

[ORIGINAL ARTICLE]

Feasibility of Continuous Geriatric Assessments as a Prognostic Indicator in Elderly People with Gastrointestinal Cancer

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Abstract:

Objective The feasibility of continuous geriatric assessments (GAs) has not been evaluated fully in elderly patients with cancer. We prospectively investigated this issue by administering a recommended-GA set (r-GA) repeatedly to patients undergoing chemotherapy for gastrointestinal cancer on an outpatient basis.

Methods We administered the r-GA before chemotherapy and every two months thereafter. Continuous GAs was defined as the completion of at least two assessments, including the pre-treatment evaluation. The r-GA included the Barthel Index [Basic Activities of Daily Living (BADL)], Mini-Mental State Examination-Japanese (MMSE-J), Instrumental Activities of Daily Living (IADL) scale, Vitality Index (VI), and Geriatric Depression Scale-15. We also used the Vulnerable Elders Survey (VES)-13 to screen overall vulnerability. We analyzed the correlations between each baseline GA score and the overall survival (OS) and the association between the OS and changes in each patient's GA scores over time.

Patients Patients ≥ 65 years of age who presented to our department for initial consultation were enrolled and followed between December 2012 and January 2017.

Results Twenty-one elderly patients (median age, 76 years old) were enrolled. GAs were completed within 20 minutes. In an age- and performance status (PS)-adjusted Cox proportional hazards analysis, the baseline BADL, MMSE-J, and VI scores correlated significantly with the OS ($p=0.012$, $p=0.032$, and $p=0.012$, respectively). During the clinical course, decreases in the MMSE-J and VES-13 scores were correlated with the OS ($p=0.022$ and $p=0.019$, respectively).

Conclusion Outpatient GA administration is feasible. Low baseline BADL, MMSE-J, and VI scores and decreased MMSE-J and VES-13 scores over time may prognosticate the OS.

Key words: ADL, cognitive function, elderly patients with cancer, geriatric assessment

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Introduction

Japan, an "aging society," has reported a high incidence of cancer-related deaths among elderly people (1). Although the number of elderly patients with cancer is projected to increase significantly (by 67%) over the next 20 years (2), most participants in clinical trials are <65 years of age (3). Elderly patients with cancer tend to experience difficulties with self-management, psychological symptoms, and the

management of complex medical information (1). Accordingly, these patients must be evaluated comprehensively, and feasible treatment strategies should be selected in consideration of their increased vulnerability (4). The Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) and/or Karnofsky Performance Status (KPS) are chemotherapeutic indexes applied to patients with cancer. However, the chronological age, PS, or KPS alone cannot be used as an adequately objective evaluation of vulnerability (5-7). Furthermore, the PS may not be adequate when applied to elderly

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erly patients (8, 9).

Recently, the National Comprehensive Cancer Network (NCCN) (10) and the International Society of Geriatric Oncology (SIOG) established guidelines for elderly patients (≥ 65 years of age) with cancer, which include recommendations concerning the use of geriatric assessments (GAs) (11-13). Previously, GAs were performed only once, typically before an intervention. In 2014, the SIOG-GA task force released a consensus agreement regarding the use of GAs in geriatric oncology, including the use of these measures to obtain comprehensive information beyond routine examinations and to predict severe complications, survival outcomes, and treatment approaches. These guidelines facilitated treatment decision-making and the selection and subsequent implementation of appropriate combinations of GAs (14). The American Society of Clinical Oncology (ASCO) determined that the use of GAs was indispensable when treating elderly patients with cancer (15). However, GAs may comprise various measures, and no true consensus currently exists regarding the most appropriate combination of scales.

