

Impact of Falls in Palliative Care Units in Japan: A Multicenter Prospective Cohort Study

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St. Luke’s International University Graduate School of Public Health

Capstone Project

Impact of Falls in Palliative Care Units in Japan: A Multicenter Prospective Cohort Study

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Abstract

17 **Background:** Falls in patients with advanced cancer present serious problems, but there is no
18 established way to predict them.

19 **Objectives:** This study was a multicenter prospective cohort study performed in palliative care units
20 to develop a falls prediction model.

21 **Method:** Patients who experienced a fall within one month of death will be included in the study,
22 and variables associated with the fall will be analyzed among the background variables. Based on the
23 result of univariate analysis, we performed a multivariate analysis using logistic regression analysis
24 and the classification tree. Finally, through these analyses, we propose a prediction model for falls.

25 **Result:** Among 1896 patients, 1633 patients were eligible for this analysis and 150 of the eligible
26 patients had experienced a fall. Twenty-two variables were found to be associated with falls ($p <$
27 0.05) in the univariate analysis. Using the variables having the p-value that is less than 0.20 as
28 explanatory variables, we performed a multivariate logistic regression analysis. The receiver
29 operating characteristic curve analysis indicated that the value of the area under the curve was 0.80
30 (95%CI: 0.754 - 0.846). In addition, the sensitivity was 71.6% and the specificity was 74.3%. From
31 these results, we found that the performance of the developed prediction model was relatively high.
32 In addition, to confirm the order of the magnitude of importance of explanatory variables on the
33 multivariate logistic regression model, the classification tree analysis was performed using variables
34 that were associated with falls. The most influential variable in predicting falls was the Palliative
35 Performance Scale.

36 **Conclusion:** Factors associated with falls in patients with advanced cancer admitted to a palliative
37 care unit have been identified through this study.

38 *Keywords:* cancer, CART, fall, palliative care units, prediction

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Introduction

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It is important to prevent falls in hospitalized patients because a fall is the leading cause of injury for elderly patients and cause serious complications (Bergen et al., 2016). 3.2% of falls occurred and 1.2% of falls caused injury in acute care hospitals. The total number of the injury were as follows: open wounds (rubbing, laceration, skin laceration) 54.9%; closed wounds (damage, hematoma) 34.7%; sprains 2.1%; dislocations 0.7%; vertebral fracture 0.7%; fractures other than vertebral fracture 5.6%; and subdural hematoma 4.0% (Barker et al., 2016). On the other hand, the frequency of falls in patients admitted to the palliative care setting with advanced cancer is high (18 - 50%), and factors such as delirium, age, length of stay, brain tumor, depression, and psychotropic medications have been cited as contributing factors (Stone et al., 2012). Previous studies have evaluated the background factors of falls (Zhang et al., 2018; Goodridge & Marr, 2002), but there are no reports of a multicenter evaluation in a large number of patients with advanced cancer.

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The purpose of this study was to identify factors associated with falls as the primary endpoint in palliative care wards in Japan and to propose a method of fall prediction that could be used in clinical practice.

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Methods

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This was a multicenter post hoc exploratory analysis of, prospective cohort studies of advanced cancer patients who were receiving palliative care in palliative care units in Japan. We compared background variables with the presence of falls within one month of death as the primary endpoint. The study was conducted in accordance with the ethical guidelines for research on human subjects based on the Declaration of Helsinki.

62 **Participants**

63 This study was a part of a multicenter prospective observational study, named East-Asian
64 Collaborative Study to Elucidate the Dying Process (EASED) . This study examined the process of
65 death and end-of-life care in terminally ill cancer patients who admitted to palliative care units in
66 Japan. In this study, we consecutively enrolled patients who were newly admitted to the palliative
67 care units during the research period. All interventions, including all tests and treatment, were
68 performed as usual clinical practice. The inclusion criteria of this study were (a) 18 years old or older,
69 (b) locally advanced or metastatic cancer (including hematological neoplasms), and (c) patients
70 admitted to palliative care units. We excluded patients who were scheduled to be discharged from
71 hospital within a week or who did not wish to participate.

72 **Data Collection**

73 We collected data from the EASED. The data we analyzed were: patient characteristics,
74 symptoms, general condition, and blood test data . We focused on the following factors as possible
75 background factors for falls.

