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Clinical pathway after gastrectomy for gastric cancer: A case series of laparoscopic gastrectomy and early oral intake with "iEat™"

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ABSTRACT

Introduction: We investigated the validity of the clinical pathway of early oral intake using a special type of food "iEat™" for patients after laparoscopic gastric cancer surgery.

Methods: Fifty-two patients who underwent laparoscopic surgery for gastric cancer between April 2012 and October 2013 were the participants. We provided postoperative care in accordance with a clinical pathway for laparoscopic gastrectomy that begins oral intake with "iEat™ the day after surgery. We examined complications resulting from oral intake, postoperative complications, and the length of postoperative hospital stay.

Results: Of the 52 patients, 30 underwent distal gastrectomy and 22 underwent total gastrectomy. 50 patients was able to start early oral intake in accordance with our clinical pathway. No anastomotic leak complications were observed, and 9 patients (17.3%) developed complications as results of surgery. There was no complication related to early oral intake with "iEat™". Re-operation were performed in two cases. Overall mean and median postoperative hospital stays were 8.3 days and 6 days, respectively. There was a single case of hospital re-admission. The completion rate of this early oral intake clinical pathway was 86.5%.

Conclusion: Clinical pathway of recovery program combined laparoscopic suregry and early oral intake with "iEat™" could be useful for gastric cancer. This study indicates that using non-liquid food like iEat™ can be feasiblel, and water or liquid food don't have to be used in early oral feeding after laparoscopic gastrectomy.

1. Introduction

In nutritional therapy, it has recently been recommended that intestine should be used if possible. This concept is also recommended in postoperative nutritional care for patients who have undergone gastrointestinal surgery [12].

The Enhanced Recovery After Surgery (ERAS) pathway proposed in Europe also involves early postoperative oral feeding, and many institution have been carried out to promote the early recovery of patients by reducing the fasting period [34].

Reports of early oral intake after gastrectomy for gastric cancer is few and usefulness of its concept has been unclear. Many of ERAS randomized controlled trials (RCTs) are about post-colectomy.

In our hospital, we have adopted the clinical pathway of early oral intake using special type of food for patients after laparoscopic colon surgery. This food “iEat™" (EN Otsuka Pharmaceutical Co., Ltd., Hanamaki, Japan) is made for people who cannot eat normal diets mainly due to deglutition disorder and consideration is given to the form and taste.

Here, we examined the validity of the clinical pathway of recovery program after gastrectomy for gastric cancer combined laparoscopic suregry and early oral intake with “iEat™".

2. Methods

The protocol, case report form, patient consent form, and study relevance were reviewed from the perspective of ethical, scientific, and medical validity, and this prospective study approved by the ethics review board at the International University of Health and Welfare.

This prospective case series was carried out in patients following laparoscopic surgery for gastric cancer between April 2012 and October 2013, arrangement on consecutive at single institution, the Department of Surgery, International University of Health and Welfare Hospital, xxxxxx, Japan. The data were collected on electronic database for a prospective design.

Curable cStageI ~ III patients were enrolled and evaluated. This study included 73 patients with gastric cancer underwent laparoscopic surgery. Of these, 21 patients were excluded, 7 patients who had antithrombotic drugs for a history of coronary disease, 2 patients who had diabetes mellitus and 12 patients for the lack of consent with this study,

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Table 1
Clinical pathway for laparoscopic gastrectomy.

POD 1
Breakfast: water
Lunch, Dinner: entire amount of "iEat™" rice, entire amount of one type of "iEat™" side dish (selected from menu)
POD 2-3
Breakfast, Lunch and Dinner
entire amount of test meal rice, entire amount of two types of "iEat™" side dish (selected from menu)
POD 4–6: Breakfast, Lunch and Dinner: hospital food
(The "iEat™" are given from postoperative days 1–3.)

POD: postoperative day.

Table 2
Patient characteristics.

Patient characteristics	
Mean age (years)	64.8 ± 11.1 (40–91)
Male/Female	31/21
Height (cm)	159 ± 8.46 (136–173)
Weight (kg)	59.4 ± 11.2 (43.0–92.8)
BMI	23.4 ± 3.35 (17.2–35.6)
Surgical characteristics	
pStage IA/IB/IIA/IIB/IIIA/IIIB/IV	37/4/4/5/1/1/0
Extent of gastrectomy distal/total	30/20
Dissection D0/D1/D1 + /D2	0/2/29/21
Mean operative time (min)	338 ± 55.7 (240–460)
Mean intraoperative blood loss (ml)	110 ± 142 (10–700)

leaving the remaining 52 patients with no comorbidities for this study (Table 2).