The component tools of a GA set should be screened to assess their feasibility and effectiveness and determine the appropriateness of the set. The Vulnerable Elders Survey (VES)-13 can be self-administered and completed quickly and is therefore useful for screening vulnerabilities in elderly patients (16). A feasible GA should be concise, quickly completable, and well-correlated with other GA scales. Furthermore, the ideal GA scale should be comprehensive and provide additional relevant information (17). Outpatients often exhibit progressive reductions in activities of daily living (ADL) performance and their cognitive function, and GAs can be applied to these patients before and after chemotherapy to help assess therapeutic efficacy. However, the significance of continuous GAs has yet to be demonstrated (17, 18).

The present study investigated the feasibility of administering continuous GAs in elderly patients undergoing chemotherapy for gastrointestinal cancer.

Materials and Methods

Study design

This prospective observational pilot study was conducted to evaluate the feasibility of regular GA application in elderly patients diagnosed with unresectable and postoperative recurrences of solid gastrointestinal cancers who were scheduled for chemotherapy. We recruited approximately 10 patients who were considered “young-old” and another 10 patients considered “old-old.” Patients >75 years old, described as “super elderly,” were also included in the study population.

Patients were screened using selected GAs before chemotherapy and every two months thereafter. We sought to evaluate 1) whether or not continuous GA application was

feasible; 2) the correlation between each baseline GA score and the overall survival (OS), which would inform decision-making with regard to treatment intensity or as a prognostic marker; and 3) the correlation between the OS and changes in the GA scores over time during treatment.

GAs

GAs were administered as recommended by the Japanese Study Group, in accordance with the Guidelines of the Comprehensive GAs (CGAs). The “Japanese Study Group based on the Guidelines of the CGA” includes members of the CGA Guidelines for Decisions in Longevity Science Research Project of Health Science Research Grants in the 2,000 General Project Research Field. The GAs included the Barthel Index, Mini-Mental State Examination (MMSE), Lawton and Brody Instrumental ADL (IADL) score, Vitality Index (VI), Geriatric Depression Scale (GDS)-15, and VES-13 (19, 20), and their combination was designated the recommended GAs (r-GAs). For each patient, the r-GAs were initially performed before the first chemotherapy session and then repeated every two months after chemotherapy initiation. We spaced these assessments at two-month intervals to match the standard-of-care intervals between computed tomography assessments used to determine the effectiveness of chemotherapy. The r-GAs were administered a maximum of 7 times over 12 months. We discontinued their administration when a direct assessment was no longer possible (e.g. primary disease exacerbation). Assessments were considered “continuous” if a minimum of two data points were collected, including before the start of treatment and after two months. The r-GAs were conducted by a professional assistant, and assistance was provided by the assistant or family members as long as the scores of each GA were not affected. The following items were assessed continuously:

1) Geriatric Assessment:

(1) Basic ADL (BADL) was evaluated using the Barthel Index (21), which comprises 10 questions pertaining to ADL, such as feeding, mobility, and grooming. All scores were weighted, and the maximum score was 100 points (100 points=PS0).

(2) Cognitive function: We used the Japanese author-certified version of the MMSE (MMSE-J) (22), which we purchased from the publisher (Nihon Bunka Kagakusha, Tokyo, Japan). The maximum test score is 30, and the lower cut-off limit is 23/24. A lower score indicates a decline in functional cognition.

(3) Emotions/moods were assessed using the GDS-15, which assesses depression in elderly patients (23). The questions were identical to those included in the GDS-Short Form (SF) (24). This yes/no questionnaire comprises 15 questions about feelings and moods. A score ≥ 5 indicates a tendency toward depression, while a score ≥ 10 indicates the presence of depressive symptoms.

(4) IADL: The Japanese version of the IADL scale (Lawton and Brody) has been validated (25) and shown to correlate positively with the MMSE and GDS (26). This scale

Table 1. Patients' Backgrounds.

