

Impact of Polymeric Formula on Outcomes in Robotic Pancreatectomy: A Randomized Controlled Trial

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Abstract

Background/Aim: Evidence regarding the benefits of nutritional therapy after robotic pancreatectomy is limited. This randomized controlled trial aimed to investigate the effects of a polymeric formula (PF) on preventing body weight loss (BWL) following robotic pancreatectomy.

Patients and Methods: This single-center, open-label, randomized trial was conducted to assign 46 patients undergoing robotic pancreatectomy in a 1:1 ratio to either the PF (ISOCAL Clear) or control group. The primary endpoint was the percentage of BWL on postoperative days 14 and 28. The secondary endpoints were postoperative outcomes.

Results: Of the 52 eligible patients between December 2023 and November 2024, 46 were analyzed using intention-to-treat principles: 23 in the ISOCAL group and 23 in the control group. The %BWL was significantly lower in the ISOCAL group compared with that in the control group on postoperative days 14 ($4.8 \pm 3.5\%$ vs. $6.6 \pm 3.2\%$, $p=0.02$) and 28 ($6.4 \pm 3.0\%$ vs. $8.4 \pm 3.5\%$, $p=0.047$). Postoperative outcomes, including major complications ($p=0.55$) and hospital stay ($p=0.83$), did not differ significantly between the groups.

Conclusion: This study demonstrates the safety and feasibility of administering PF to patients undergoing robotic pancreatectomy. The results showed the beneficial effects of PF on mitigating BWL without compromising short-term outcomes.

Keywords: Robotic pancreatectomy, nutrition, polymeric formula, outcomes.

Introduction

Hepatobiliary-pancreatic surgery is highly invasive, particularly pancreatic resection, which is associated with

a high incidence of postoperative complications (1). To improve perioperative clinical outcomes, the concept of enhanced recovery after surgery (ERAS), which aims to facilitate early postoperative recovery, has gained



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Received September 13, 2025 | Revised October 7, 2025 | Accepted October 10, 2025



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popularity in the field of gastrointestinal surgery (2, 3). However, the safety and effectiveness of ERAS during minimally invasive pancreatectomy have not been sufficiently investigated (4). Although our group has suggested the feasibility of the ERAS protocol in patients undergoing robotic pancreatectomy (5), few studies have examined the efficacy of nutritional therapy as an integral component of ERAS during the perioperative period. Postoperative body weight loss (BWL) is one of the simplest indicators of recovery after pancreatectomy. However, the effect of nutritional therapy in preventing postoperative BWL in patients undergoing robotic pancreatectomy has rarely been studied.

In the present study, we conducted a randomized controlled trial to evaluate the effects of a polymeric formula (PF) on preventing BWL in patients following robotic pancreatectomy.

Patients and Methods

Trial design. This was a single-center, prospective, open-label, randomized controlled trial with two parallel intervention groups: after robotic pancreatectomy, one received PF (ISOCAL group) and the other did not (control group). The study was approved by the Ethics Committee of Okayama University Hospital (approval no. CRB23-004) and conducted in accordance with the principles of the Declaration of Helsinki. The trial was registered with the Japan Registry of Clinical Trials (registration number: jRCTs061230068).

Participants. All patients aged 20 years or older undergoing robotic pancreatectomy between December 2023 and November 2024 at Okayama University Hospital were eligible for enrollment. Exclusion criteria included: inability to provide consent; severe respiratory dysfunction (arterial PaO₂ <70 mmHg); severe cardiac dysfunction (New York Heart Association class ≥3); severe hepatic dysfunction (Child–Pugh class C); severe renal dysfunction requiring hemodialysis; acute bacterial infection; severe psychiatric disorder; uncontrolled

diabetes; milk allergy; palliative or emergency surgery; and unavailability of an investigator. Written informed consent was obtained from all patients prior to enrollment and randomization.