76 ***Data on Admission***

77 For the patient background we used: age, gender, metastatic site, systemic complications
78 (Charlson Comorbidity Index (CCI)), and treatment history for cancer. Neurological data included
79 consciousness, delirium, and cognitive function. The presence, cause, and severity of delirium and
80 the history of delirium were recorded. The diagnosis of delirium was based on the American
81 Psychiatric Association DSM-V, the severity of delirium was based on item nine of the Memorial
82 Delirium Assessment Scale (MDAS), and perceptual disturbances and hallucinations were based on
83 the item "perceptual disturbances and hallucinations" of the Delirium Rating Scale R-98.

84 ***General Condition and Physician's Prediction of Prognosis***

85 The ECOG PS, the Karnofsky Performance Scale (KPS), the Global Health, and the
86 Palliative Performance Scale (PPS) were used to assess general health. Clinician Prediction of
87 Survival (CPS) based on the physician's experience was recorded.

88 ***Medical Treatment***

89 We documented opioid use, opioid dose (converted to oral morphine), antipsychotic use,
90 type of antipsychotic used (haloperidol, risperidone, quetiapine, olanzapine, chlorpromazine, other),
91 and antipsychotic dose (haloperidol 5 mg/day, risperidone 2.5 mg/day, quetiapine 166 mg/day,
92 olanzapine 6.3 mg/day, and chlorpromazine 250 mg/day or higher were considered high doses.). The
93 presence or absence of psychotropic medication use, the type of psychotropic medication used
94 (benzodiazepines, non-benzodiazepines sleeping pills, antidepressants, anticonvulsants,
95 anti-dementia drugs, drugs with Anticholinergic Risk Scale ≥ 2), and the presence or absence of
96 indwelling urinary catheters were all recorded.

97 ***Data at Time of Death***

98 Discharge status included discharge from hospital with death and discharge from hospital
99 with survival. Quality of life at the end of life was noted using the Good Death Scale (GDS), which
100 is a five-item scale developed in Taiwan to assess quality of life at the end of life. The items are as
101 follows based on the original material of GDS (Chang, et al., 2016):

102 1. Has the patient known the fact that he/she is dying?

103 0 = *Complete ignorance*, 1 = *Ignorance*, 2 = *Partial awareness*, 3 = *Complete awareness*

104 2. Could the patient accept his/her illness well?

105 0 = *Complete unacceptance*, 1 = *Unacceptance*, 2 = *Acceptance*, 3 = *Complete acceptance*

106 3. Has the patient arranged everything according to his/her own will?

107 0 = *No reference to the patient's will*, 1 = *Following the family's will alone*, 2 = *Following the*
108 *patient's will alone*, 3 = *Following both the patient and the family's will*

109 4. Was the timing appropriate for the patient to pass away?

110 0 = *No preparation*, 1 = *The family alone had prepared*, 2 = *The patient alone had prepared*,

111 3 = *Both the patient and family had well prepared*

112 5. How about the physical condition of the patient at that time?

113 0 = *A lot of suffering*, 1 = *Suffering*, 2 = *A little suffering*, 3 = *No suffering*

114 Death consideration during hospitalization included expressions of wanting to die quickly
115 and wanting death to be actively hastened and the reasons for these expressions were recorded. The
116 reasons for the desire to die quickly were categorized as follows: 0 = No expression, 1 = Pain, 2 =
117 Dyspnea, 3 = Fatigue, 4 = Other physical symptoms, 5 = Burden on others, 6 = Loss of control over
118 the future, 7 = Inability to take care of oneself, 8 = Nothing to look forward to or play a role in, 9 =
119 Lack of hope, 10 = Fear of death or dying process, 11 = Loneliness, and 12 = Lack of
120 self-worth/meaninglessness of one's existence.

121 Delirium details were recorded as presence or absence of delirium during the hospitalization,
122 the severity of hyperactive delirium (using MDAS), and the final treatment for delirium. The
123 treatment for delirium was categorized as follows: 0: none, 1 = antipsychotics, 2 = antipsychotics
124 plus intermittent sedation (or benzodiazepins for sleep), 3 = shallow continuous sedation with

125 sedatives (*), and 4 = deep continuous sedation with sedatives (*sedatives: midazolam, barbiturates,
126 propofol). Falls during hospitalization within one month before death, complications of falls,
127 purpose of the patient's behavior before the fall, and death within 48 hours of the fall were recorded.