		Patients (n=21)	%
Age (years)	Median	75	-
	Range	67-86	-
	The first quartile	71	-
	The third quartile	83	-
Sex	Male	14	66.7
	Female	7	33.3
ECOG (PS)	0	11	52.4
	1	8	38.1
	2	2	9.5
Primary tumour	Colorectal	6	28.5
	Pancreas	4	19.0
	Stomach	3	14.3
	Liver	3	14.3
	Biliary tract	3	14.3
	Oesophagus	1	4.8
	Duodenum	1	4.8
	Clinical Stage (UICC)	III	3
	IV	18	85.7

ECOG PS: Eastern Cooperative Oncology Group Performance Status, UICC: Union for International Cancer Control

evaluates various ADL, including 1) using the telephone, 2) shopping, 3) preparing meals, 4) housework, 5) laundry, 6) using transportation, 7) managing medication, and 8) managing property. The maximum score is 5 for men (excludes abilities 2, 3, 4) and 8 for women. We converted the points into a percentage of the total to adjust for sex-based differences in maximum scores.

(5) VI: This scale was originally developed as a measure of activity among elderly people with disabilities in Japan (27) and evaluates five activities: 1) getting up, 2) communicating, 3) feeding, 4) toileting, and 5) rehabilitation or other activities. The scores are weighted, and the maximum score is 10. A score reduction of even 1 point indicates reduced volition.

(6) VES-13: This self-completed questionnaire allows the comprehensive screening of vulnerabilities in elderly people (16). The Japanese version was previously verified (28). A total score of ≥ 3 indicates vulnerability.

Statistical analyses

Data were analyzed using the Statistical Analysis Software (SAS) for Windows, version 9.3 (SAS Institute, Cary, USA). The Kolmogorov-Smirnov test was used to assess the normality of continuous variables. To determine the predictive value of r-GA scores for the OS, we first analyzed the correlations between the baseline r-GA scores and the OS and then the correlations between the changes in continuous r-GA scores and the OS using a Cox regression model after adjusting for age and PS. A p value < 0.05 was considered statistically significant.

Patients

The study protocol was approved by our institutional review board, and all patients provided their written informed consent before study enrollment in accordance with the principles of the Declaration of Helsinki. Elderly patients who presented to the Faculty of Medical Oncology at Kyorin University Hospital for an initial consultation were enrolled and followed from December 2012 to January 2017. The maximum total follow-up duration was two years.

The following study inclusion criteria were applied: 1) ≥ 65 years old, 2) a diagnosis of unresectable or recurrent solid gastrointestinal cancer, and 3) scheduled to receive first-line outpatient chemotherapy. We excluded patients with non-cancerous conditions that might reduce their cognitive function and/or the ability to perform ADL. We also measured the following serum parameters that might influence the ADL or cognitive function: iron, trace elements (copper, zinc), nutrients (vitamins B1, B2, and B12, folic acid), and thyroid-related hormones [thyroid-stimulating hormone (TSH), free triiodothyronine (FT3), and free thyroxine (FT4)]. If reductions in the ADL performance or cognitive function were noted, we performed standard blood counts and blood biochemistry tests after enrollment. If we suspected a deficiency in any of these factors, we suspended treatment until appropriate supplementation had been administered.

Results

Patients' characteristics

We enrolled 21 patients with unresectable solid gastrointestinal cancers. Tables 1 and 2 show the characteristics of the patients and the administered anticancer drugs. In all patients, the levels of vitamins B₁, B₂, and B₁₂; folic acid; copper; zinc; and thyroid-related hormones were within the standard ranges (Table 3A). The results of pre-treatment blood tests revealed mild iron-deficiency anemia and low ferritin levels in four patients. We started iron supplementation with these individuals and delayed r-GA performance until the blood iron and ferritin levels had normalized. Three of these four patients died within two months after chemotherapy induction. The remaining patient experienced a resolution of anemia symptoms and received chemotherapy for 12 months. A follow-up revealed that the patient's serum Fe and ferritin levels had returned to normal (Table 3B).

