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## **Research Article**

# What is related to postoperative outcome of frail status in elective colorectal cancer surgery?



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## ABSTRACT

*Background:* The population affected by colorectal cancer is growing, and there is an increasing need for prevention of functional decline following treatment. We proposed that the Kihon Checklist published by the Japanese Ministry of Health, Labor, and Welfare would be an appropriate means of frailty assessment for prediction of postoperative complications in older patients with colorectal cancer. This prospective cohort study aims to identify the factors influencing postoperative frailty.

*Methods:* We prospectively enrolled consecutive patients with colorectal cancer and aged  $\geq$ 65 year (N = 500) between May 2017 and December 2018. Eligible patients were assessed with the Kihon Checklist prior to surgery and 30 days after surgery. The main measures were variables related to postoperative change in view of frail status. *Results:* According to the Kihon Checklist questionnaire, 164 patients were frail preoperatively and 172 patients were frail postoperatively, whereas 38 patients changed from "nonfrail" before surgery to postoperative "frail." Overall complications were counted in 97 patients (19.4%), and 5 patients died. Performance status  $\geq$  2, history of laparot-

omy, open surgery, complication, ostomy creation, and delirium were significantly associated with changing postoperative "frail" (P = .014, P = .023, P = .006, P < .001, P = .023, and P = .024, respectively). In multivariate analysis, independent related factors of changing postoperative "frail" were complication (odds ratio 2.69, 95% confidence interval 1.19–6.09, P = .018) and ostomy creation (odds ratio 2.32, 95% confidence interval 1.01–5.33, P = .047).

*Conclusion:* The Kihon Checklist questionnaire could identify the factors related to postoperative change of frailty status in older patients with colorectal cancer. This cohort concluded that whether postoperative complication occurred or not was closely associated with perioperative change of frailty status.

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## **INTRODUCTION**

Colorectal cancer is the second most common cause of cancer death worldwide following lung cancer [1]. The worldwide population is aging, and the incidence of cancer is rapidly growing. Older patients show biological heterogeneity regarding comorbidity, physical capacity, cognitive faculty, and mental health impairments. Frailty is considered to be a phenotype of decreased physiological reserves and impaired

\* Corresponding author at: Second Department of Surgery, School of Medicine, Wakayama Medical University, 811-1, Kimiidera, Wakayama, 641-8510, Wakayama, Japan. Tel.: + 81-73-441-0613; fax: + 81-73-446-6566. resistance to stressors [2]; it influences the morbidity and mortality in older patients with colorectal cancer [3]. Frailty assessment tools have been developed to identify subsets of older patients that may be at risk of adverse outcomes after surgery, including the Kihon Checklist (KCL).

KCL was established by the Japanese Ministry of Health, Labor, and Welfare to identify whether individuals  $\geq$  65 years old might require medical care or social support. It is composed of 25 self-reported responses to questions. KCL was validated by a score  $\geq$  8 of the total 25 questions equating to frailty defined by the Cardiovascular Health Study criteria set by Fried et al [2,4], and it is now being accepted for frailty screening worldwide [5–7]. KCL screening meets almost all aspects of geriatric assessment: physical function, social activities,

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nutrition, cognition, and psychological status, so it has been suggested to be suitable for use in geriatric research. We previously reported that preoperative frailty assessed by KCL was significantly associated with postoperative complications in older patients with colorectal cancer [8]. Many researchers have shown a preoperative subset of frail patients to be a risk factor for not only worse postoperative outcomes but also decline in functional status or quality of life [3,9–11]. To our knowledge, however, pre- and postoperative status of frailty in older patients with colorectal cancer has not been widely examined.

In this multicenter cohort, we prospectively analyzed perioperative evaluation of frailty using KCL assessment and predictors of postoperative change of frail status in older patients who underwent elective surgery for colorectal cancer.

## METHOD

**Study Design and Participants.** This multicenter cohort study was prospectively managed by the Second Department of Surgery at Wakayama Medical University Hospital (WMUH). It was conducted in accordance with the ethical principles of the Declaration of Helsinki and was approved by the ethics committees of all participating institutions (approval number 1975; WMUH). It was registered to UMIN-CTR, registration number UMIN00026689.

