

NUTRITIONAL MANAGEMENT IN SEVERE MALNUTRITION POST-WHIPPLE PROCEDURE: A CASE REPORT

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Abstract

Background: Ampulla of Vater carcinoma is a rare gastrointestinal malignancy with a better prognosis than pancreatic cancer. However, patients often experience severe malnutrition that negatively affects clinical outcomes, particularly during the perioperative period. **Objective:** To report perioperative nutritional management and its impact on nutritional status, physical function, and clinical recovery in a patient with severe malnutrition undergoing Whipple procedure. **Methods:** A case report of a 51-year-old woman with pancreatobiliary-type adenocarcinoma and severe malnutrition. Medical nutrition therapy was provided stepwise according to the Enhanced Recovery After Surgery (ERAS) protocol, initiated preoperatively with enteral and parenteral nutrition, and continued postoperatively until full oral intake was achieved. Outcomes were assessed by improvements in clinical status and physical function. **Results:** Preoperative intervention included oral supplementation and carbohydrate loading. Postoperatively, the patient received a combination of enteral and parenteral nutrition with micronutrient supplementation. Energy and protein targets of 1,840 kcal and 78 g/day were achieved within 7 days. The patient showed improved clinical condition and physical function during hospitalization without serious complications, leading to favorable postoperative recovery. **Conclusion:** Structured and individualized perioperative nutritional management can improve nutritional status, enhance physical function, and support clinical recovery in patients with severe malnutrition undergoing major surgery. Integration of nutritional therapy is an essential component of perioperative management in gastrointestinal cancer patients

Keywords : severe malnutrition, *ampullary carcinoma*, perioperative nutritional medical therapy, *Whipple procedure*

Abstrak

Latar belakang: Karsinoma ampula Vater merupakan keganasan saluran cerna yang jarang dengan prognosis lebih baik dibanding kanker pankreas. Meski demikian, pasien sering mengalami malnutrisi berat yang berdampak negatif terhadap luaran klinis, terutama pada periode perioperatif. **Tujuan:** Melaporkan penatalaksanaan nutrisi perioperatif dan dampaknya terhadap status gizi, fungsi fisik, serta pemulihan klinis pada pasien dengan malnutrisi berat yang menjalani prosedur Whipple. **Metode:** Laporan kasus seorang wanita 51 tahun dengan adenokarsinoma tipe pankreatobiliari dan malnutrisi berat. Terapi gizi medik diberikan secara bertahap mengikuti protokol Enhanced Recovery After Surgery (ERAS), dimulai sejak pra-operasi melalui nutrisi enteral dan parenteral, kemudian dilanjutkan pascaoperasi hingga diet oral penuh. Luaran dinilai melalui perbaikan status klinis dan fungsi fisik. **Hasil:** Intervensi praoperatif meliputi suplementasi oral dan pemuatan karbohidrat. Pascaoperasi, pasien mendapat kombinasi nutrisi enteral, parenteral, dan suplementasi mikronutrien. Target energi 1.840 kkal dan protein 78 g/hari tercapai dalam 7 hari. Selama perawatan, kondisi klinis dan fungsi fisik pasien membaik tanpa komplikasi serius, sehingga mendukung pemulihan pascaoperasi. **Kesimpulan:** Penatalaksanaan gizi perioperatif yang terstruktur dan individual dapat memperbaiki status gizi, meningkatkan fungsi fisik, dan menunjang pemulihan klinis pada pasien dengan malnutrisi berat yang menjalani operasi mayor. Integrasi terapi gizi merupakan bagian penting dalam manajemen perioperatif pasien kanker gastrointestinal.

Kata kunci: malnutrisi berat, karsinoma ampula Vater, terapi medik gizi perioperatif, prosedur Whipple

Introduction

Ampullary carcinoma is a malignant tumor that originates in the ampulla of Vater, the junction of the pancreatic duct and the distal common bile duct.^{1,2} However, it still presents substantial nutritional challenges, particularly in the perioperative setting. In a cohort of patients undergoing pancreaticoduodenectomy for ampullary carcinoma, severe malnutrition (PG-SGA>9) was observed in approximately 39.1% of cases, highlighting the high prevalence of nutritional risk in this population. Unlike pancreatic cancer, which is often associated with late-stage cachexia and systemic catabolism, ampullary carcinoma more frequently leads to early biliary obstruction, resulting in anorexia, cholestasis-induced fat malabsorption, and micronutrient deficiencies.³ These distinct pathophysiologic features contribute to a unique pattern of nutritional deterioration and warrant a targeted perioperative nutrition strategy.

