabilitation in Acute Inpatient Rehabilitation: Prognostic Factors and Functional Outcomes in Patients with Cancer

Jegy M. Tennison<sup>1,\*,</sup>, Arash Asher<sup>2</sup>, David Hui<sup>3,</sup>, Milind Javle<sup>4</sup>, Roland L. Bassett<sup>5,</sup>, Eduardo Bruera<sup>3</sup>

<sup>1</sup>Section of Physical Medicine & Rehabilitation, Department of Palliative, Rehabilitation, and Integrative Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

<sup>2</sup>Samuel Oschin Comprehensive Cancer Institute at Cedars-Sinai Medical Center, Los Angeles, CA, USA

<sup>3</sup>Section of Palliative Medicine, Department of Palliative, Rehabilitation, and Integrative Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

<sup>4</sup>Department of Gastrointestinal Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, USA <sup>5</sup>Department of Biostatistics, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

\*Corresponding author: Jegy M. Tennison, MD, Department of Palliative, Rehabilitation, and Integrative Medicine, Unit 1414, The University of Texas MD Anderson Cancer Center, 1515 Holcombe Boulevard, Houston, TX 77030, USA. Tel: +1 713 745 2327; Fax: +1 713 792 6092; Email: jmtennison@mdanderson.org

# Abstract

**Background:** Prognosis has a vital role for patients with cancer undergoing palliative rehabilitation in acute inpatient rehabilitation. This study aimed to identify the proportion of patients who survived <2 months after discharge and the associated prognostic factors.

**Materials and Methods:** This was a secondary analysis of a retrospective study of 163 consecutive patients admitted to acute inpatient rehabilitation from September 1, 2017, to February 28, 2018 at a cancer center. Baseline demographics, clinical characteristics, and putative prognostic factors, including Activity Measure for Post-Acute Care (AM-PAC) functional scores, were analyzed.

**Results:** Of 163 patients, 27 (17%; 95% Cl, 11-23) died within 60 days of discharge. These patients were more likely to be male (OR = 2.83; 95% Cl, 1.16-6.92; P = .017); have longer hospital stays (OR = 1.02; 95% Cl, 1-1.04; P = .015); receive  $\geq$  weekly packed red blood cell (OR = 5.31; 95% Cl, 1.86-15.1; P = .003) or platelet (OR = 4.57; 95% Cl, 1.44-14.5; P = .014) transfusions; have lower AM-PAC daily activity scores upon discharge (OR = 0.90; 95% Cl, 0.83-0.97; P = .006); and have lower AM-PAC basic mobility scores upon admission (OR = 0.91; 95% Cl, 0.85-0.98; P = .018) and discharge (OR = 0.88; 95% Cl, 0.82-0.94; P = <.001). Multivariate analysis showed that the male sex (OR = 2.71; 95% Cl, 1.03-7.15; P = .037) was independently associated with  $\leq$ 2 months survival, whereas AM-PAC basic mobility score at admission of >33 (OR = 0.24, 95% Cl, 0.07-0.79; P = .022) was less likely.

**Conclusion:** Approximately 1 in 6 patients who completed acute inpatient rehabilitation died within 2 months of discharge, had poorer baseline functional status, and were less likely to regain function than those who lived longer.

Key words: palliative care; neoplasms; inpatient; rehabilitation; end-of-life care; functional decline.

#### **Implications for Practice**

This study showed a remarkable early mortality rate in patients with cancer after completing acute inpatient rehabilitation. These patients with early mortality risk factors were less likely to significantly improve their physical functional status as expected with an intense, acute inpatient rehabilitation program. Therefore, these patients would be more appropriate for a reassessment of prognosis, which can then assist with deciding on rehabilitation setting and intensity to provide more individualized and meaningful palliative rehabilitation goals.