Included in this study were consecutive patients aged  $\geq$  65 years for whom elective colorectal cancer surgery was planned between May 2017 and December 2018. Eligible patients were recruited from WMUH and 8 affiliated tertiary hospitals [8]. Written informed consent was obtained from all participating patients prior to our enrollment.

**Frail Scoring.** We evaluated the status of frailty based on a validated scoring system, KCL, a patient-reported questionnaire (Table 1). KCL questionnaire was divided into 7 domains: instrumental (3 questions), social (4 questions), activities of daily living and physical function (5 questions), nutritional status (2 questions), oral function (3 questions), cognitive function (3 questions), and depressive mood (5 questions). As previously reported, a total score  $\geq$  8 was considered as being a state of frailty and score  $\leq$  7 was classified as prefrail or robust in conformity to the Cardiovascular Health Study criteria [4]. In this cohort, patients with

## Table 1

The Kihon Checklist

a KCL score  $\geq$  8 were regarded as "frail," whereas those scoring  $\leq$  7 as were regarded as "nonfrail."

Eligible patients answered KCL within 14 days before surgery and 1 month after surgery, a reflection of the perioperative course and events. They answered KCL questionnaire at the outpatient clinic or in hospital during the study period by themselves.

**Data Collection.** We collected the following data: age, sex, body mass index (BMI), comorbidity (history of cerebrovascular disease, chronic respiratory disease, myocardial disease, orthopedic lower limb disease, hypertension, diabetes mellitus, use of anticoagulant agent, and malignancy), American Society of Anesthesiologists score, and performance status (PS) score. We also retrieved other variables of preoperative biochemical blood examination (hemoglobin, serum concentration of albumin, surgical findings [operation time, blood loss, history of laparotomy, and laparoscopic versus open approach], and postoperative factors [complications or mortality within 30 days, delirium, and final TNM staging]). According to WHO criteria [12], *anemia* was defined as hemoglobin levels  $\leq$  13.0 g/dL in men or  $\leq$  12.0 g/dL in women, and *hypoalbuminemia* was set as serum albumin levels  $\leq$  3.5 g/dL. Finally, we investigated length of hospital stay and 30-day mortality.

We retrieved case registration and all data from the 8 participating hospitals with electronic data capturing system.

**Statistical Analysis.** Differences between postoperative "Change frail" group and "Stay nonfrail" group were analyzed using Mann–Whitney test or  $\chi^2$  test. In all variables with a *P* value < .05 in univariate analysis, multivariate logistic regression models were adopted to calculate odds ratios (ORs) with corresponding 95% confidence intervals (CIs). All analyses were performed using JMP Version 14 (SAS Institute Inc, Cary, NC).

## RESULTS

There were 521 patients identified within our study period. As our previous report [8], 500 patients were assessed, and 21 patients were excluded from our examination. Five patients (1.0%) died within 30 days after surgery: 3 of cancer progression, 1 from severe pneumonia,

No.	Questions	Answer		
1	Do you go out by bus or train by yourself?	□0. YES	□1. NO	
2	Do you go shopping to buy daily necessities by yourself?	D. YES	□1. NO	
3	Do you manage your own deposits and savings at the bank?	D. YES	□1. NO	
4	Do you sometimes visit your friends?	D. YES	□1. NO	
5	Do you turn to your family or friends for advice?	D. YES	□1. NO	
6	Do you normally climb stairs without using handrail or wall for support?	D. YES	□1. NO	
7	Do you normally stand up from a chair without any aids?	D. YES	□1. NO	
8	Do you normally walk continuously for 15 min?	D. YES	□1. NO	
9	Have you experienced a fall in the past year?	□1. YES	□0. NO	
10	Do you have a fear of falling while walking?	□1. YES	□0. NO	
11	Have you lost 2 kg or more in the past 6 months?	□1. YES	□0. NO	
12	BMI: kg/m <sup>2</sup> ; if BMI is less than 18.5, this item is scored.	□1. YES		
13	Do you have any difficulties eating tough foods compared to 6 months ago?	□1. YES	□0. NO	
14	Have you choked on your tea or soup recently?	□1. YES	□0. NO	
15	Do you often experience having a dry mouth?	□1. YES	□0. NO	
16	Do you go out at least once a week?	DO. YES	□1. NO	
17	Do you go out less frequently compared to last year?	□1. YES	□0. NO	
18	Do your family or your friends point out your memory loss?	□1. YES	□0. NO	
	eg, "You ask the same question over and over again."			
19	Do you make a call by looking up phone numbers?	D. YES	□1. NO	
20	Do you find yourself not knowing today's date?	□1. YES	□0. NO	
21	In the last 2 weeks have you felt a lack of fulfilment in your daily life?	□1. YES	□0. NO	
22	In the last 2 weeks have you felt a lack of joy when doing the things you used to enjoy?	□1. YES	□0. NO	
23	In the last 2 weeks have you felt difficulty in doing what you could do easily before?	□1. YES	□0. NO	
24	In the last 2 weeks have you felt helpless?	□1. YES	□0. NO	
25	In the last 2 weeks have you felt tired without a reason?	□1. YES	□0. NO	