Approximately 50% of ampullary carcinomas are amenable to curative resection—significantly higher than the resectability rate of pancreatic adenocarcinoma, which is less than 10%. However, most patients still experience recurrence and ultimately mortality from progressive disease. Several studies have demonstrated a potential survival benefit from adjuvant chemotherapy, although the role of radiotherapy remains limited. Most

tumors are adenocarcinomas, with two main histologic subtypes: intestinal and pancreatobiliary. The pancreatobiliary subtype is associated with a worse prognosis than the intestinal type (median survival: 16 vs. 115.5 months; $p < 0.001$).^{2,4}

Pancreaticoduodenectomy (PD), or the Whipple procedure, is a complex surgery involving resection and reconstruction of the gastrointestinal tract. The two main techniques are distal gastrectomy or pylorus-preserving gastrectomy, the latter being more commonly used due to its preservation of gastric reservoir function and hormonal control. However, distal gastrectomy tends to cause less severe delayed gastric emptying (DGE). Abdominal exploration—by laparotomy or laparoscopy—is performed before resection to assess for metastases. The mortality rate for this procedure ranges from 2–5%, with morbidity of 20–50%. Postoperative complications include pancreatojejunal anastomotic leak (3–20%), pancreatic fistula, DGE, alkaline gastritis, gastric outlet obstruction, and systemic complications such as infection and bleeding.^{4,6}

Severe malnutrition is common in patients with gastrointestinal cancer and is an independent predictor of increased risk of complications, length of hospital stay, and mortality.⁷ Therefore, perioperative medical nutritional intervention is an integral part of the management of cancer patients

undergoing major surgical procedures such as pancreato-duodenectomy (Whipple procedure). This case report aims to illustrate the important role of nutritional therapy in supporting the clinical recovery of a patient with severe malnutrition and ampulla of Vater carcinoma.

Case Report

A 51-year-old female patient presented to Dr. Kariadi General Hospital with complaints of jaundice for three months, accompanied by tea-like urine, sometimes accompanied by black stools in the past two months. The patient also complained of intermittent upper right abdominal pain, nausea, and vomiting after eating. Initially, the patient was diagnosed with cholecystitis at Ngesti Waluyo Hospital in August 2021, and was then referred to Dr. Kariadi General Hospital in January 2022.

The patient was hospitalized for 16 days before finally being consulted with the clinical nutrition department. The patient underwent PRC transfusions and PTBD for the management of obstructive jaundice. He also experienced a decreased appetite, suboptimal solid diet intake for the past month, and his weight reached 65 kg at the beginning of 2021 and 50 kg by the end of 2021 (23% loss of body weight).

Physical examination revealed compos mentis consciousness, moderate pain impression, stable hemodynamics. Conjunctival examination showed anemia and icteric, heart and lung examination within normal limits. Abdominal examination revealed tenderness in the right hypochondriac with minimal distension, and a PTBD pigtail with positive production. Loss of subcutaneous fat (+2) was found in the triceps. Muscle wasting (+3) was found in *m. temporalis*, *m. quadriceps femoris* & *m. gastrocnemius*. Anthropometric examination revealed weight 46 kg, MUAC 23 cm, height 150 cm, BMI 20.44 kg/m². The patient's laboratory showed severe anemia (5.5 g/dl), leukocytosis (25.6 g/dl), hyperbilirubinemia (total bilirubin 14.5 mg/dl; Direct bilirubin 8.55 mg/dl; Indirect bilirubin 5.5 mg/dl), hypoalbuminemia (2.0 g/dL), increased platelet levels (428 thousand/uL), AST (142 U/L), ALP (45 U/L). MRCP (05/01/2022) showed a solid mass in the distal CBD (size ± 1.04 x 1.09 x 2.6 cm) which caused dilation of the extra and intrahepatic bile ducts. ERCP concluded a tumor of the ampulla of Vater. The results of the anatomical pathology biopsy showed that the patient had Ampullary adenocarcinoma, pancreatobiliary-type.