# Introduction

Palliative rehabilitation is largely under-studied<sup>1,2</sup> and under-addressed, but it is a national priority owing to growing needs.<sup>3</sup> The purpose of palliative rehabilitation is to improve the quality of life in patients by optimizing function, decreasing symptom burden,<sup>4,5</sup> preventing immobilityinduced complications, and improving psychosocial well-being.<sup>4</sup> Palliative rehabilitation has been reported primarily in hospice or palliative care units.<sup>2</sup> However, rehabilitation services can be delivered in various settings, such as acute care hospitals, acute inpatient rehabilitation services, long-term acute care hospitals, skilled nursing facilities, outpatient clinics, homes, or hospices.<sup>3,4</sup> Acute inpatient rehabilitation is appropriate for medically stable patients who can tolerate 3 h of intensive rehabilitation with multiple rehabilitation

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disciplines (eg, physical therapy, occupational therapy) at least 5 times per week.<sup>6</sup> It is typically designed for patients who can make substantial, measurable improvements in functional status within a short prescribed time. This occurs under the supervision of a rehabilitation physician with face-to-face visits at least 3 days per week using a coordinated, interdisciplinary approach.<sup>4,6</sup>

Compared to typical patients in the acute inpatient rehabilitation settings,<sup>7</sup> patients with advanced cancer often have intense and dynamic symptoms, psychological distress,<sup>3</sup> ongoing various medical complications,<sup>8</sup> muscle loss, and poor baseline function. A high rate of symptom burdens and medical complications can decrease these patients' tolerance and participation in intensive acute inpatient rehabilitation,<sup>9</sup> resulting in unplanned transfers back to acute care services.<sup>8</sup> Accordingly, among patients with advanced cancer receiving palliative rehabilitation in an acute inpatient rehabilitation setting, the rehabilitation goals may vary according to life expectancy, symptom burden, functional status, and goals.

A patient's life expectancy is one of the critical drivers of clinical decision-making. Because patients with advanced cancer generally experience a continual functional decline in the last 1-3 months of life,<sup>2</sup> the palliative rehabilitation goals for these patients should be set with lower expectations for functional improvement. The emphasis should be on reducing the risk of complications, maximizing the palliation of symptoms, educating caregivers, and supporting care planning. To our knowledge, no studies have examined the prognostic factors for early mortality among patients with cancer who underwent acute inpatient rehabilitation. A better understanding of these prognostic factors may help the patients, families, and rehabilitation clinicians set realistic, personalized goals for rehabilitation. This retrospective study examined the proportion of patients on an acute inpatient rehabilitation service who died within 60 days of discharge. We also examined prognostic factors associated with early mortality to help identify patients who would have been appropriate for more focused palliative rehabilitation goals.

## Methods

#### Patient Population and Data Source

This study was a secondary analysis of a retrospective study that initially included 165 patients whose basic demographics, clinical characteristics, and procedures for data collection have been published previously.<sup>8</sup> Approval for data collection was obtained from the Institutional Review Board. Data was collected from the institutional electronic health records and managed using Research Electronic Data Capture software.

In brief, the original cohort study and this study included all consecutive patients admitted to the acute inpatient rehabilitation service of a comprehensive cancer center between September 1, 2017, and February 28, 2018. The uniqueness and details of this acute inpatient rehabilitation program have been previously described.<sup>10</sup> Six patients were readmission to the acute inpatient rehabilitation service during this timeframe and were excluded, which resulted in 165 patients in the original study. This study excluded 2 additional patients with missing survival data; thus, the total of evaluable patients was 163. The current study compared data for patients with early mortality ( $\leq$ 60 days) vs. those who lived longer after completing acute inpatient rehabilitation.