128 The physician recorded all data on a structured data-collecting sheet. Patients were observed
129 from the time of admission until the time of discharge. The observer checked for symptoms while
130 providing usual medical care. Patients whom had difficulty communicating verbally had their
131 symptoms identified based on their proxy's opinion.

132 **Data Analysis and Statistics**

133 For the first step, we calculated descriptive statistics; we calculated the summary statistics
134 for each variable. Next, to investigate the relationship between each continuous variable and the
135 main outcome (fall), we performed the univariate analysis based on the Mann–Whitney U test. Also,
136 based on the Fisher’s exact test, we carried out the univariate analysis for the relationship between
137 each categorical variable and fall. Finally, we performed the multivariate analysis for the
138 investigation of the relation between the significant variables on univariate analyses and the outcome
139 (fall) through multivariate logistic regression analysis and classification and regression trees.
140 Significance was accepted at $p < .05$ and statistical analysis was performed with R version 3. 6. 3.

141 **Statement about Institutional Review Board Approval**

142 This capstone project and the EASED study was approved by the Seirei Mikatahara
143 Hospital Institutional Review Board in July 2016.

144 **Results**

145 **Baseline Patients’ Characteristics**

146 A total of 1,896 patients participated from 22 PCUs in Japan from January 2017 to June
147 2018. Of the patients enrolled, 263 were excluded because they were discharged alive. Thus, the
148 total number of patients were evaluated in this study was 1,633. Of the patients included, 150
149 patients (9.2%) fell within one month of death. Characteristics are summarized in Table 1. Median
150 age was 74.0 years old. The major comorbidities were cerebrovascular disease were 7.0% (n = 115),
151 dementia 8.1% (n = 132), and hemiplegia 1.5% (n = 24). The proportions of ECOG PS 0/1 were
152 0.6% (n = 10), ECOG PS 2 - 6.2% (n = 102), ECOG PS 3 - 40.5% (n = 661) and ECOG PS 4 -
153 52.7% (n = 860). The median prognosis predicted by the physician at the time of admission was 21
154 days.

155 **Univariate and Multivariate Analyses of Factors Associated With Falls**

156 In the univariate analysis, to investigate the relationship between the primary outcome that
157 is “fall or no fall” and the other categorical variable, we performed the Fisher’s exact test. In addition,
158 to assessing the relation between “fall or no fall” and the continuous variable, we carried out the
159 Mann–Whitney U test. As a result, the following variables were statistically significant in the
160 univariate analysis: age (continuous variable), gender (categorical variable), cerebrovascular disease
161 (categorical variable), ECOG PS (categorical variable), KPS (continuous variable), GH (continuous
162 variable), PPS (continuous variable), palliative care phase (categorical variable), urine catheter
163 (categorical variable), psychotropic drug (categorical variable), nonbenzodiazepine hypnotics
164 (categorical variable), antidepressants (categorical variable), Good Death Scale: “Has the patient
165 known the fact that he/she dying?” (categorical variable), output of suicidal ideation (categorical
166 variable), statement of reasons for suicidal ideation (categorical variable), suicidal ideation for pain
167 (categorical variable), suicidal ideation for loss of control for the future (categorical variable),
168 presence of delirium (categorical variable), severe delirium (categorical variable), therapy for

169 delirium (categorical variable), length of hospital stay (continuous variable), prognosis (continuous
170 variable). These are shown in Table 2.