Continuity of r-GA: feasibility in outpatient settings

Continuous assessments (at least 2 data points) were possible in all 21 patients. One r-GA session required approximately 15-20 minutes (maximum: 35 minutes) to complete. All 7 observations were completed in 7/21 patients (33.3%) over a 12-month period. In 12 patients (57.2%), the observations were discontinued mid-study because of cancer progression; however, each of those patients were able to complete between 2 and 6 observations. For the other 2 patients

Table 2. Cancer Type and Treatment Regimens for All Patients.

Type of cancer	n	Age (years)/Sex	Regimen	Session periods (months)
Oesophageal	1	70/M	5-FU+CDDP	2
Duodenal	1	81/F	S-1 [†]	2
Gastric	3	76/M	S-1 [†]	6
		74/M	1st S-1 [†]	12
Hepato-cellular	3	81/M	2nd weekly PTX	
		76/F	S-1 [‡]	12
		82/M	sorafenib	6
		86/M	sorafenib	12
Biliary tract and/or gall bladder	3	67/F	GEM+CDDP	2
		68/M	GEM+CDDP	8
		69/M	1st GEM+CDDP	12
Pancreatic	4	69/F	2nd S-1 [†]	
		86/M	GEM	2
		72/F	GEM	2
		71/F	GEM	8
Colorectal	6	81/M	1st S-1	10
			2nd GEM	
			1st mFOLFOX4	2
			2nd IRI+Cetuximab	
		85/F	Capecitabine	2
		73/M	Capecitabine+OX	6
85/M	Cetuximab	10		
72/M	mFOLFOX4	12		
83/F	Capecitabine	12		

[†] Alternative regimen; 2 weeks chemotherapy and 1-week rest, [‡] Original regimen; 4 weeks chemotherapy and 2 weeks rest. 5-FU: 5-fluorouracil, CDDP: Cisplatin, PTX: Paclitaxel, GEM: Gemcitabine, OX: Oxaliplatin; IRI: Irinotecan, mFOLFOX4: modified Folinic acid, (5-)Fluorouracil, and Oxaliplatin 4

(9.5%), we discontinued observation because one withdrew consent for further observation and the other died of an acute heart attack. We showed the scores of all r-GAs at graphs (Figure), along with the average and standard deviation for each session (Table 4).

Correlation between r-GA scores and the OS at baseline and through the clinical course of the disease

When assessing the r-GAs, we noted a significant correlation between the OS and the baseline BADL, MMSE-J, and VI scores ($p=0.01$, $p=0.03$, and $p=0.01$, respectively) after adjusting for the age and PS (Table 5). We did not observe any significant relationship between the OS and a change in PS ($p=0.473$) after adjusting for age (Table 6A). Nonetheless, the OS was significantly associated with reductions in MMSE-J and VES-13 scores throughout the clinical course ($p=0.022$ and $p=0.019$, respectively) after adjusting for the age and PS (Table 6B).

Discussion

This study evaluated elderly patients with cancer (≥ 65 years of age) who underwent repeated r-GAs before chemo-

therapy and every 2 months thereafter during evaluation sessions with durations of approximately 20 minutes. The r-GA set appears feasible for use in this cohort and in daily clinical practice. When we analyzed the correlation between the baseline r-GA scores and OS, we found that the BADL, MMSE-J, and VI values were useful prognostic indicators. The BADL and VI are patient-reported outcomes (PROs) and can be administered more simply and rapidly than the MMSE-J. PROs can typically be completed by outpatients during waiting periods. However, because these measures are self-administered, they may suffer from a lack of objectivity. If this limitation is pronounced, the MMSE-J or another more objective cognitive function test that correlates with the MMSE-J can and should be considered.