The patient is severely malnourished based on the GLIM chronic malnutrition

criteria.⁸ Subjective Global Assessment (SGA category C), BMI 20.4 kg/m², MUAC 23.5 cm, and muscle wasting grade +3. MNT was initiated before the Whipple procedure with a stepwise approach using oral enteral formula or via nasogastric tube (NGT), as well as parenteral nutrition administration according to clinical conditions. Monitoring was carried out on clinical, anthropometric, HGS (Hand Grip Strength), and laboratory parameters (albumin, electrolytes, hemoglobin, and inflammation).

Patient's target energy requirement was set at 40 kcal/kgBW/day (1,840 kcal) with protein 1.7 g/kgBW/day (78 g/day). The planned macronutrient distribution consisted of 60% carbohydrate, 25% fat (with emphasis on MUFA and PUFA), and 15% protein. Preoperatively, nutritional support was provided through a semi-solid diet (1,300 kcal/40 g protein), supplemented with two servings of hospital blenderized formula (2 × 200 ml) and egg white pudding twice daily. In accordance with the Enhanced Recovery After Surgery (ERAS) protocol, perioperative nutritional optimization included avoidance of prolonged fasting, administration of oral carbohydrate loading (hospital blenderized formula 250 ml at 6 hours before surgery and sugar water containing 50 g glucose in 200 ml water at 2 hours before surgery), and individualized prehabilitation to minimize catabolic stress. The patient subsequently underwent Whipple procedure on the 27th

day of hospitalization. Postoperatively, medical nutrition therapy was continued progressively following ERAS principles, consisting of early initiation of enteral feeding within 24 hours, gradual transition of intake from oligomeric to polymeric formulas, supplementation with parenteral nutrition when oral or enteral intake was insufficient, provision of micronutrients to support wound healing, and structured monitoring of clinical, anthropometric, and functional outcomes.

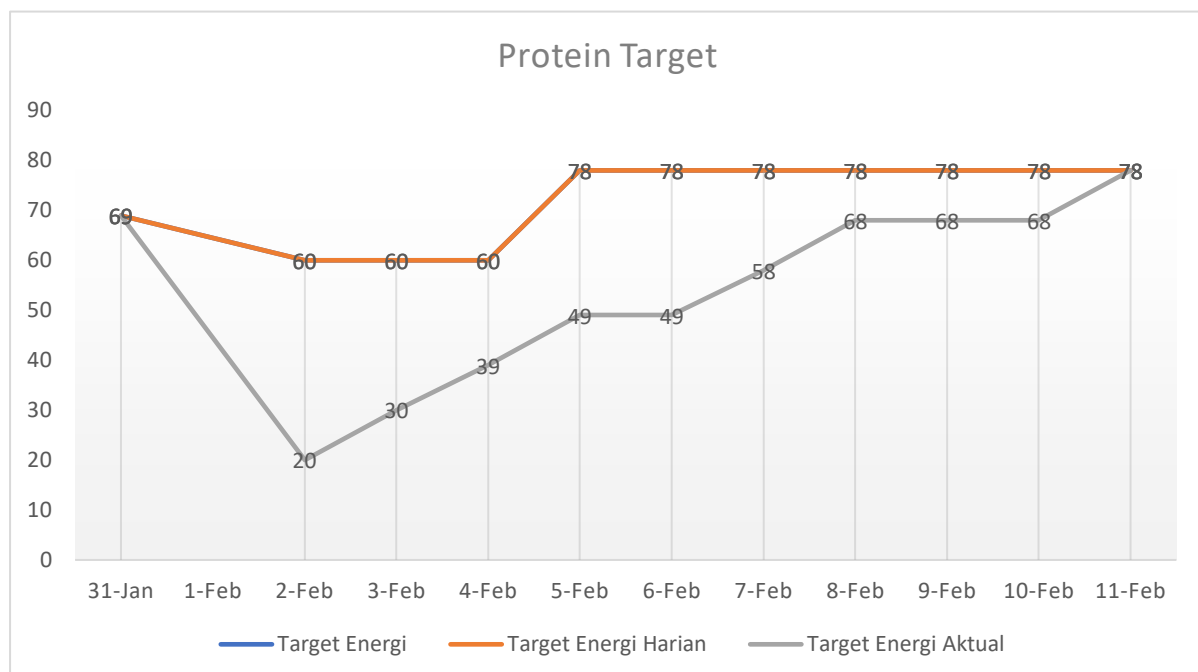
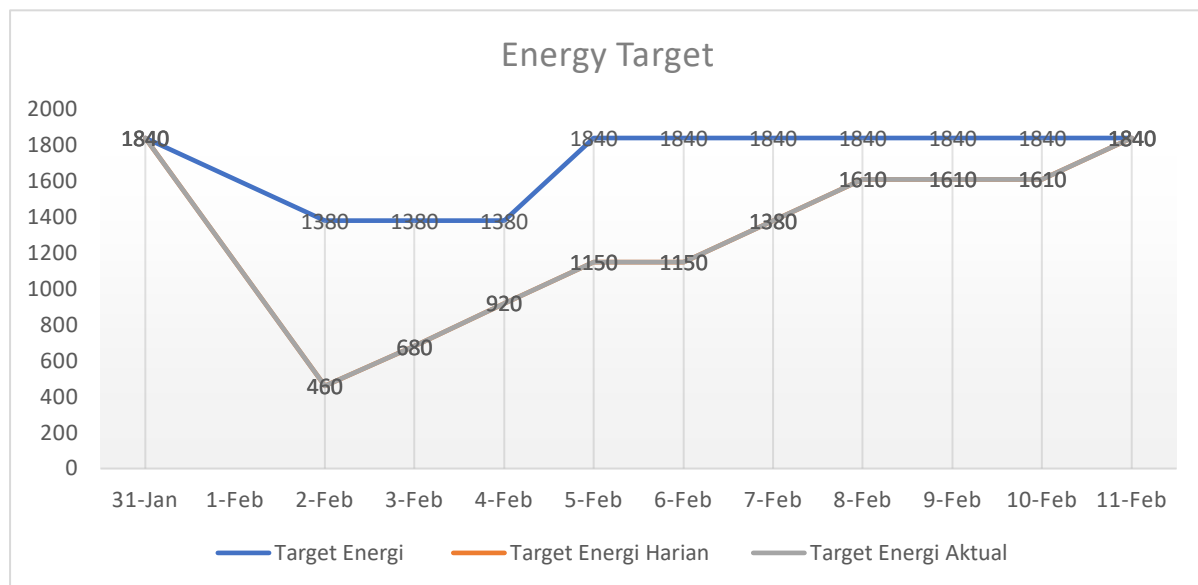
Results