# Variables

Data collected at the time of admission for acute inpatient rehabilitation included demographics (age, sex, race, ethnicity, and marital status) and clinical characteristics (primary neoplasm type, length of hospital stay, comorbidities, and the presence or absence of the following during the acute inpatient rehabilitation: urinary incontinence, stool incontinence, cognitive deficits, and weekly or more frequent transfusions of packed red blood cells and platelets). Comorbidities were dichotomized using Elixhauser measures, and a total score was calculated for each patient as described previously.<sup>11</sup>

The patient's physical activity status was assessed at admission and discharge from the acute inpatient rehabilitation service using Activity Measure for Post-Acute Care (AM-PAC) Inpatient "Six Clicks" Short Forms. Physical therapists computed the 6-Clicks basic mobility scores, and occupational therapists calculated the 6-Clicks daily activity scores within 24 h of admission and 24 h before discharge from the acute inpatient rehabilitation service. These validated<sup>12</sup> and reliable<sup>13</sup> forms are derived from a traditional AM-PAC instrument<sup>14</sup> for post-acute care. As described by Jette et al<sup>13</sup> each form has 6 activities, for which therapists give scores on a scale from 1 (unable to do or total assistance required) to 4 (no difficulty or no assistance required).<sup>13</sup> The total scores provide a raw score of 6-24 for each form, and the raw score is standardized to a t score whose mean is 50, and the SD is 10.13 Lower scores correspond to lower physical activity levels.

#### Statistical Analyses

The primary outcome was death within 60 days after discharge from the acute inpatient rehabilitation service. The secondary outcomes were the prognostic factors associated with early mortality. Logistic regression models were fit considering various covariates of interest, including functional scores and demographic and clinical characteristics. Univariate models were considered first, and then a multivariate model was fit based on the statistically significant variables identified in the univariate analyses. In some cases, the number of patients in 1 or more categories was too small; for these, Firth's penalized likelihood method was used to fit models.

The admission and discharge AM-PAC basic mobility scores were highly correlated and could not be fit into a multivariate model simultaneously. We chose to use the admission instead of the discharge AM-PAC basic mobility scores for the multivariate analyses because, when additional service involvement (ie, oncology, palliative/supportive care, and hospice) may be needed in the course of a patient's care, it is helpful to identify prognostic factors earlier rather than later. There was no threshold for collinearity.

This study further categorized the patients into 2 functional stages: those with AM-PAC basic mobility scores of  $\leq 33$  (the group with limited movement) and those with scores of 34-65 (the group with limited mobility indoors or moving around indoors) as guided by the AM-PAC Instruction Manual.<sup>15</sup> All statistical analyses were performed using R version 4.1.1, and *P*-values of less than .05 were considered statistically significant. No adjustments for multiple testing were made.

# Results

The cohort included 163 unique patients with survival data (Table 1). Most patients were White (71%) and married

Table 1. Characteristics of patients with cancer who underwent acute inpatient rehabilitation.