The following deta was collected: age, sex, height, weight, body mass index (BMI), clinical and pathological stage, extent of gastrectomy and lymph node dissection, operative time, intraoperative blood loss, oral and nutrient intake, postoperative hospital stay, oral intake rate, complications, re-admission rate, postoperative hospitalization and clinical pathway variance.

As for pre-intervention taken prior to surgery, all patients were permitted to have meals until the evening before surgery and water was permitted until bedtime the night before surgery.

Operative intervention is as follows. D1 to D1+ resection was performed for early gastric cancer and D2 resection was performed for advanced gastric cancer according to the criteria of gastric cancer treatment guidelines of JGCA [67]. According to the location and extension of the cancer, distal gastrectomy or total gastrectomy were selected. Operator of this study was a single well-experienced surgeon who is one of the co-author (H.O.).

Post operative intervention of our clinical pathway is as follows. As for oral intake, a special type of food, iEat™ was used on postoperative day 1 [89]. This iEat™ is a special food for people who cannot eat normal diets mainly due to deglutition disorder. It has the same appearance and taste as a normal diet but is soft enough to be mashed by the tongue. iEat™ is manufactured with enzymatic softening technology. The nutritional value (protein, carbohydrates, and fat) is nearly the same as that of a normal diet. Most of this products contain meat or fish as a source of protein.

Patients switched to hospital food on postoperative day 4, and transitioned to more solid meals (rice porridge made with a rice-to-water ratio of 1:10 and 1:7. On day 5, patients consumed rice porridge made with a rice-to-water ratio of 1:5.

Peri -operative intervention is as follows. In accordance with the principles of ERAS, nutritional and pharmaceutical rehabilitation guidance was provided preoperatively by the co-medical division. Epidural anesthesia was typically used for three days, and early ambulation was started from postoperative day 1. Fluid resuscitation was provided until postoperative day 3.

This above-mentioned clinical pathway was implemented regardless of the patient's age or the presence of comorbidities., Discharge was permitted on day 5–7 (Table 1).

As post discharge intervention, follow-up was conducted by the ward nurse via telephone. In this follow-up, the patients were asked whether they have any trouble (nausea, vomit, abdominal bloating, defecation, decrease of oral intake) after hospital discharge with telephone call by the next outpatient visit. Blood and radiographic exam were performed at the first visit of outpatient clinic if there were any problems.

Complications related with early oral intake, postoperative surgical complications, clinical pathway variance and length of postoperative hospital stay were examined with Common Terminology Criteria for Adverse Events (CTCAE) v4.0. As for quality control of this study. Clinical pathway variance was analyzed and classified into the following four categories: Grade 1, variance that does not affect discharge; Grade 2, variance that affects discharge; Grade 3, variance that requires deviation from the clinical pathway; and Grade 4, variance that results in death.

The results of our work has been reported in line with the PROCESS criteria (Agha RA, Fowler AJ, Rammohan S, Barai I, Orgill DP and the PROCESS Group. The PROCESS Statement: Preferred Reporting of Case Series in Surgery. International Journal of Surgery (2016); 36(Pt A):319–323.) [5].

3. Results

As mentioned in Method, 52 patients with no comorbidities finished this study. Patient characteristics are shown in Table 2. 30 patients underwent distal gastrectomy and 22 underwent total gastrectomy. The patients were followed-up 12-months (median), and eventually the dates of the data collection was registrated on December 2013. There was no loss to follow-up.

Fifty patients (96.1%) started very early oral intake. The start was postponed in 2 patients with postoperative intestinal paralysis. Of the 50 patients who started early oral intake in accordance with the clinical pathway as Table 1 shows. Oral intake rates are shown in Table 3 and nutrient intake rates are shown in Table 4.

Postoperative complication is shown in Table 5. No anastomotic leakage was observed in any cases, but 9 patients (17.3%) developed complications as a result of surgery. Re-operation were performed in two cases.

One re-operation case was port site hernia, who was an 87-year-old woman. She underwent distal gastrectomy and started eating from postoperative day 1. On postoperative day 3, she experienced sudden abdominal pain and a port site hernia was found in the left upper site, developing into prolapse of the small intestine. She was discharged from the hospital 13 days after the reoperation.