Intervention. The experimental group received two bottles of ISOCAL Clear (200 kcal/200 ml per bottle: 10 g protein, 0 g lipids, and 40 g carbohydrates per bottle; Nestlé, Kobe, Japan) daily from the start of oral intake until discharge. ISOCAL Clear was not administered to the control group. Both groups received comparable perioperative management based on the ERAS protocol, including scheduled mobilization supervised by the rehabilitation team (4, 5). Oral intake was initiated on postoperative days (POD) 2 and 3.

Endpoints. The primary endpoint was the percentage of BWL on POD14 and POD28. A subgroup analysis stratified by type of procedure was also performed. Secondary endpoints included postoperative outcomes, such as changes in body composition and complications.

The following clinical data were extracted from the hospital database: age, sex, body weight, body mass index, body composition [soft lean mass (SLM) and body fat mass (BFM)], American Society of Anesthesiologists physical status, comorbidities (diabetes and hypertension), primary diagnosis (pancreatic cancer, biliary tract cancer, intraductal papillary mucinous neoplasm, benign tumor, or other), type of procedure [robotic pancreatoduodenectomy (RPD) or robotic distal pancreatectomy (RDP)], operative time, estimated blood loss, mortality, defined as Clavien–Dindo grade ≥3, postoperative pancreatic fistula (POPF) (6), postoperative hospital stay, readmission, and textbook outcome (defined as absence of: mortality, major complications, POPE, and re-admission) (7). Body composition was measured using an InBody S10 instrument (InBody Japan, Tokyo, Japan) before and 28 days after surgery. The percentages of SLM loss and BFM loss on POD28 were calculated.

Sample size. The sample size was calculated based on the primary endpoint, %BWL on POD14. Based on our

unpublished data, %BWL was assumed to be 1.5%, with a standard deviation of 3.0% in the ISOCAL group. Assuming a power of 80%, a two-sided α of 0.05, and a dropout rate of 10%, 46 patients were required to detect a statistically significant difference between the two groups.

Randomization. Randomization was conducted using stratified block randomization. Participants were stratified into eight groups based on three factors: Surgical procedure (RPD or RDP), diagnosis (benign or malignant disease), and diabetes status (present or absent). Block sizes of two or four were used. A randomization list was generated using Stata version 18 (StataCorp LLC, College Station, TX, USA) with a fixed random seed. An independent allocation manager who was not involved in the study design, participant enrollment, or outcome assessment managed the randomization process. Upon notification of participant registration by the study physician, the allocation manager referred to the list and informed the physician of the assigned group. Randomization was performed after registration was completed. The randomization list was maintained as a Microsoft Excel file (Microsoft Cooperation, Redmond, WA, USA) and stored on a password-protected computer accessible only to the allocation manager. To prevent prediction of the allocation sequence, no other study personnel had access to the list or information on block sizes until the end of the study.

Monitoring. Central monitoring was performed in the initial five cases using a central monitor appointed by the principal investigator. On-site monitoring was also conducted.

Statistical methods. Intention-to-treat analyses were performed to assess the primary endpoints. Values are presented as proportions for categorical data and as medians with interquartile range (IQR) or means \pm standard deviation for continuous variables. Differences between the groups were assessed using the chi-squared test for categorical variables and Student *t*-test or the Mann-Whitney *U*-test for continuous variables. Statistical significance was set at $p < 0.05$. All statistical analyses were

performed using JMP software version 11 (SAS Institute, Cary, NC, USA).

Results

Participant flow. Fifty-two patients were assessed for eligibility, and 46 were randomized between December 2023 and November 2024 (Figure 1). Of the 46 patients, two were excluded: one for conversion to open surgery and one for exploratory laparotomy due to peritoneal dissemination. Finally, data analysis was performed for 22 patients each in the ISOCAL and control groups.

Baseline data. The characteristics of the 44 patients are summarized in Table I. There were 23 men and 21 women, with a median age of 72 years (IQR=63-76 years). The most common primary diseases were pancreatic cancer ($n=15$) and intraductal papillary mucinous neoplasm ($n=12$). This cohort included 25 and 19 patients who underwent RPD and RDP, respectively. The median operative time was 405 min (IQR=371-437 min) for RPD and 178 min (IQR=158-253 min) for RDP. The overall incidence rates of major complications and POPF were 6.8% and 6.8%, respectively. Textbook outcomes were achieved in 84.0% of patients (Table II).