The patient underwent pancreatic neck and proximal jejunum excision and reconstruction: pancreato-jejunostomy, hepatico-jejunostomy, and gastro-jejunostomy (while maintaining the gastric pylorus). After the Whipple procedure (H12 of treatment), the patient underwent intensive care in the ICU for 3 days and received a combination of enteral therapy (Polymeric Commercial Formula and Hospital Blenderized Formula and additional semi liquid diet) and supplemental parenteral nutrition (containing BCAA) with a gradual increase in intake from 10 kcal/kgBW/day to reach a target of 35–40 kcal/kgBW/day on the 9th day after surgery. Micronutrient supplementation was given to support postoperative wound healing (Vitamin A 100,000 *single dose*, Vitamin B Complex 1 tablet/8 hours, Vitamin C 250 mg/8 hours, Zinc 20 mg/24 hours).

Nutritional status was assessed through MUAC, HGS, daily intake, and laboratory results. Within 10 days postoperatively, the patient showed good tolerance to a hospital diet, achieving 100% of the target energy and protein intake. HGS improved from 4.5 to 9.1 kg/F, and no serious nutritional complications occurred during treatment. Serum albumin also improved from 2.0 g/dL at admission to 2.8 g/dL after surgery, partly supported by intravenous albumin infusion administered by the surgical team (20% albumin 100 cc preoperatively and 25% albumin postoperatively). At discharge, the patient was hemodynamically stable, able to feed herself, and received further nutrition education. The progress of the nutrition therapy provided to the patient is shown in Table 1.

Table 1. Follow Up of Patient Nutritional Medical Therapy (diet changes and graphs)