Characteristics	Total patients $N = 163$	Alive 2 months after discharge N = 136	Died within 2 months after discharge N = 27	P-value <sup>a</sup>
Age, years, median (IQR 25-75)	64 (55-71)	64 (55-71)	67 (55-71)	.500
Length of hospital stay, days, median (IQR 25-75)	26 (20-36)	25 (19-35)	34 (24-51)	.009
Elixhauser medical comorbidity index, median (IQR 25-75)	3 (2-5)	3 (3-4)	4 (2-5)	1.000
AM-PAC basic mobility score, admission, median (IQR 25-75)	41 (35-42)	41 (39-42)	39 (33-41)	.010
AM-PAC daily activity score, admission, median (IQR 25-75)	37 (35-40)	38 (35-40)	36 (33-39)	.090
AM-PAC basic mobility score, discharge, median (IQR 25-75)	42 (39-45)	44 (41-48)	37 (33-42)	<.001
AM-PAC daily activity score, discharge, median (IQR 25-75)	40 (37-42)	40 (38-44)	37 (33-40)	.002
Male sex, <i>n</i> (%)	81 (50)	62 (46)	19 (70)	.020
Race, <i>n</i> (%)				.560
White	116 (71)	97 (71)	19 (70)	
Black	20 (12)	17 (13)	3 (11)	
Asian	7 (4)	7 (5)	0 (0)	
Other	20 (12)	15 (11)	5 (19)	
Hispanic ethnicity	26 (16)	19 (14)	7 (27)	.140
Married, $n$ (%)	116 (71)	95 (70)	21 (78)	.490
Primary neoplasm type <sup>b</sup> , $n$ (%)				.060
Brain and other nervous systems	38 (23)	34 (25)	4 (15)	
Hematologic/lymphatic	35 (21)	27 (20)	8 (30)	
Bones and connective tissues	25 (15)	25 (18)	0 (0)	
Genitourinary system	19 (12)	14 (10)	5 (19)	
Breast	12 (7)	9 (7)	3 (11)	
Respiratory system	12 (7)	9 (7)	3 (11)	
Digestive system	10 (6)	9 (7)	1 (4)	
Skin	6 (4)	5 (4)	1 (4)	
Others <sup>c</sup>	6 (4)	4 (3)	2 (7)	
Metastatic solid tumor, <i>n</i> (%)	60 (37)	48 (35)	12 (44)	.390
Urinary incontinence, <i>n</i> (%)	42 (26)	33 (24)	9 (33)	.340
Stool incontinence, n (%)	38 (23)	31 (23)	7 (26)	.800
Cognitive deficits, <i>n</i> (%)	42 (26)	33 (24)	9 (33)	.340
Red blood cell transfusions, $\geq$ weekly, <i>n</i> (%)	18 (11)	10 (7)	8 (30)	.003
Platelet transfusions, $\geq$ weekly, $n$ (%)	14 (9)	8 (6)	6 (22)	.010

<sup>a</sup>Boldface indicates statistical significance (P < .05).

<sup>b</sup>Other neoplasms included endocrine, oral cavity and pharynx, and other soft-tissue neoplasms.

Abbreviation: AM-PAC, Activity Measure for Post-Acute Care Inpatient "Six Clicks" Short Forms.

(71%). Half of these were men, and the most frequent primary neoplasms were brain or other nervous system neoplasms (23%). The median age was 64 years, and the median hospital stay was 26 days. Twenty-seven of 163 (17%; 95% CI, 12-23) patients died within 60 days of discharge from acute inpatient rehabilitation. These patients had fewer improvements in their AM-PAC daily activity scores and greater declines in their basic mobility scores upon discharge than those who lived longer. Of the 27 patients who died, only 5 (19%) patients had received palliative or supportive care actively during acute inpatient rehabilitation, and 2 (7%) patients were discharged to home hospice care after completing acute inpatient rehabilitation. There were no deaths in this cohort during acute inpatient rehabilitation, likely because of the high rate (19%) of unplanned transfers back to acute care services for medical instability management.8

The results of the univariate logistic regression models for early mortality among patients undergoing acute inpatient cancer rehabilitation are summarized in Table 2. In this cohort, mortality within 60 days after acute inpatient rehabilitation was significantly associated with male sex, prolonged hospital stays, weekly or more frequent red blood cell or platelet transfusions, lower AM-PAC basic mobility scores at admission and discharge, and lower AM-PAC daily activity scores at discharge.

The multivariate logistic regression model results for the probability of early mortality after discharge from acute inpatient rehabilitation are summarized in Table 3. Of the variables considered, the male sex was a significant independent factor for mortality within 60 days after discharge from acute inpatient rehabilitation. The patients with an AM-PAC basic mobility score of >33 at admission were substantially less likely to die within 2 months. In Table 2, the admission

Table 2. Univariate logistic regression models for patients who died within 2 months after discharge from acute inpatient cancer rehabilitation.