and 1 from multiple organ failure during the study period. Consequently, 495 patients were subject to pre- and postoperative analyses of frail status.

In preoperative assessment, there were 164 patients (32.8%) regarded as frail, whereas there were 172 patients (34.7%) postoperatively. Of 336 preoperative "nonfrail" patients, 38 patients changed into "frail" postoperatively except for 1 mortality. The details of our study flowchart are presented in Figure 1.

Characteristics of the 500 patients who were enrolled in preoperative assessment are shown in Table 2. Median age of all patients in this study was 76 years old, ranging between 65 and 96 years. Creation of a temporary or permanent stoma was required in 100 patients (20.0%). Short-term postoperative complications were counted in 97 patients (19.4%), and the details are shown in Table 3. In examination variables, median BMI, median operation time, and median blood loss were 21.5, 220 minutes, and 25 mL, respectively. In this cohort, we set these median values as cutoff for our next analyses.

Main analysis was carried out for 335 preoperative "nonfrail" patients (KCL  $\leq$  7) to detect related factor of changing into postoperative "frail." According to univariate analysis, significant factors of changing frail postoperatively were PS  $\geq$  2 (P = .014), history of laparotomy (P = .023), open surgery (P = .006), complication (P < .001), ostomy creation (P = .023), and postoperative delirium (P = .024). In multivariate logistic regression analysis, complication (OR 2.69, 95% CI 1.19–6.09, P = .018), and ostomy creation (OR 2.32, 95% CI 1.01–5.33, P = .047) were independently related to postoperative changing frail. These results are shown in Table 4. In these 335 patients, the median KCL score of patients who suffered from complications got worse from 4.5 (preoperative assessment) to 12.8 (postoperative assessment), and that of patients who required ostomy creation worsened from 4.0 to 14.5.

Table 2 Patient characteristics

Measure	(N = 500)		
Age*	76 (65-96)		
Male/female	291/209		
BMI*	21.5 (13.4-38.2)		
Tumor location			
Colon	334 (66.8%)		
Rectum	166 (33.2%)		
Preoperative bowel obstruction			
Yes	83 (16.6%)		
No	417 (83.4%)		
Tumor stage			
fStage 0	7 (1.4%)		
fStage I	102 (20.4%)		
fStage II	168 (33.6%)		
fStage III	161 (32.2%)		
fStage IV	62(12.4%)		
Operation time*	220 (43-652)		
Intraoperative bleeding*	25 (5-1476)		
Stoma construction			
Yes	100 (20.0%)		
No	400 (80.0%)		
Preoperative living conditions			
Living with a partner	232 (46.4%)		
Living with family	163 (32.6%)		
Living alone	87 (17.4%)		
Living in a care facility	18 (3.6%)		

\* Median (range)

## DISCUSSION

Older patients who changed from being preoperative "nonfrail" to postoperative "frail" by KCL screening had significant relations to