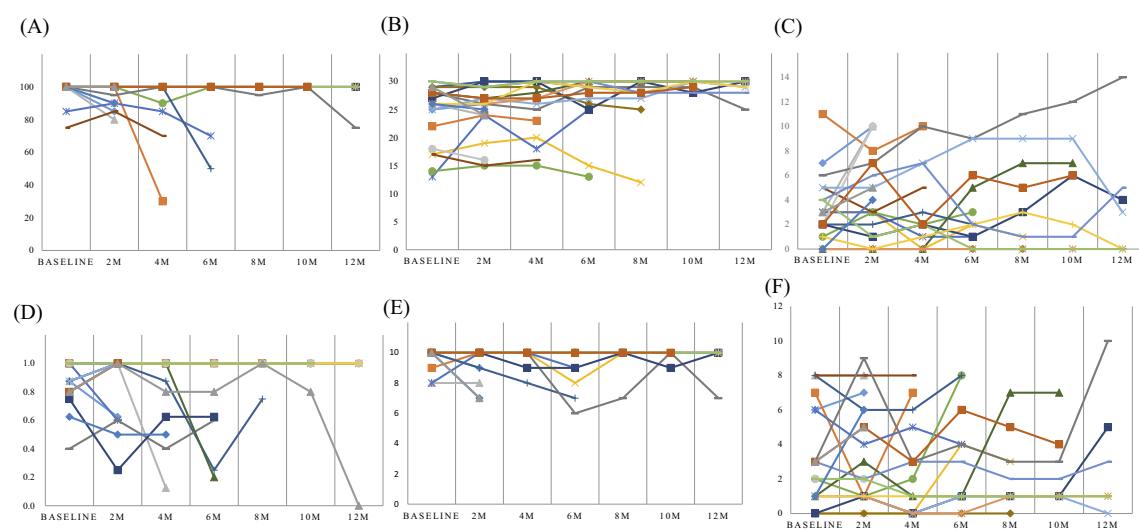
In addition, the OS was found to be positively correlated with lower MMSE-J and higher VES-13 scores, suggesting that changes in these scores serve as prognostic indicators of the survival, even when the scores were initially within normal ranges. One previous study identified a correlation between the survival and pre-treatment MMSE-J scores (18). However, we found no previous studies that performed r-GAs continuously at two-month intervals. We postulate that continuous assessments may help practitioners understand their patients' conditions during periods of rapid symptom

Table 3. (A) Levels of Minerals (Zn, Fe, and Cu), Vitamins (Vitamins B₁, B₂, B₁₂, and Folic Acid), and Thyroid-related Hormones (TSH, FT3, and FT4). (B) In Four Patients, Changes in Fe, Hemoglobin (Hgb), and Ferritin Levels with Iron-deficiency Anemia were Noted before and after Fe Supplementation.

(A)	Items	Unit	Normal range	Range	Average	95% CI	
	Zn	(µg/dL)	59-139	57-84	67.75	63.52	71.98
	Fe	(µg/dL)	80-180	11-176	91.75	67.84	115.66
	Cu	(µg/dL)	66-130	99-130	119.1	114.85	123.35
	Vitamin B ₁	(ng/mL)	21.3-81.9	21.3-81.3	40	33.01	47.02
	Vitamin B ₂	(µg/dL)	4.1-8.8	4.1-9.8	5.69	4.99	6.38
	Vitamin B ₁₂	(pg/mL)	233-914	238-911	540.7	449.7	631.6
	Folic acid	(ng/mL)	3.6-12.9	3.6-20	9.04	6.87	11.21
	TSH	(µIU/mL)	0.41-5.27	0.88-5.2	2.72	2.02	3.42
	FT3	(pg/mL)	1.63-3.20	1.61-2.97	2.37	2.2	2.55
	FT4	(ng/dL)	0.73-1.53	0.84-1.54	1.16	1.07	1.26

(B)	Fe (80-180 µg/dL)	Ferritin (male; 25-280/ female; 18-60 ng/mL)	Hgb (male; 13.5-17.0/ female; 11.5-15.5 g/dL)	GA observation period (months)
	Baseline	Baseline	Baseline	
	After Fe supplementation	After Fe supplementation	After Fe supplementation	
	15	12	11.7	2
	11	9	10.3	2
	26	18	10.3	2
	24	15	9.9	12