Another re-operation case was bowel obstruction due to kinking of the jejuno-jejunostomy, who was a 53-year-old woman. She underwent total gastrectomy and started eating from postoperative day 1. On postoperative day 3, she had nausea and could not eat food. She was

Table 3
Oral intake rate (%).

		LADG	LATG	Total
1POD	staple food	25.8 ± 23.3	18.0 ± 20.3	22.5 ± 22.2
	side dish	36.6 ± 24.9	24.7 ± 19.7	31.6 ± 23.4
	total	29.3 ± 22.8	20.2 ± 19.7	25.5 ± 21.8
2POD	staple food	32.2 ± 19.3	23.5 ± 18.5	28.5 ± 19.3
	side dish	33.2 ± 19.0	29.1 ± 17.8	31.4 ± 18.4
	total	32.7 ± 17.8	26.4 ± 17.5	30.0 ± 17.8
3POD	staple food	34.9 ± 21.1	22.6 ± 19.7	29.7 ± 21.2
	side dish	36.8 ± 20.9	31.6 ± 26.4	34.6 ± 23.2
	total	35.8 ± 19.1	27.2 ± 22.1	32.2 ± 20.7

Table 4
Nutrient intake.

		LADG	LATG	Total	Parenteral
1POD	energy (kcal)	195 ± 163	130 ± 127	168 ± 152	344
	protein (g)	9.5 ± 7.4	6.1 ± 5.7	8 ± 7	0
	fats (g)	4.5 ± 5.0	3.3 ± 3.7	4 ± 4.5	0
	carbohydrates (g)	26.9 ± 23	17.8 ± 18.4	23.1 ± 21.5	0
	Na (mg)	350 ± 255	216 ± 200	293 ± 240	1800
	energy/kg (g/kg)	3.38 ± 2.86	2.15 ± 2.01	2.86 ± 2.6	5.98 ± 1.05
	protein/kg (mg/kg)	162 ± 126	110 ± 89	137 ± 116	0
2POD	energy (kcal)	450 ± 249	320 ± 223	395 ± 247	238
	protein (g)	22.6 ± 12.7	17.6 ± 11.3	20.5 ± 12.4	0
	fats (g)	11.1 ± 8.2	7.8 ± 6	9.7 ± 7.4	0
	carbohydrates (g)	60.8 ± 36.6	42.5 ± 31.9	53.1 ± 35.5	0
	Na (mg)	888 ± 527	683 ± 442	801 ± 499	1350
	energy/kg (g/kg)	7.68 ± 4.11	5.32 ± 3.63	6.68 ± 4.09	4.14 ± 0.72
	protein/kg (mg/kg)	382 ± 204	274 ± 178	344 ± 202	0
3POD	energy (kcal)	463 ± 268	332 ± 273	408 ± 275	172
	protein (g)	24.9 ± 14.9	19.6 ± 16.9	22.7 ± 15.8	0
	fats (g)	11.7 ± 10.2	8.8 ± 7.6	10.5 ± 9.2	0
	carbohydrates (g)	60.1 ± 35.8	41 ± 34.1	52 ± 36.1	0
	Na (mg)	924 ± 541	768 ± 657	858 ± 592	900
	energy/kg (g/kg)	8.09 ± 4.72	5.62 ± 4.83	7.04 ± 4.92	2.99 ± 0.52
	protein/kg (mg/kg)	431 ± 261	287 ± 302	391 ± 288	0

Table 5
Postoperative complications.

Postoperative complications	
Atelectasis	2 (3.8%) (Grade 2: 2)
Arthragia from gout attack	1 (1.9%) (Grade 1: 1)
Postoperative intestinal paralysis	2 (3.8%) (Grade 2: 2)
Pancreatic leakage	(3.8%) (Grade 1: 1 Grade2: 1)
Port site hernia	1 (1.9%) (Grade 3 b: 1)
Bowel obstruction	1 (1.9%) (Grade 3 b: 1)
	Total 9 (17.3%)
Re-operation	2 (3.8%)
Re-admission	1 (1.9%)

(CTCAE v4.0 Grade classification).

diagnosed with intestinal obstruction and underwent reoperation on postoperative day 20. She was discharged from the hospital 14 days after the reoperation.

There was a single case of hospital re-admission with the diagnosis of pancreatitis. This case was detected with the follow-up call by the ward nurse. He, who was 70-year-old man, underwent total gastrectomy, started eating on postoperative day 1, and was discharged on postoperative day 9. Eighteen days after surgery, he had an abdominal pain and was diagnosed with pancreatitis. He was discharged from the hospital 11 days after readmission without surgical intervention.