Outcomes. The patient characteristics and outcomes of the ISOCAL and control groups are shown in Table I. Demographic and operative factors were similar for the two groups.

Regarding the primary endpoint, the %BWL in the ISOCAL group was significantly improved compared to the control group on POD14 (ISOCAL vs. control: $4.8 \pm 3.5\%$ vs. $6.6 \pm 3.2\%$, $p=0.02$) (Figure 2A) and POD28 ($6.4 \pm 3.0\%$ vs. $8.4 \pm 3.5\%$, $p=0.047$) (Figure 2B). The %BWL on POD14 stratified by procedure showed significantly less BWL in those who underwent RDP and received ISOCAL Clear ($p=0.03$) but no significant difference in those who underwent RPD ($p=0.21$) (Figure 2C). No significant differences were found in the %BWL on POD28 by RPD ($p=0.19$) or RDP ($p=0.11$) (Figure 2D).

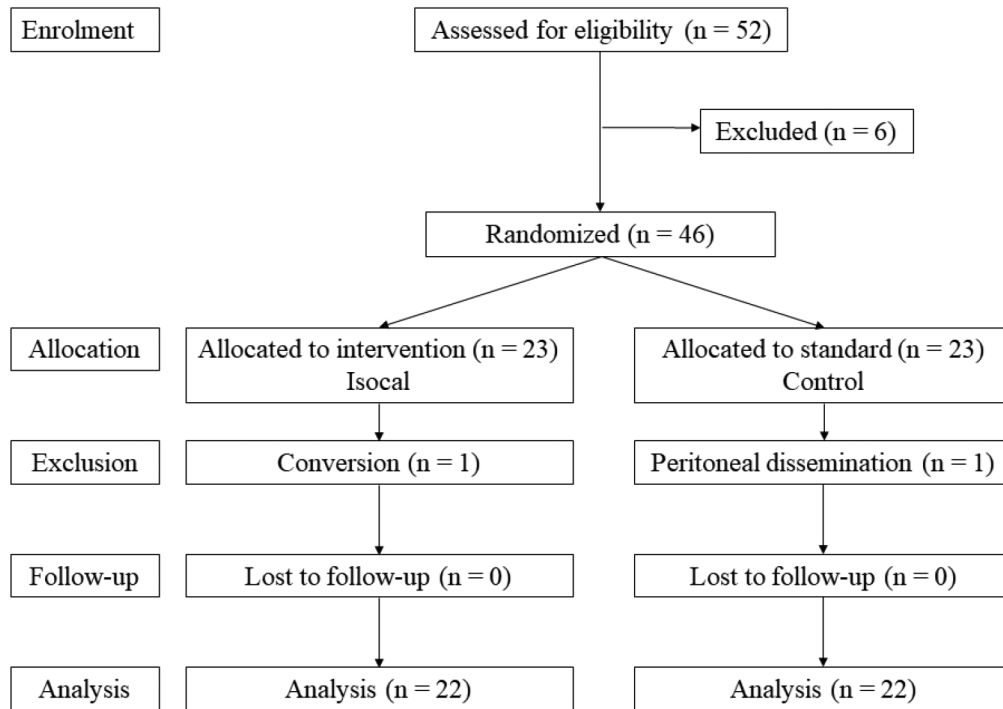


Figure 1. CONSORT flow diagram for this trial.

Figure 3 shows the changes in body composition. The %SLML ($p=0.24$) and %BFML ($p=0.12$) values did not differ significantly between the groups. The ISOCAL group received a mean of 14.5 (standard deviation=6.6) bottles of ISOCAL Clear postoperatively. The ISOCAL group had equivalent incidences of postoperative complications, including major complications ($p=0.55$) and POPF ($p=0.55$), to the control group (Table II). Moreover, no significant differences were found in postoperative hospital stay ($p=0.83$) or textbook outcomes ($p=0.21$) between the two groups.