171 In general, if the number of explanatory variables on the multivariate logistic regression
172 analysis is large, we often face the problem of multicollinearity. In this situation, it can be considered
173 that there is a possibility that the estimated odds ratios were not stable in the logistic regression
174 analysis. In addition, among the important explanatory variables from the point of view of prediction,
175 it was also possible that multiple occurrences of a variable had similar information. For this situation,
176 when we applied the variable selection method to the obtained multivariate logistic regression model,
177 the explanatory variables that were not appropriate from a clinical point of view were selected. From
178 these backgrounds, we next confirmed whether or not there was multicollinearity on the estimated
179 multivariate logistic regression model. With that in mind, we assessed the multicollinearity based on
180 the values of the variance inflation factor and generalized variance inflation factor, As a result, we
181 excluded the three explanatory variables: (a) KPS, (b) statement of reasons for suicidal ideation, and
182 (c) presence of delirium, from the multivariate logistic regression model. We found that the number
183 of candidate explanatory variables was 22 after the univariate analysis, but, by checking the
184 multicollinearity, we finally used the variables that are age, gender, cerebrovascular disease, ECOG
185 PS, GH, PPS, palliative care phase, urine catheter, psychotropic drug, nonbenzodiazepine hypnotics,
186 antidepressants, Good Death Scale (“Has the patient known the fact that he/she dying?”), output of
187 suicidal ideation, suicidal ideation for pain, suicidal ideation for loss of control for the future, severe
188 delirium, therapy for delirium, length of hospital stay, and prognosis as the explanatory variables on
189 the multivariate logistic regression model. With this prediction model, we performed the ROC curve
190 analysis. In this case, the value of AUC was 0.80 (95%CI: 0.754 - 0.846). In addition, the values of
191 sensitivity and specificity were 71.6% and 74.3%, respectively.

192 **Classification Tree Analysis**

193 Breiman et al. (1984) proposed the classification and Regression Tress (CART) and its
194 method has been used in various fields. In the CART model, there are two advantages relative to the
195 multivariate logistic regression model. The first advantage is that it is possible to visually confirm
196 the relations among explanatory variables and to understand the order of the magnitude of the
197 importance of explanatory variables for the target outcome. The second advantage is that it is
198 possible to obtain the cut-off point in terms of the important explanatory variable to predict the
199 outcome. Therefore, based on the value of the cut-off point, we can develop a guideline to provide
200 appropriate treatment or to give appropriate diagnostic results. In this study, to verify the prediction
201 model obtained from the multivariate logistic regression, we also developed the CART model. The
202 name of “CART” implies the two methods that are the approaches of the classification and
203 regression. In this study, the outcome is “fall or no fall” that is categorical variable. Therefore, by
204 using the classification tree, we were able to verify the developed multivariate logistic regression
205 model. We applied the CART method to the target data in this study with the 19 variables that were
206 statistically significant ($p < 0.05$) in the univariate analysis: age, gender, cerebrovascular disease,
207 ECOG PS, GH, PPS, palliative care phase, urine catheter, psychotropic drug, nonbenzodiazepine
208 hypnotics, antidepressants, Good Death Scale (“Has the patient known the fact that he/she dying?”),
209 output of suicidal ideation, suicidal ideation for pain, suicidal ideation for loss of control for the
210 future, severe delirium, therapy for delirium, length of hospital stay, and prognosis,. In general, we
211 drew a tree figure called a decision tree using the CART method. The node of the top level of
212 decision tree represents the most important variable in terms of classification for the outcome.
213 Likewise, the nodes at the second level of decision tree indicate the second most important variables
214 to classify the outcome. Figure 4 depicts the decision tree and shows that the most important variable
215 in predicting falls was PPS. The second important variables to predict falls were ECOG PS and GH.

216 The third important variable was from the Good Death Scale: “Has the patient known the fact that
217 he/she dying?” and finally the presence of severe delirium.

218 An example of how this might be used in a clinical setting: if a patient spends some time
219 sitting through the day, he or she may have a score of 50 or higher on the PPS (The cut-off point of
220 45 represents the midpoint value between 40 and 50.). If this is the case, falls should be a concern. In
221 addition, if the patient has a PPS score of less than 40, but has comorbid severe delirium, there is still
222 a possibility of a fall. The patient's awareness of his or her own mortality may also be a predictor of
223 falls. In this study, we were able to suggest some clinically noteworthy variables for predicting falls,
224 as described above.

225 **Discussion**

226 What is clinically important about this study is that it shows the prediction of falls with
227 existing assessment measures. In general, whether a patient with advanced disease will fall or not is
228 usually based on the experience of medical personnel. This has led to different judgments depending
229 on the experience of the healthcare provider. This is why it has been so difficult to educate people to
230 anticipate falls. In this study, we showed which items medical professionals should focus on in their
231 clinical evaluation of fall risk. It is hoped that this perspective can be applied to measures and
232 education to prevent falls. “Which patient falls should we pay attention to?” is a question of great
233 clinical importance. It is difficult to pay attention to all patients. It would be unacceptable from the
234 standpoint of cost-effectiveness of medical resources to invest a lot of human resources to prevent all
235 patients from falling. The medical field is faced with the dilemma of patient safety and distribution
236 of medical resources. In addition, there is a concern that prioritizing patient safety over human
237 dignity in the final stages of life may degrade QOL. For example, a patient who wishes to be
238 independent in defecation may be forced to defecate in an unwanted way in order to prioritize safety.