Day of Care at Nutri-tion Referral	Medical Nutritional Therapy	Vitamin Supplementation
DOC1	40 kkal/1,7gP/kgBW/day: Semi Solid Diet + Polymeric ONS + Egg White Pudding + ERAS protocol	-
DOC2 (DOC1-ICU)	30 kkal/1,3 gP/kgBW/day: Glucose Water 50 cc/4 hour and immediate innitiation 10 kkal/kgbw/day Oligomeric Enteral Nutrition	
DOC3 (DOC2-ICU)	15kkal/kgBW/day: Oligomeric Enteral Nutrition + supplemental Parenteral Nutrition	
DOC4 (DOC3-ICU)	20 kkal/kgBW/day: Polymeric Enteral Nutrition + supplemental Parenteral Nutrition	
DOC5	25 kkal/kgBW/day: Enteral Nutrition: Polymeric (Commercially-prepared Formula + Plant-Based Formula)	Supplementation Vitamin A, Vitamin B Complex, Vitamin C dan Zinc
DOC7	30 kkal/kgbw/day: Polymeric Enteral Nutrition + Extra Semi Liquid Diet (Rice Pudding)	Supplementation Vitamin B Complex, Vitamin C dan Zinc
DOC8	30 kkal/kgbw/day: Polymeric Enteral Nutrition + Extra Semi Liquid Diet (Rice Pudding)	Supplementation Vitamin B Complex, Vitamin C dan Zinc
DOC9	35 kkal/kgbw/day: Semi Liquid Diet (Rice Pudding) + Polymeric ONS + Extra Late Evening ONS	Supplementation Vitamin B Complex, Vitamin C dan Zinc
DOC10	35 kkal/kgBW/day: Semi Solid Diet (Chopped/Ground) + Polymeric ONS	Supplementation Vitamin B Complex, Vitamin C dan Zinc
DOC11	40/1,7/kkal/kgBW/day: Semi Solid Diet (Chopped/Ground) + Polymeric ONS	Supplementation Vitamin B Complex, Vitamin C dan Zinc
DOC13	40/1,7/kkal/kgBW/day: Semi Solid Diet (Chopped/Ground) + Polymeric ONS	Supplementation Vitamin B Complex, Vitamin C dan Zinc



Favourable outcome is characterized by achieving energy and protein targets, satisfactory wound healing, increased functional capacity, optimal nutritional status, and improved other clinical outcome and quality of life. No serious complications related to the Whipple procedure occurred in patients. No evidence of refeeding syndrome, significant electrolyte imbalance, catheter-

related infection, or feeding intolerance was noted. Bowel function resumed promptly without signs of ileus or delayed gastric emptying.

Discussion

This case demonstrates the importance of a comprehensive perioperative medical nutritional therapy approach in patients with

severe malnutrition and gastrointestinal cancer. Malnutrition in cancer patients results from a complex interaction between increased metabolic demands, decreased intake, and the effects of the tumor on the digestive system. Pre- and postoperative nutritional interventions have been shown to improve immune responses, prevent muscle loss, and promote wound healing.

Pancreaticoduodenectomy (PD), also known as *the Whipple procedure*, can be performed using the standard technique of *distal gastrectomy* or the more commonly performed technique of pylorus preservation. The surgical procedure begins with abdominal exploration to find evidence of metastases or advanced local lesions. Exploration can be initiated using laparoscopy, with the areas explored including the peritoneal cavity, the surface of the liver, the duodenum, and the pancreas.⁷ The PD technique with pylorus preservation has the advantage of maintaining gastric reservoir function so that gastric emptying and hormonal control continue to function normally, while the PD technique with distal gastrectomy is associated with less frequent and milder delayed gastric emptying (DGE) events compared to the pylorus preservation technique. The mortality and morbidity rates of this procedure range between 2-5% and 20-50%, respectively.^{5,6}

Pancreatic surgery, such as pancreatico-duodenectomy (PD), significantly impacts pancreatic function and the patient's nutritional status. Common complications include pancreatic fistula, delayed gastric emptying, dumping syndrome, diabetes mellitus, weight loss, and various nutritional deficiencies. Although nutritional status may decline after surgery, most biochemical parameters (albumin, transferrin, and total protein) recover within 3 months, while anthropometric parameters such as body weight and subcutaneous fat may take up to 6 months to return to preoperative levels.^{4,10}

PD also increases the risk of micronutrient deficiencies, including vitamin B12 (due to antral resection and loss of intrinsic factor), fat-soluble vitamins (especially in the presence of exocrine pancreatic insufficiency (EPI), and iron and zinc. Zinc deficiency has been reported in 68% of patients after PD, particularly in classic PD compared to pylorus-preserving PD. This condition is often subclinical, necessitating regular screening of vitamin and mineral levels.^{4,10}