CI: confidence interval, GA: geriatric assessment

**Figure.** Graphs of all GA scores for all patients. (A) Barthel Index, (B) MMSE-J, (C) GDS-15, (D) IADL, (E) Vitality Index, and (F) VES-13. GA: geriatric assessment, MMSE-J: Mini-Mental State Examination, Japanese version, GDS: Geriatric Depression Scale, VES: Vulnerable Elders Survey

progression or when the underlying factors cannot be identified based on blood biochemical examination results alone. Given the results of these two analyses, we speculate that patients with low BADL scores and poor cognitive functioning at baseline may demonstrate a poor prognosis, regardless of treatment. Caution should be exercised if a cognitive decline and progressively increasing vulnerability are observed during the clinical course of the disease, even in patients

with normal cognition or pre-treatment vulnerabilities.

The ideal frequency of GA is still being debated. However, we have identified numerous benefits associated with the continuous administration of GAs. Reductions in the cognitive function and BADL and VI scores over the course of regular assessments (every one to two months) may indicate changes in the cognitive function and correspond with disease progression. Thus, detailed GAs, when combined

Table 4. The Average Scores of All r-GAs from the Baseline to 12 Months After. Assessments were Considered "Continuous" if a Minimum of Two Data Points Were Collected, Including before the Start of Treatment and after Two Months.

GA	Session periods	Baseline	2 months	4 months	6 months	8 months	10 months	12 months
	N	21	21	16	14	11	9	7
BADL	Average	98	96	92	94	100	100	96
	SD	6.2	6.4	18.5	15.0	1.5	0.0	9.4
MMSE	Average	24	25	25	26	27	29	29
	SD	5.4	4.7	5.3	5.5	5.2	0.9	1.8
GDS15	Average	3	4	3	3	4	5	4
	SD	2.7	3.4	3.5	3.1	3.9	4.3	5.0
IADL	Average	0.9	0.9	0.8	0.8	1.0	1.0	0.9
	SD	0.16	0.22	0.27	0.29	0.08	0.07	0.38
Vitality Index	Average	9.8	9.5	9.8	9.2	9.7	9.9	9.6
	SD	0.6	1.0	0.5	1.3	0.9	0.3	1.1
VES-13	Average	3	3	3	3	2	2	3
	SD	2.8	2.9	2.7	2.8	2.1	2.1	3.5

SD: standard deviation, GA: geriatric assessment, BADL: basic activities of daily living, IADL: instrumental ADL, VES: Vulnerable Elders Survey, GDS: Geriatric Depression Scale, MMSE-J: Mini-Mental State Examination-Japanese

Table 5. The Correlation between Baseline r-GA Scores and Overall Survival. Age, PS-Adjusted Cox Proportional Hazards Analysis. 95% CI, p<0.05.

GA scores at baseline	Age, PS-adjusted Hazard Ratio (95% CI)	p value
Basic ADL	1.43 (1.081-1.888)	0.012
MMSE-J	0.84 (0.721-0.986)	0.032
Vitality Index	0.11 (0.019-0.608)	0.012

CI: confidence interval, GA: geriatric assessment, ADL: activities of daily living, MMSE-J: Mini-Mental State Examination-Japanese, PS: performance status

with blood chemistry and imaging, can enhance comprehensive assessments, guide treatment planning, and inform decisions regarding the continuation of chemotherapy. Further research is needed to determine the ideal interval between assessments. Although a previous study reassessed 202 elderly patients with cancer after 6 months, the authors provided no rationale for this choice of interval (17). A previous study examined GDS-15, IADL, ADL, and MMSE scores before chemotherapy initiation and three and six months after in patients with colon and breast cancers; however, both of these malignancies have relatively long disease courses (18). These findings suggest that reassessments should be timed in consideration of the cancer type and chemotherapy regimen.