239 The findings from this study may provide a solution to this important dilemma for both
240 patients and providers. It may be possible to prevent falls, with fewer burdens on providers, by
241 identifying patients at higher risk for targeted attention.

242 In addition, the CART analysis revealed a quantitative assessment of items that are effective
243 in predicting falls. Of course, patients who are bedridden with reduced physical function do not fall.
244 In order to predict falls, it is necessary to identify the decline in physical function that is likely to
245 lead to falls. Also, other studies provide suggestions for this clinical concern. As an example, a score
246 of 40 and 50 on the PPS may be a valid cutoff for predicting falls. Therefore, health care providers
247 could consider a specific assessment of whether the patient spends time in a sitting position. By
248 comparing the results of multivariate logistic regression with those of classification tree, both
249 methods revealed that PPS, GH, ECOG PS, and severe delirium were important variables. Moreover,
250 we found that the multivariate logistic regression analysis result was almost similar to the analysis
251 result of the classification tree.

252 The analysis of the Good Death Scale as an explanatory variable is an interesting aspect of
253 this study. The possibility of the influence of the presence of spiritual pain on the prediction of falls
254 is a new finding in the study of falls. It is known that spiritual pain is more likely to manifest in the
255 final stages of life. Especially in situations where bodily functions are declining, the suffering of
256 being unable to take care of oneself tends to be stronger. Patients with high levels of such suffering
257 may have a tendency to behave in ways that are not commensurate with their physical functions. For
258 example, it has been clinically experienced that a patient may attempt to walk to the bathroom alone,
259 even though it is objectively difficult to walk. From this perspective, support for physical functions
260 and consideration of the environment alone may not be sufficient to prevent falls in cancer patients at
261 the end of life. The essential approach of palliative care to alleviate the patient's spiritual anguish

262 may occupy a very important role in preventing falls. The discussion on spirituality is very important
263 in palliative care. Further research is needed on the relationship between spiritual pain and falls. An
264 example would be an intervention study that compared the frequency of falls in groups with and
265 without spiritual care intervention.

266 **Evaluation of Analytical Results Stability**

267 Kashiwagi, Hayashi, Mori, & Otani (2020) proposed an evaluation method for the analysis
268 of results of the CART model. Here, we induced a perturbation at the point of a variable on the
269 classification tree model and quantitatively evaluated the stability of the developed classification tree
270 model. If we use our proposed evaluation approach, we can assess the stability of the magnitude
271 order of importance of the explanatory variables on the target CART model. Also, we can evaluate
272 the ease of coupling between important explanatory variables to predict an outcome. For example,
273 we can use our evaluation approach for classifying the risks to a target outcome. In Kashiwagi, et al.,
274 (2020), used a set of explanatory variables different from the subset of 19 explanatory variables in
275 this study and we performed the CART analysis on the same dataset. After that, we applied our
276 proposed assessment method in terms of stability to the obtained the CART model. As a result, we
277 carried out the classification of risks in the context of predicting “fall or no fall”. In addition, we
278 confirmed that the findings acquired by applying our assessment approach were very interesting
279 from the clinical viewpoint. In the future, we are willing to apply its assessment method to the
280 developed CART model based on the subset of explanatory variables used in this study and to get
281 more findings that are important from the point of view of clinical application.

282

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V. Limitation

284 This study was conducted as an ancillary study to the EASED study with the primary
285 outcome of prognosis of cancer patients admitted to a palliative care unit. Therefore, the analysis
286 may not have included all factors associated with falls. The same palliative physician completed all
287 observations on the participants. Therefore, while consistency in ratings might be an advantage,
288 observer bias also needs to be considered. Inter-rater reliability should be developed.

289 **VI. Conclusion**

290 We analyzed the background factors associated with the frequency and prediction of falls in
291 cancer patients admitted to a palliative care ward. The accuracy of predicting falls in the palliative
292 care ward can be improved by focusing on the decline in physical function to the extent that the
293 frequency of falls increases.

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