Postoperarive hospitalization is shown in Table 6. The overall mean and median postoperative hospital stays were 8.3 days and 6 days, respectively. In patients who underwent distal gastrectomy, the mean and median postoperative hospital stays were 7.0 days and 6 days, respectively. In patients who underwent total gastrectomy, the mean and median postoperative hospital stays were 9.8 days and 7 days, respectively.

In a ward nurse telephone call, all patients except one case for re-admission had no complaint and touble after hospital discharge At first outpatient clinic visits after discharge, there were no complaint and touble in these patients. Therefore, blood and radiographic exam were not performed.

Table 6
Postoperative hospitalization.

	Distal gastrectomy (n = 30)	Total gastrectomy (n = 22)	Total (n = 52)
Mean postoperative hospital stay (days)	7.0 ± 3.0	9.8 ± 6.9	8.3 ± 5.1
Median hospital stay (days)	6	7	6

Clinical pathway variance is shown in Table 7. Five patients were noto able to continue oral intake because of fever due to atelectasis (n = 1), pancreatic leakage (n = 2), port site hernia (n = 1), or bowel obstruction (n = 1).

The clinical pathway completion rate for very early oral intake (no variance, Grade1 and Grade2) was 86.5%. There were 7 patients with Grade 3 variance deviated from the clinical pathway. No patients

Table 7
Clinical pathway variance analysis.

Variance analysis	Complication (CTCAE v4.0 Grade)		postoperative hospital stay (days)
No variance		26 (50%)	5.7 ± 0.8 (5–7)
Variance Grade 1		7 (13.5%)	5.7 ± 0.5 (5–6)
	Bloating (Grade1)	4	
	Nausea (Grade1)	3	
Variance Grade 2		12 (23.1%)	10.2 ± 2.7 (8–17)
	Bloating (Grade 1–2)	3	
	Nausea (Grade 1–2)	3	
	Vomiting (Grade1)	2	
	Atelectasis (Grade 2)	1	
	Gout (Grade1)	1	
	Personal circumstances	2	
Variance Grade 3		7 (13.5%)	17.3 ± 8.3 (10–34)
	Postoperative intestinal paralysis (Grade 2)	2	
	Pancreatic leakage (Grade 1–2)	2	
	Atelectasis (Grade 2)	1	
	Port site hernia (Grade 3 b: 1)	1	
	Bowel obstruction (Grade 3 b: 1)	1	
Variance Grade 4		0	

Classification of variance analysis: Grade 1, no effect on discharge; Grade 2, affects discharge; Grade 3, deviation in pathway; Grade 4, death.

showed Grade 4 variance.

4. Discussion

Traditionally in Japan, early oral intake after gastrointestinal surgery was considered difficult and dangerous due to intestinal paralysis and anastomotic leakage. For this reason, there were postoperative managements to abstain from eating and drinking for a certain period of time following surgery in many hospitals.

Furthermore, due to the capacity of the remnant stomach, after upper gastrointestinal surgery in Japan, oral intake was started by drinking water after the recovery of intestinal function with the onset of flatulence, followed by taking of small amounts of liquid food to reduce the risk for tanastomotic leakage. Subsequently, patients had rice porridge in progressively increasing amounts and with increasing firmness (rice-to-water ratio of 1:20 → 1:10 → 1:7 → 1:5) [101117].

On the other hand, it is reported that bowel movement recovers prior to the postoperative onset of flatulence (recovery within 4–8 h in the small intestine, 24 h in the stomach, and 3–5 days in the colon) [12]. In recent years it has been considered that nutritional care using the digestive tract is desirable to provide if possible [213]. The usefulness of early enteral or oral nutrition has also been reported [14–18].

Liu et al. reported a meta-analysis of RCTs of early oral feeding after gastric cancer surgery.

Suehiro et al. showed that the postoperative onset of flatulence and hospital stay were significantly earlier and shorter, respectively, in an early oral feeding group that began a liquid diet on postoperative day 2 compared to patients in a conventional perioperative care group who began a liquid diet after confirming the onset of flatulence; no differences were seen between the two groups in terms of the incidence of postoperative complications [19]. In addition, Yamada et al. reported that, compared to patients who received conventional perioperative care, patients who received early oral feeding showed a significantly earlier onset of flatulence and defecation after surgery for gastric cancer and a significantly greater rate of weight gain during the first week after surgery [20].