#### Fig 1. Flowchart of the patients' status in this study.

#### Table 3

Short-term postoperative complications

Complication	Preoperative nonfrail group ( $n = 336$ )	Preoperative frail group ( $n = 164$ )	Total (N = 500)
Surgical			
Bowel obstruction disorder	9	10	19
Surgical site infection	12	6	18
Anastomotic leakage	5	7	12
Intra-abdominal abscess	6	2	8
Wound dehiscence	4	2	6
Medical			
Cardiopulmonary event	9	11	20
Urinary tract disorder	3	4	7
Cerebrovascular event	0	1	1
Other	2	4	6
Total	50	47	97

postoperative complication and ostomy creation in colorectal cancer surgery. Older patients, particularly those classified as frail, have poorer postoperative outcomes, decline of physical function, and impaired health-related quality of life (HRQL) associated with colorectal cancer [13–15]. Previous observational studies have not shown what would

Table 4

induce postoperative change of frail status in older patients with colorectal cancer. This is thus the first prospective study to examine predictable factors leading to change from "nonfrail" patient into postoperative "frail" patient during colorectal cancer surgery.

KCL was originally created to identify older individuals requiring health care and social support in the Japanese long-term insurance system. Several researchers have examined the validation of frailty screening, and it has been translated into English [16], Portuguese [5], Spanish [6], and Turkish [7]. We previously demonstrated that preoperative frailty screening using KCL could be useful for predicting postoperative complication in older patients with colorectal cancer [8].

There could be several reasons why the factors that predict the preoperative frail status differed from those of the postoperative status in older patients that underwent colorectal cancer surgery. Multidisciplinary intervention before surgical management or treatment decision-making might lead to prevention of postoperative frailty [3,17]. The implementation of enhanced recovery after surgery (ERAS) programs could bring favorable postoperative outcomes in patients with colorectal cancer. The ERAS program has been widely used in practice for older patients who are in a state of vulnerability or frailty [18,19]. The participating hospitals in this study treated the enrolled patients with standardized ERAS protocol and managed their reduction of organ dysfunction and length of postoperative

Variables		Univariate analysis			Multivariate analysis		
		Change frail ( $n = 38$ )	Stay nonfrail (n = 297)	P value	OR	(95% CI)	P value
Sex	Female	Female 16 115 .68	.687				
	Male	22	182				
BMI	21.5	16	124	.967			
	≥21.5	22	173				
Cerebrovascular disease	Yes	3	22	.914			
	No	35	264				
Chronic respiratory disease	Yes	3	33	.547			
	No	35	264				
Myocardial disease	Yes	2	39	.164			
	No	36	258				
Orthopedic disease	Yes	4	20	.393			
	No	34	277				
History of malignancy	Yes	5	30	.562			
	No	33	267				
Hypertension	Yes	23	168	.642			
<i></i>	No	15	129				
Diabetes mellitus	Yes	9	61	.653			
	No	29	236				
Anticoagulant therapy	Yes	5	57	.367			
0 19	No	33	240				
ASA	3, 4	7	59	.833			
	1, 2	31	238				
PS	2, 3, 4	2	2	.014	7.71	(0.84-70.38)	.070
	0, 1	36	295		1	()	
Anemia	Yes	8	57	.785			
	No	30	240				
Hypoalbuminemia	Yes	5	24	.295			
- J F	No	33	273				
Tumor location	Colon	25	200	.848			
	Rectum	13	97	.010			
History of laparotomy	Yes	14	61	.023	2.16	(0.99-4.73)	.054
instory of inpurotonity	No	24	236	.025	1	(0.55 1.75)	.051
Surgical approach	Open	8	22	.006	2.49	(0.94-6.62)	.067
Surgicul upprouen	Lap	30	275	.000	1	(0.51 0.02)	.007
Operation time (min)	≥220	18	155	.576	1		
operation time (min)	220	20	142	.570			
Blood loss (mL)	≥25	20	145	.292			
	~25	16	152	.232			
Complication	Yes	13	37	<sup></sup> .001	2.69	(1.19-6.09)	.018
complication	No	25	255	.001	2.09	(1.15-0.05)	.010
Ostomy creation	Yes	12	49	.023	2.32	(1.01-5.33)	.047
	No	26	248	.023 No	2.32	(1.01-3.55)	.047
Delirium (postoperative)	Yes	5	13	.024	2.40	(0.72-8.02)	.159
Demium (postoperative)	Yes No	5 33	284	.024	2.40 1	(0.72-8.02)	.159

ASA, American Society of Anesthesiologists score; Lap, laparoscopic surgery; Open, open surgery.

stay. In addition, we made a guess that 5 questions of depressive mood in KCL questionnaire had a potential for affecting change of frail status early in postoperative phase.