Discussion

To our knowledge, this is the first randomized controlled trial to investigate the effect of PF on BWL after robotic pancreatectomy. We found that PF had a positive effect in preventing BWL after robotic pancreatectomy. Because of the limited evidence on nutritional therapy within the ERAS concept, the results of this study contribute to

expanding the evidence base for ERAS in the field of minimally invasive pancreatectomy.

Several studies have evaluated the effects of PF in critically ill patients and in patients with inflammatory bowel disease (8, 9). However, studies on the efficacy of PF in gastrointestinal surgery are limited (10). Although the benefits of nutritional therapy in open pancreatectomy have been reported (11), few studies have examined its significance in minimally invasive pancreatectomy. Therefore, we conducted this study to investigate the effects of PF on robotic pancreatectomy outcomes.

An estimated sample size was used in this randomized controlled trial. Moreover, both groups were well-balanced using stratified block randomization. As %BWL is a commonly used parameter for evaluating nutritional status after surgery (12), we selected it as the primary outcome in this study.

A previous study reported that the median %BWL values after pancreatectomy at 1, 3, and 12 months were

Table I. Patient characteristics and operative outcomes of study groups.

Variable		Total (n=44)	ISOCAL (n=22)	Control (n=22)	p-Value
Preoperative factors					
Age, years	Median (range)	72 (63-76)	73 (64.5-76.8)	71 (54.5-76.3)	0.43
Sex, n (%)	Male	23 (52.3)	11 (50.0)	12 (54.5)	0.76
	Female	21 (47.7)	11 (50.0)	10 (45.5)	
BMI, kg/m ²	Median (range)	22.0 (20.5-24.5)	22.7 (20.5-23.9)	21.9 (20.2-25.0)	0.83
ASA	1	8 (18.2)	3 (13.6)	5 (22.7)	0.17
	2	30 (68.2)	14 (63.6)	16 (72.7)	
	3	6 (13.6)	5 (22.7)	1 (4.5)	
Comorbidity, n (%)	Diabetes	13 (29.5)	8 (36.4)	5 (22.7)	0.32
	Hypertension	16 (36.4)	7 (31.8)	9 (40.9)	0.53
Primary disease, n (%)	PDAC	15 (34.1)	7 (31.8)	8 (36.4)	0.88
	Biliary tract cancer	6 (13.6)	4 (18.2)	2 (9.1)	
	IPMN	12 (27.3)	5 (22.7)	7 (31.8)	
	Benign tumor	9 (20.5)	5 (22.7)	4 (18.2)	
	Other	2 (4.5)	1 (4.6)	1 (4.6)	
Operative factors					
Type of procedure, n (%)	RPD	25 (56.8)	13 (59.1)	12 (54.6)	0.76
	RDP	19 (43.2)	9 (40.9)	10 (45.4)	
Median operative time (range), min	RPD	405 (371-437)	405 (371-435)	408 (360-439)	0.96
	RDP	178 (158-253)	180 (149-256)	176 (165-226)	
Median estimated blood loss (range), mL	RPD	35 (15-140)	35 (5-215)	40 (30-58)	0.87
	RDP	35 (0-50)	50 (2.5-63)	0 (0-93)	

BMI: Body mass index; ASA: American Society of Anesthesiologists; PDAC: pancreatic ductal adenocarcinoma; IPMN: intraductal papillary mucinous neoplasm; RPD: robotic pancreatoduodenectomy; RDP: robotic distal pancreatectomy.

Table II. Postoperative outcomes.

Variable		Total (n=44)	ISOCAL (n=22)	Standard (n=22)	p-Value
First liquid intake, days	Median (range)	3 (2-3)	3 (2-3)	3 (2-3)	0.95
First solid intake, days	Median (range)	4 (3-4.8)	4 (3-4.3)	4 (3-5)	0.87
ISOCAL bottles, n	Mean±SD	-	14.5±6.6	0	-
Mortality, n (%)	Yes	0 (0)	0 (0)	0 (0)	-
Major complications, n (%)	Grade ≥3	3 (6.8)	2 (9.1)	1 (4.6)	0.55
	POPF, n (%)	3 (6.8)	2 (9.1)	1 (4.6)	
Postoperative hospital stay, days	Median (range)	10 (9-13.8)	10 (8.8-13.3)	10 (9-14)	0.83
Re-admission, n (%)	Yes	5 (11.4)	4 (18.2)	1 (4.6)	0.14
Textbook outcome, n (%)	Yes	37 (84.0)	17 (77.3)	20 (90.9)	0.21

POPF: Postoperative pancreatic fistula; SD: Standard deviation.