Variable	Total $N = 163$	Died within 2 months after discharge N = 27	Odds ratio	Lower CI	Upper CI	P-value <sup>a</sup>
Male sex	81	19	2.83	1.16	6.92	.017
Race <sup>b</sup>						1.000
White	116	19	3.00	0.164	54.7	
Black	20	3	3.00	0.137	65.6	
Other	20	5	5.32	0.259	109.5	
Asian	7	0	_	_	_	
Hispanic ethnicity	26	7	0.441	0.163	1.19	.120
Married	116	21	0.662	0.249	1.76	.397
Primary neoplasm type <sup>b</sup>						
Brain and other nervous systems	38	4	_	_	_	1.000
Hematologic/lymphatic	35	8	2.37	0.681	8.25	
Bone and connective tissue	25	0	0.15	0.007	2.92	
Genitourinary system	19	5	2.91	0.725	11.66	
Breast	12	3	2.82	0.167	8.79	
Respiratory system	12	3	2.82	0.587	13.59	
Digestive system	10	1	1.21	0.167	8.79	
Skin	6	1	2.09	0.267	16.33	
Others <sup>c</sup>	6	2	4.26	0.682	26.60	
Metastatic solid tumor	60	12	1.47	0.635	3.39	.372
Red blood cell transfusions, ≥weekly	18	8	5.31	1.86	15.1	.003
Platelet transfusions, ≥weekly	14	6	4.57	1.44	14.5	.014
Urinary incontinence	42	9	1.56	0.64	3.8	.336
Stool incontinence	38	7	1.19	0.459	3.06	.728
Cognitive deficits	42	9	1.56	0.64	3.8	.336
Age	163	27	1.01	0.979	1.04	.554
Length of hospital stay	163	27	1.02	1	1.04	.015
Elixhauser medical comorbidity index	163	27	0.995	0.761	1.3	.973
AM-PAC basic mobility score, admission	163	27	0.912	0.846	0.984	.018
AM-PAC daily activity score, admission	163	27	0.97	0.884	1.06	0.523
AM-PAC basic mobility score, discharge	163	27	0.878	0.821	0.938	<.001
AM-PAC daily activity score, discharge	163	27	0.899	0.834	0.97	.006

<sup>a</sup>Boldface indicates statistical significance (P < .05).

<sup>b</sup>Indicates model fit with the Firth penalized likelihood method owing to the small number of patients.

Other neoplasms included oral cavity and pharynx, endocrine, and other soft-tissue neoplasms.

Abbreviation: AM-PAC, Activity Measure for Post-Acute Care Inpatient "Six Clicks" Short Forms.

AM-PAC daily activity score was not statistically significant and thus it was not included in the multivariate analysis.

# Discussion

This study found that a substantial proportion of patients with cancer undergoing acute inpatient rehabilitation died (17%) within 60 days after discharge. Moreover, only 19% of these patients received palliative or supportive care management during acute inpatient rehabilitation, and only 7% were discharged to hospice services. These patients with early mortality had fewer improvements in their AM-PAC daily activity scores and greater declines in their basic mobility scores upon discharge than those who lived longer. Hence, these patients could not make the substantial functional improvements expected in an intensive, acute inpatient rehabilitation program. In contrast, the patients with a longer survival time improved their functional scores by discharge, a finding similar to that in other studies<sup>16,17</sup> of the inpatient cancer rehabilitation population overall improved their functional status. These findings highlight the need to assess patients' prognosis and anticipated survival time as part of the acute inpatient rehabilitation criteria for realistic rehabilitation goal setting for patients with cancer.

Warren et al<sup>18</sup> demonstrated that patients with AM-PAC basic mobility scores ≤40.78 and daily activity scores ≤40.22 had higher odds of discharge with the need for rehabilitation (home health rehabilitation, acute inpatient rehabilitation, or subacute rehabilitation).<sup>18</sup> Our study showed that an AM-PAC basic mobility score >33 was less associated with

Table 3. Multivariate logistic regression model for patients who died within 2 months after discharge from acute inpatient cancer rehabilitation.