The ERAS protocol during pancreatico-duodenectomy has been shown to reduce morbidity, length of stay, and costs, while improving recovery and patient

satisfaction. Although PD remains the only curative therapy for periampullary cancer, this procedure still carries a high morbidity (30–40%). We implemented a comprehensive Enhanced Recovery After Surgery (ERAS) protocol tailored to the Whipple (pancreatoduodenectomy) context. Pre-operatively, patients were advised to consume clear carbohydrate-rich drinks (~50 g) 2–3 hours before surgery, to reduce insulin resistance and improve early metabolic response. Studies demonstrate this approach can shorten time to flatus and hospital stay by approximately 0.3–1.0 days in major abdominal surgery settings.^{11,12}

The Whipple procedure is a complex surgery that carries a high risk of complications, especially in patients with poor nutritional status. Gradual adjustment of energy and protein intake, along with regular monitoring, are key to successful therapy. The use of a peptide enteral nutrition formula in combination with PPN has yielded good clinical outcomes in this case. Preoperatively, our patient received oral supplements and, when needed, supplemental enteral feeding for 10 days before surgery to achieve energy and micronutrient targets. After surgery, early oral feeding was initiated within 12–24 hours, as recommended by ERAS guidelines; enteral tube feeding supplemented intake when oral intake was inadequate, and parenteral nutrition was tapered off once enteral/oral

energy targets were reached (typically within 5–7 days).¹³

Preoperative nutritional status will influence outcomes after the *Whipple procedure*. Research in a group of malnourished patients found a higher rate of pancreatic fistula complications. Biochemical parameters such as QoL, BMI, and stool elastase were lowest in the malnourished group postoperatively. Patients with preoperative malnutrition should be monitored and given adequate treatment to improve their nutritional status.¹⁴ In patients with severe malnutrition, preoperative enteral nutrition is administered 10–14 days before the procedure. If the enteral route is not possible, the parenteral route may be chosen.¹⁵

In the first 24 hours postoperative patients in the ICU are given trophic feeding, defined as providing a diet of 10–20 kcal/hour or up to 500 kcal/day, in the form of 50 cc/4 hours of sugar water and oligomeric (60 ml) via NGT with the aim of preserving intestinal epithelium, stimulating enzymes in the intestinal brush border, improving immune system function, maintaining intestinal tight junction function and preventing bacterial translocation.^{13,14} Early administration of EN in small amounts aims to avoid overfeeding considering that postoperative patients are classified as critically ill and the presence of endogenous energy production is considered.¹⁵

On days 1-3 of MNT, patients are given a diet via NGT according to ESPEN 2019 if oral intake is not possible early EN can be given (<48 hours in critically ill patients rather than delaying EN. It is also stated that early EN is preferred over early PN.^{13,16} An observational cohort study showed that the introduction of an early oral feeding strategy, with NJT feeding, reduced the time to resumption of adequate oral intake and LoS after PD, without a negative impact on postoperative morbidity.¹⁹

Early PN was administered to patients on day 2 in the ICU. The 2019 ESPEN guidelines state that in cases where oral and EN are contraindicated, PN should be administered for 3 to 7 days. Early PN can be given instead of withholding nutrition in cases where EN is contraindicated in patients with severe malnutrition. In patients who cannot tolerate a full dose of EN in the first week of the ICU, consideration of PN administration should be made on a case-by-case basis. The patient was admitted to the ICU for 3 days and on day 3 achieved a daily TEP of 20 kcal. According to the 2019 ESPEN guidelines, to avoid overfeeding, early EN and PN administration to critically ill patients is not recommended for 3 to 7 days.²⁰

Formula selection on the first to second day after surgery uses an oligomeric commercial formula with 100% hydrolyzed

Whey Protein (peptide) features rich in BCAA to accelerate gastric emptying and increase gastrointestinal tolerance, high in MCT (Medium-Chain Triglyceride), as a source of energy that is quickly used and helps improve fat malabsorption, Omega-3 and Omega-6 to help cardiovascular function and as an anti-inflammatory, low osmolality (315 mOsm/L) to prevent osmotic diarrhea, macro and micro nutrient content to ensure critical patients get adequate nutrition and are lactose free.²¹ Whey protein has a high biological value so it can maximize the anabolic response. Critically ill patients who receiving whey protein, were more protected from skeletal muscle atrophy and were more metabolically stable.²² In patients with gastrointestinal cancer undergoing surgical procedures, omega-3 supplements are recommended as an immunomodulator.²³