6.2%, 7.2%, and 6.6%, respectively (13). In our study, patients undergoing robotic pancreatectomy had a mean %BWL of 5.6±3.5% on POD14 and 7.4±3.4% on POD28. Postoperative fasting and hypercatabolism associated with surgical stress may cause BWL following robotic pancreatectomy (12). Interestingly, we found a positive impact of PF in preventing BWL after robotic pancreatectomy without compromising outcomes, and

the findings represent acceptable results compared to international benchmarks (14, 15).

As ISOCAL Clear contains adequate energy and protein and is easy to drink because of its flavor, it was used in this study. Although the ISOCAL group received a short-term intake of ISOCAL Clear, administration of two bottles daily for approximately 7 days contributed to improving postoperative BWL after robotic pancreatectomy. However,

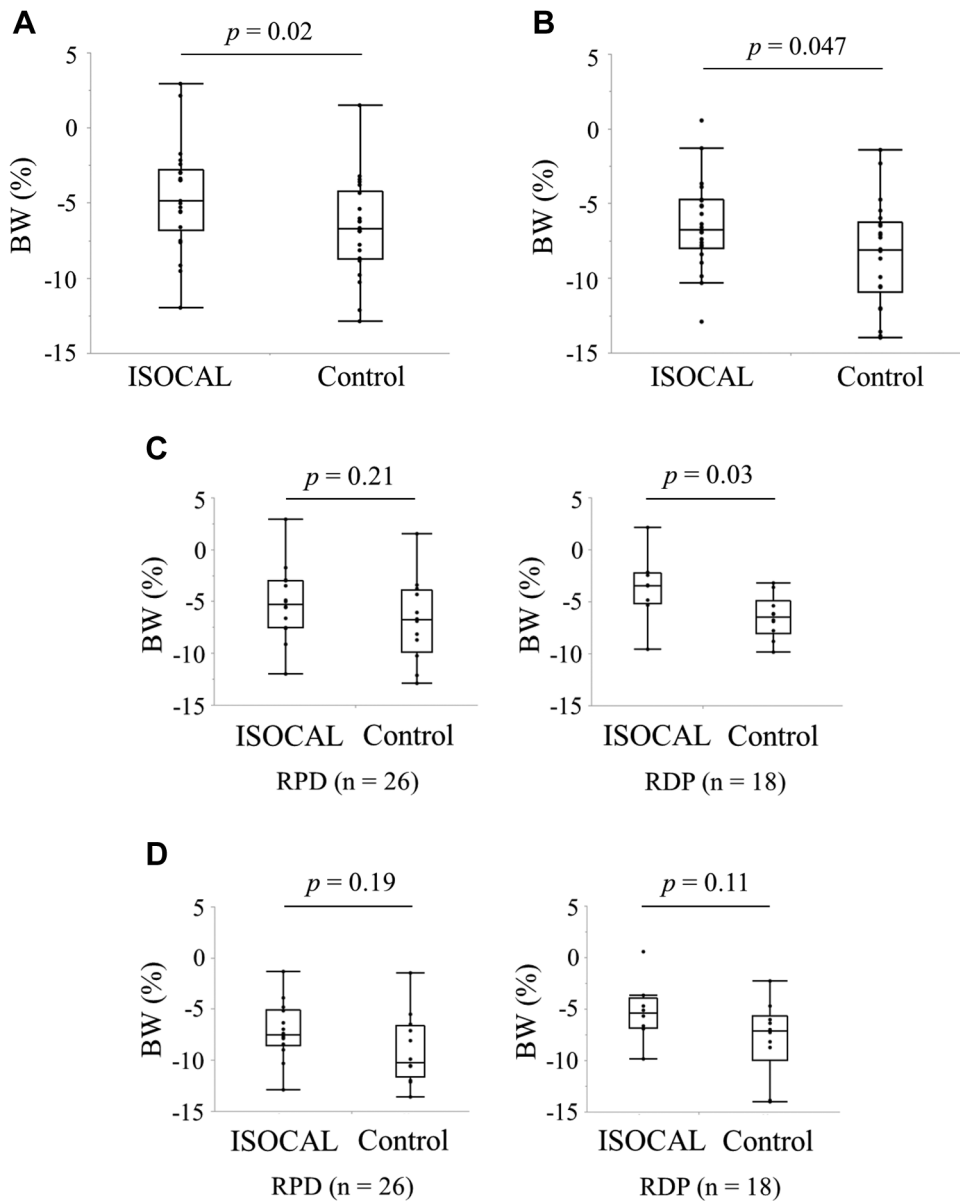


Figure 2. Comparison of change in body weight (BW) between ISOCAL and control groups on postoperative days 14 (A) and 28 (B). BW change stratified by procedure on postoperative days 14 (C) and 28 (D). The line inside boxes indicates the median value, the box indicates the interquartile range and whiskers indicate the range.

we observed no improvement in body composition (%SLML and %BFML). The clinical benefits of nutritional therapy and exercise have been suggested for patients undergoing pancreatic surgery (16-18); however, all patients in this study were managed with scheduled perioperative mobilization. Therefore, nutritional

intervention alone was not sufficient to improve postoperative body composition.

Study limitations. Although this was a randomized controlled trial, the sample size was small. Further clinical studies with larger sample sizes are warranted. Although we calculated

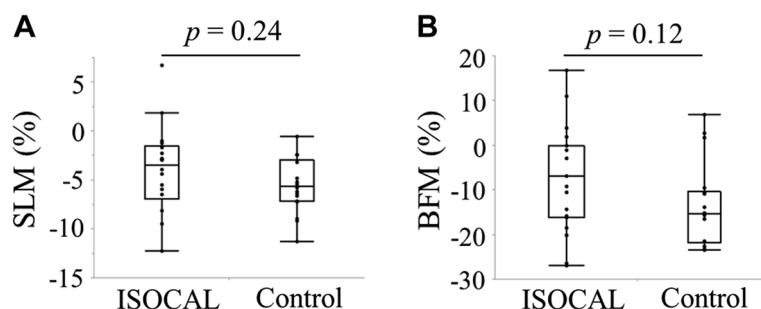