Variables	Odds ratio	Lower 95% CI	Upper 95% CI	P-value*
Length of hospital stay ≤60 days >60 days	2.966	0.752	11.697	.129
AM-PAC basic mobility score, admission ≤33	0.241	0.073	0.791	.022
34-65 Sex Female	2.713	1.030	7.145	.037
Male Red blood cell transfusions, ≥weekly No	2.220	0.597	8.260	.243
Yes Platelet transfusions, ≥weekly	2.149	0.511	9.032	
No Yes				.304

<sup>a</sup>Boldface indicates statistical significance (P < .05).

Abbreviation: AM-PAC, Activity Measure for Post-Acute Care Inpatient "Six Clicks" Short Forms.

mortality within 60 days after discharge. Thus, a poor mobility score can indicate the need to reassess a patient's disease and symptom burdens to reconsider the patient's rehabilitation goals and settings according to disease prognosis and life expectancy. When considering rehabilitation settings, subacute rehabilitation (at a long-term acute care hospital or skilled nursing facility) can also serve as a transitional setting for patients who are ready for discharge from the hospital but who cannot safely be discharged home. Subacute rehabilitation is less intense than acute inpatient rehabilitation and provides coordinated interdisciplinary services for patients who cannot tolerate 3 h of rehabilitation per day.

The statistical analyses underscore the importance of functional status in forecasting outcomes in patients with cancer. For example, Asher et al found that the motor Functional Independence Measure on admission to acute inpatient rehabilitation is the best predictor for patients with cancer needing to be transferred back to acute care.<sup>19</sup> Indeed, functional capacity can reliably predict survival in patients with cancer. Oncologists often use a patient's functional capacity to make decisions about treatment, including entry into clinical trials.<sup>20</sup> The Karnofsky Performance Status score, for example, is among the most commonly used tools to quantify performance status. Numerous studies have demonstrated an association between survival in patients with cancer and their Karnofsky Performance Status scores.<sup>21,22</sup> Furthermore, patients with cancer in the terminal stage can experience a decline in physical function between 1 and 3 months before death.<sup>2</sup> Our findings reaffirm the importance of recognizing poor basic mobility as a risk factor for mortality.

In a 2012 study, Spill et al<sup>23</sup> noted that only 8% of medical oncologists and 35% of physiatrists would recommend inpatient rehabilitation for patients with advanced cancer and an estimated survival time of 6-12 months.<sup>23</sup> More recently, it has been suggested that some patients with a life expectancy of fewer than 3 months may want to undergo 2 weeks of inpatient rehabilitation to reduce caregiver burden.<sup>24</sup> This may be appropriate for patients under the care of a cancer rehabilitation physiatrist, who is more comfortable managing patients with advanced cancer<sup>24</sup> and can refer the patient for palliative care services for intense and dynamic symptom management if needed. However, the decision to pursue inpatient rehabilitation is often tempered by the patient's limited life expectancy and time away from family.<sup>25</sup> It is also difficult to ascertain what proportion of these patients with early mortality would have still wanted to pursue intensive acute inpatient rehabilitation, even if they knew there was a possibility that they would succumb to the illness. Perhaps, given our study's findings, males are more likely than females to pursue an intensive acute inpatient rehabilitation program toward the end of life.

The direct clinical implications of the 2 prognostic factors (male sex and admission AM-PAC mobility score) and how this data would influence rehabilitation setting and intensity decisions are debatable. The effectiveness of acute inpatient rehabilitation for patients with a short survival time, such as 2 months, is unknown. When faced with a life-threatening illness, decision-making is quite nuanced, complicated, uncertain, and fluid. It can be influenced by the age and functional status of the patient as well as cultural factors, family preferences, financial resources, caregiver burden, and clinician guidance, among others.<sup>26</sup> Redirecting efforts to engage clinicians and families in high-quality conversations about what matters most may be prudent in the setting of short survival time. Patients with short survival times of 2 months or less should be apprised of lower expectations regarding functional gains, and rehabilitation session content can be highly individualized based on the current presentation. Rehabilitation should focus on adapting to impairments, training family members or caregivers, and dispensing adaptive equipment, regardless of the rehabilitation setting, to improve patients' quality of life.