On the 3rd day after surgery, the use of a commercial polymeric formula was chosen. The primary consideration in selecting this type of commercial formula is to meet the patient's macronutrient needs. Commercial formulas contain approximately 50% protein. is whey protein.¹⁹ This commercial formula is also a high-protein polymeric formula, containing 14 grams (22.4%) of protein per serving. This formula also contains vitamin A, which plays a vital role in epithelialization during wound

healing. Vitamin A also plays a role in maintaining the integrity of the mucosa of the digestive and respiratory tracts.²⁴

After being transferred to the regular ward, the patient was given supplementation for wound healing. Nutritional therapy adhered to severe malnutrition guidelines, with an energy target of 40 kcal/kg/day and a protein target of 1.7 g/kg/day. The patient was given supplementation to gradually increase dietary consistency and was given high-protein oral nutritional supplementation (ONS) to meet the daily energy and protein provision. During treatment in the regular ward, no signs of EPI, such as steatorrhea, bloating, or abdominal pain, were found. The patient was discharged home 10 days postoperatively.

After treatment and after discharged, there were no complaints of diarrhea, abdominal cramps, trembling, and cold sweats after eating (signs of dumping syndrome) and complaints of steatorrhea, bloating, and abdominal pain (signs of EPI). The patient complained of bloody stools 1 day after discharge. The follow-up was carried out again on 3rd day after discharged. The patient was informed that the bloody stools experienced were residual bleeding from the surgical procedure. The patient returned for a check-up 1 week later and did not complain of bloody stools again. The patient experienced a weight loss from 46 kg to 43 kg within 1 month after being hospitalized, but

HGS began to improve after surgery (although not yet reaching the normal threshold value).

Limitation

This case illustrates that a structured and individualized perioperative nutritional approach, integrated with ERAS principles, may support metabolic recovery, improve nutritional status, and enhance functional outcomes in malnourished patients undergoing major gastrointestinal surgery. However, as a single case report, the findings should be interpreted with caution. The outcomes observed may not be generalizable to all patients with ampullary carcinoma or severe malnutrition, given the inherent limitations of case reports, such as lack of control, potential confounding factors, and limited external validity. Further research involving larger cohorts is needed to confirm these observations and guide standardized nutritional protocols in similar surgical oncology settings.

Conclusion

This case report highlights that structured and individualized perioperative nutritional management, integrated with ERAS principles, plays a pivotal role in patients with severe malnutrition undergoing Whipple procedure. The interventions, which included preoperative nutritional optimization, carbohydrate loading, early initiation of

enteral nutrition, combination with parenteral support, and micronutrient supplementation, successfully improved energy and protein intake, increased handgrip strength, and supported recovery without serious complications. These findings emphasize that perioperative nutrition not only optimizes nutritional status and functional outcomes but also contributes to reducing postoperative risks and promoting faster clinical recovery in gastrointestinal cancer surgery.

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Conflict of Interest

The authors declare that they have no conflict of interest.

List of Abbreviations

BCAA : Branch-chained Amino Acid

BMI : body mass index

DGE : delayed gastric emptying

EN : enteral nutrition

EPI : Exocrine Pancreatic Insufficiency

ERAS : Enhance Recovery After Surgery

ESPEN: European Society of Parenteral and Enteral Nutrition

GLIM : Global Leadership Initiative on Malnutrition

HGS : Hand Grip Strength

ICU : Intensive Care Unit

MNT : Medical Nutrition Therapy

MRCP : Magnetic Resonance

Cholangiopancreatography

MUAC : mid upper arm circumference

MUFA : Monounsaturated Fatty Acid

NGT : nasogastric tube

NJT : nasojejunal tube

ONS : Oral Nutritional Supplement

PD : pancreaticoduodenectomy

PN : parenteral nutrition

PRC : packed red cell

PTBD : percutaneous trans-biliary drainage

PUFA : Polyunsaturated Fatty Acid

SGA : Subjective Global Assessment

Authors' Contribution

I Putu Prayoga Ratha – performed perioperative nutritional assessment and management, conducted literature review, collected clinical data, and prepared the manuscript.

Niken Puruhita – supervised nutritional therapy planning and critically reviewed the manuscript.

Febe Christianto – supervised nutritional therapy planning and critically reviewed the manuscript.

Martahadinan – performed the Whipple procedure, provided surgical management, and contributed to clinical interpretation and critical revision of the manuscript.

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