Based on these reports, the timing of starting postoperative nutritional care have been changing drastically over the past 10 years [2122]. Traditionally, many institutions started oral feeding around 5–7 days post-gastrectomy. In recent years, however, an increasing number of institutions have started oral intake within 3–4 postoperative days. In addition, since many surgical procedures including laparoscopy have become less invasive, the postoperative recovery of gastrointestinal function can be achieved rapidly [2122].

Unique point of our study is that we started oral feeding with iEat™ from postoperative day 1. This iEat™ is a special type of food formulated by an enzymatic homogeneous permeation method that was developed for patients who are recovering the eating function [8]. iEat™ looks like normal food, but provides a low-residue meal that is disintegrative and easily digestible. Shimizu et al. reported that iEat™ can be used safely as a postoperative meal after gastric cancer surgery, and that a high degree of overall satisfaction was reported in the patient survey, although some individual differences were seen [9].

Our difference from other study is that “foods” was used with oral intake on day 1 after gastric surgery. There is the result of meta-analysis showed early oral feeding after gastric cancer surgery seems feasible and safe [23]. However, this analysis include studies that used water or liquid food for early feeding, sometimes using feeding tube.

Oral feeding in our study began on postoperative day 1.2 (mean) or day 1 (median). This indicates that using non-liquid food like iEat™ can be feasiblel, and water or liquid food don't have to be used in early oral feeding after laparoscopic gastrectomy.

Completion rate of 86.5% was achieved. The overall mean and median postoperative hospital stays were 8.3 days and 6 days, respectively. In patients who underwent distal gastrectomy, the mean and median postoperative hospital stays were 7.0 days and 6 days, respectively. These results were comparable to those of a pilot study on early oral feeding after distal gastrectomy by Hoon et al. (mean postoperative hospital stay, 8.0 days), supporting the efficacy of our clinical pathway [24].

Although we were concerned that anastomotic leakage would develop due to early oral feeding, there were no leakage in this study. Moreover, because no patient had abdominal pain due to early oral intake, we did not need to the use of a pain score. Of the 9 patients with complications caused by surgery, patients with pancreatic leakage were classified as CTCAE v4.0 Grades 1 and 2, and improved by administration of the antibiotics. There were two patients with CTCAE v4.0 Grades 3 b performed re-operation. The remaining 5 patients were classified as CTCAE v4.0 Grades 1–2, and the conditions improved without surgical intervention.

Our results were comparable to those from prospective studies on early oral feeding after gastrectomy by Suehiro et al. [19] and Shinohara et al. [25], indicating that our early oral feeding can be performed safely.

Clinical pathway variance analysis in Table 7 showed that postoperative complications in Table 5 were observed in more than Grade 2 clinical pathway variance patients. All complications in Grade 3 clinical pathway variance developed as a result of the surgical procedure. Not early oral feeding. These complications were not considered to be caused by early oral intake. These results indicate that our clinical pathway of early oral feeding has the possibility to apply for patients after laparoscopic gastrectomy.

However, impact of Grade 1–2 bloating, nausea and vomiting is unclear. These were seen both in Grade 1 and 2 of the clinical pathway variance. Attention should be paid to the postoperative conditions such as characteristics, extent of gastrectomy, intestinal paralysis and pancreatic leakage. Studies including a control group are required.

The limitations of this study are the sample size and the single institution. Gastric cancer treatment guidelines of JGCA recommends laparoscopic gastrectomy for cStageI. This is the reason why majority of our patients were pStage I. Furthermore, there was no control group in this study. A larger sample size including advanced cancer cases could provide further safety assessment. Another study limitation is that the cost of iEat™ is not covered by Japanese health insurance. In this study, we bought iEat™ with a part of our department operating cost and provided to the enrolled patients. This limitation could be overcome by understanding and corporation of hospitals and patients.

5. Conclusion

Although larger sample size including control group are required, our clinical pathway of recovery program combined laparoscopic suregry and early oral intake with “iEat™" could be useful for gastric cancer. This study indicates that using non-liquid food like iEat™ can be feasiblel, and water or liquid food don't have to be used in early oral feeding after laparoscopic gastrectomy.

Ethical approval

13-B-35.

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Author contributions

Yuichi Nakaseko collected the data and drafted the manuscript. Masaki Kitajima and Yutaka Suzuki designed this study. Hironori Ohdaira and Masashi Yoshida participated in its design and helped to draft the manuscript.

Conflicts of interest

No authors have any conflicts of interest.

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Guarantor

The Guarantor is the one or more people who accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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