Among the many goals of palliative rehabilitation, the only one that the US payors currently mandate for acute inpatient rehabilitation is that of making measurable functional improvements within a short prescribed time.<sup>6</sup> Consequently, the functional scores are the only outcome measurements required to be documented with acute inpatient rehabilitation stay since this is the primary goal of acute inpatient rehabilitation. Patients need to be medically stable to participate in the standard 3 h of rehabilitation per day; thus, patients' symptoms should be sufficiently controlled before starting acute inpatient rehabilitation. One approach to assessing a patient's rehabilitation tolerance level is to have the patient participate in 2 h of rehabilitation sessions on consecutive days in the acute care service before transferring to acute inpatient rehabilitation. The drawback to consider with these criteria is that patients with cancer may have dynamic symptoms, medical problems, and disease statuses that affect their functional status even during acute inpatient rehabilitation.

The continued refinement of a patient's physical function status is of critical importance as it has important implications for allocating healthcare resources and the types of rehabilitation settings. One study noted that patients receiving rehabilitation through an inpatient palliative care service had a death rate of 65% and that 20% of patients had stable or unimproved physical functional scores.1 Patients with cancer who die at a hospital have been reported to have worse quality of life than those who die at home.<sup>27</sup> Thus, researchers have recommended decreasing hospitalization and enhancing the quality of life in patients with advanced cancer.<sup>27</sup> A palliative care consultation is helpful for patients with advanced cancer, particularly those with functional decline.<sup>28</sup> For patients at risk of early mortality, palliative care is beneficial because it provides symptom control, emotional support, goalsof-care conversations, and discharge planning. Our study found that few patients with early mortality had active palliative care interventions, highlighting substantial opportunities to improve care. Further studies should examine how integrated models of rehabilitation and palliative care teams can provide optimal palliative rehabilitation globally.

## Limitations

Since the data in this study were examined retrospectively and were from a small cohort at a single cancer center, the generalizability of the results is limited. The analysis was performed using the available data, and other unaccounted prognostic factors could have confounded the results. A larger, prospective study would allow for the capturing of more data and would be more suitable for evaluating the various goals of palliative rehabilitation. The power is limited in light of the small number of cases analyzable for deaths. Post hoc power calculations are, however, not useful and are generally not recommended.

Some palliative rehabilitation goals, such as symptom control and decreasing immobility-related complications, were not measured in this secondary analysis study; thus, the influence of these factors is unknown. Because the patient's quality of life was not assessed, it is also unknown whether the patients with early mortality considered acute inpatient rehabilitation beneficial. Nevertheless, this study's results indicate that when the patients' functional status does not improve substantially or declines, these patients may be more appropriate for referral back to an oncologist for a medical status and prognosis reassessment and evaluation of life expectancy.

# Conclusion

In this study, a significant percentage of patients with cancer who underwent acute inpatient rehabilitation died within 2 months after discharge. Compared with patients who lived longer, the patients with early mortality did not make substantial functional improvements and were more likely to be men. Future research should be done to validate our findings and identify other prognostic factors for early mortality. Future studies should also assess symptom burden, immobility-related complications, and patient's perception of quality of life to comprehensively evaluate the effects of palliative rehabilitation.

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# **Conflict of Interest**

The authors indicated no financial relationships.

## Author Contributions

Conception/design: J.T., D.H., M.J., E.B. Provision of study material or patients: J.T. Collection and/or assembly of data: J.T. Data analysis and interpretation: J.T., A.A., D.H., R.L.B., E.B. Manuscript writing: All authors. Final approval of manuscript: All authors.

# **Data Availability**

The data supporting this study's findings are available from the corresponding author upon reasonable request.

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