Figure 3. Comparison of change in soft lean mass (SLM) (A) and body fat mass (BFM) (B) between ISOCAL and control groups on postoperative day 28. The line inside boxes indicates the median value, the box indicates the interquartile range and whiskers indicate the range.

total PF intake, it was difficult to precisely assess the total caloric intake from the regular diet. As this study focused on the effect of PF on short-term outcomes, future studies should investigate its effects on long-term outcomes.

Conclusion

This randomized controlled trial demonstrated that PF administration is safe and feasible in patients undergoing robotic pancreatectomy. The results suggest positive effects of PF on BWL without compromising short-term outcomes after robotic pancreatectomy.

Conflicts of Interest

The Authors declare no conflicts of interest regarding this study.

Authors' Contributions

KT was involved in the development of the overall study design, conducted overall study management and data collection, contributed to writing of the manuscript, and was responsible for enrolment and informed consent for general population participants. TosF, KY, MY, TN, YN, and TomF were involved in the study design and conducted the study. MH conducted monitoring of this study. MT was involved in the study design, calculated the sample size, and wrote the manuscript as a statistician. All Authors edited, read and approved the final manuscript.

Funding

The Authors declare that they received no funding for this report.

Artificial Intelligence (AI) Disclosure

No artificial intelligence (AI) tools, including large language models or machine learning software, were used in the preparation, analysis, or presentation of this manuscript.

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