Ostomy creation is a serious matter in colorectal cancer surgery and causes delayed recovery and spiritual decline [20,21]. In this study, ostomy creation was significantly related to changing into postoperative "frail," which would strongly be related to the psychological aspects of KCL questionnaire. The degree of psychological problems is influenced by whether individuals have received permanent or temporary stoma, and their time and effort of stoma care which may depend on self-care ability, family, environment or social support. Perioperative stoma education as part of ERAS program has been reported to be meaningful [22].

HRQL is attracting attention as a measurement of postoperative status and functional and physical decline in geriatric research. Assessment of HRQL represents a certain concept to determine how variables within the dimension of health relate to dimensions of life that have been determined to be important to people in general (generic HRQL) or to people who have a specific disease (disease-specific HRQL) [23–25]. HRQL is a multidimensional survey comprising physical, mental, emotional, social, and cognitive aspects, which in concept resemble the physical, social, nutritional, cognitive, and psychological aspects of KCL. The current study showed that perioperative functional decline assessed by KCL was associated with postoperative complication and ostomy creation. KCL screening survey seemed to have compatibility with monitoring of disease-specific HRQL deterioration in older patients with colorectal cancer.

Despite the meaningful results, our prospective cohort survey also has some limitations to be mentioned. First, it did not consider the differences in patients' living environments (eg, living alone, living with a family, and nursing facility). Almost all elements concerned with the frailty assessment, including ostomy care, might be affected by the individual circumstance and the degree of familial or social supports, so these could be regarded as a potential characteristic bias. Second, there could be differences in rehabilitation programs, in particular implementation of prehabilitation, and enhancing courses among each participating hospital. Prehabilitation strategies, which express the multimodal process of improving the whole functional capacity of patients to enable them to confront coming stressors [26], are required for close coordination within multidisciplinary interventions. Some participants could receive inadequate opportunities for prehabilitation because of shorter periods before elective surgery or the provider's lower capacity. Third, this study protocol limited the period for response of KCL questionnaire within 14 days before and a month after surgery. There might be a possibility of answering the questionnaire insufficiently depending on complexed comorbidities or delay of complication healing. It might be better that the perioperative interval of assessing with KCL questionnaire was modified longer than that of our fixed protocol particularly in prolonged hospitalization. Finally, the current study does not consider other screening tools generally used for identifying the degree of HRQL deterioration, for example, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ) [27], Short-Form Health Survey (SF-36 or SF-12) [28], and Functional Assessment of Cancer Therapy-Colorectal (FACT-C) [29]. There are also hundreds of assessment tools to identify the frail status in geriatric research, and each of them has its own characteristic and purpose. We should pay attention to each domain of their tools and select appropriate tools in accordance with the study rationale. Additional research for determining more optimal assessment tools including KCL, EORTC-QLQ, SF, and FACT-C would be required. Using these tools, we are preparing the next observational study for clarifying the association between frail status and long-term outcome in the same setting subsequently to this cohort.

In conclusion, patient-reported KCL assessment could distinguish patients who would change frail status perioperatively, and it could extract complication that was significantly related factor to perioperative impairments of older patients with colorectal cancer. Further study of optimal intervention or assessment, not only KCL, is necessary to prevent postoperative worse outcome and prognosis in older patients with colorectal cancer.

## **Author Contribution**

Conception and design of this study: KT, KM, and HY Acquisition of data: KT, YF, SS, HK, NY, TH, HI, and YM Analysis and interpretation of data: KT Manuscript writing: KT and KM Approval of the final article: HY

## **Conflict of Interest**

The authors have no conflicts of interest to declare.

## **Funding Source**

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## **Ethics Approval**

For this prospective multicenter study, the authors received approval of Wakayama Medical University Ethics Committee following ethical guidelines for medical and health research involving human subjects.

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