This study had some limitations that warrant consideration. First, as this was a pilot study, we enrolled only 21 patients with varying types of gastrointestinal cancers, all of whom were undergoing different treatment regimens. Cancer manifests differently in different organs, and each cancer requires a specific treatment approach. Consequently, various

Table 6. (A) Age-adjusted Cox Proportional-hazards Analysis. (B) Age, PS-adjusted Cox Proportional Hazards Analysis. 95% CI, p<0.05. BADL, MMSE-J, Vitality Index, VES-13, IADL, and PS were Evaluated Every 2 Months from the Time of Enrolment up to 12 Months after Enrolment and Treated as Time-dependent Variables.

Scales	Age-Adjusted	
	Hazard Ratio (95% CI)	p
BADL	0.979 (0.955-1.004)	0.095
MMSE-J	0.899 (0.821-0.983)	0.020*
GDS 15	1.109 (0.988-1.245)	0.080
Vitality Index	0.661 (0.410-1.065)	0.089
VES-13	1.237 (1.021-1.500)	0.030*
IADL	0.990 (0.976-1.005)	0.198
PS	0.933 (0.773-1.127)	0.473

Scales	Age, PS-Adjusted	
	Hazard Ratio (95% CI)	p
BADL	0.979 (0.955-1.004)	0.101
MMSE-J	0.901 (0.824-0.985)	0.022*
GDS 15	1.127 (0.991-1.280)	0.068
Vitality Index	0.643 (0.396-1.044)	0.074
VES-13	1.276 (1.041-1.564)	0.019*
IADL	0.989 (0.973-1.004)	0.143

CI: confidence interval, GA: geriatric assessment, ADL: activities of daily living, BADL: basic ADL, IADL: instrumental ADL, VES: Vulnerable Elders Survey, GDS: Geriatric Depression Scale, MMSE-J: Mini-Mental State Examination: Japanese version, PS: performance status

anticancer drugs can produce different adverse events, which can in turn affect GA scores. Additional GA data are required for each cancer type and the associated treatment regimens. Second, a reduced cognitive function may have affected the patients' responses to screening questions. Therefore, the use of a highly objective scale instead of a questionnaire may provide a better understanding of the patients' overall condition in cases where reductions in cognition are evident. All patients included in this study were enrolled from a single center. Therefore, prospective studies should consider a multicenter trial approach to encourage appropriately tailored treatment decisions and facilitate the generalization of the findings. Third, the process of subject recruitment took a considerable amount of time. The young-old patients underwent chemotherapy for a median duration of six months. Patients in the young-old population group with a relatively good condition tended to refuse to participate in this study. Accordingly, the participants tended to be rather frail, and many were facing decisions regarding their ability to continue chemotherapy. Furthermore, patients >80 years old (i.e., "super elderly") underwent a median of 4 months of chemotherapy. We saw approximately 160 patients within this group over a 4-year period, during which we recruited 0-1 patient per month. Elderly patients often do not undergo aggressive treatment like chemotherapy and are likely to receive less burdensome treatment (irradiation if possible) and/or best supportive care (palliative care). Their treatment decisions may be biased by their families and doctors and not entirely reflect the intention of the patients themselves. Finally, future studies should evaluate the effects of social support groups on elderly patients with cancer (29).

In conclusion, we confirmed that the continuous performance of GAs was feasible in elderly (≥ 65 years old) patients with cancer when the r-GA set was administered before treatment and every 2 months thereafter. Second, we found that the BADL, MMSE-J, and VI values were correlated significantly with the OS. These indexes therefore appear to be useful screening tools to supplement PS. Finally, observed reductions in the MMSE-J and VES-13 scores over time were correlated significantly with the OS, suggesting that these scores are useful as prognostic indicators for the survival. GAs reveal a patient's general condition and provide insights into how a patient interacts with his or her surroundings. As this information cannot be obtained purely by reviewing hospital-based medical records or examination results, we believe that GAs can help clarify the best course of action when treating elderly patients with cancer, including deciding whether or not treatments such as chemotherapy are optimal or will unduly burden the patient.

The authors state that they have no Conflict of Interest (COI).

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