

Assessment of nutritional status and quality of life in patients with percutaneous endoscopic gastrostomy

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**UNIVERSITY OF SPLIT
SCHOOL OF MEDICINE**

BORNA LOJPUR

**ASSESSMENT OF NUTRITIONAL STATUS AND QUALITY OF LIFE IN
PATIENTS WITH PERCUTANEOUS ENDOSCOPIC GASTROSTOMY**

Diploma thesis

Academic year

2021/2022

Mentor

Assist. prof. Andre Bratanić, MD, PhD

Split, September 2022

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List of Abbreviations

ALS - Amyotrophic lateral sclerosis

BIA - Bioelectrical impedance analysis

BMI - Body mass index

CHI - Creatinine height index

CT - Computed tomography

DXA - Dual energy x-ray absorptiometry

EQ VAS - EuroQol visual analogue scale

GDA - Guideline daily amounts

HIV - human immunodeficiency virus

HNC - Head and neck cancer

HRQoL - Health-related quality of life

MRT - Magnetic resonance tomography

MUST - Malnutrition Universal Screening Tool

PEG - Percutaneous endoscopic gastrostomy

PG - Percutaneous gastrostomy

PJ - Percutaneous jejunostomy

PSP - Progressive supranuclear palsy

QoL - Quality of life

SFT - Skinfold thickness

WHO - The World Health Organization

1. INTRODUCTION

1.1 Nutrition

Nutrition represents many biological processes that are responsible for the intake and utilization of food with the purpose of supporting growth and other functions of the human body. The first process with which the nutritional cascade begins is the ingestion of food, followed by digestion and absorption of food. The rest of the process includes transport, metabolism, and elimination. All these processes affect each other and therefore also affect the nutritional status (1).

Nutritional status represents the ability of nutrients to perform many functions that are necessary for life. Nutritional status varies from person to person. Therefore, it can affect individual responses to medical and dietary interventions (1).

Nutrients are substances needed by the body to support basic functions and are obtained through a healthy diet. There are six different types of nutrients that are fundamental to human health, and we can divide them into macronutrients, micronutrients and water. Macronutrients include carbohydrates, proteins and lipids, and they serve as a source of energy. Micronutrients include minerals and vitamins and play crucial roles in metabolic processes (2). Macronutrients are required in large amounts compared to micronutrients which are required in small amounts. Nutrients can also be classified into essential and non-essential nutrients. Essential nutrients must be taken into the body through food because humans do not have the ability to produce in sufficient quantities or at all, while non-essential nutrients can be produced by the organism itself (3). Carbohydrates are the primary source of energy in the human body. One gram of carbohydrates provides 4 kilocalories of energy. Carbohydrates are also important for immune function and gut health. The main sources of carbohydrates are plant-based foods, milk, and milk products. Proteins are essential for the regulation of various bodily processes. Proteins contribute to mechanical and structural functions of the body, but they can also provide energy if needed. Proteins are made of amino acids and can be found in various foods such as meats, dairy products, grains, and vegetables. Lipids function as the main source of stored energy, with each gram of fat providing 9 kilocalories of energy. Lipids are also important for organ protection, temperature regulation and their contribution to cellular function and structure. Vitamins belong to the group of organic micronutrients, and can be further divided as fat soluble or water soluble.

Minerals belong to the group of inorganic micronutrients and can be further divided into microminerals or macrominerals (2).

Water does not yield energy, but it is still needed in large amounts because it has multiple roles in the human body (2,4). Water serves as a building material, carrier for nutrients, carrier for waste products, lubricant, shock absorber, solvent, reactant, and reaction medium. It also plays an important role in thermoregulation (4).

1.2 Malnutrition

Malnutrition is a frequent health problem, but there is still no global agreement regarding its definition, methods of identification, or prevalence. As a result, malnutrition has many definitions. Malnutrition can be defined as any kind of nutritional imbalance, which means that the term malnutrition includes both undernutrition and overnutrition, as shown in Figure 1. Undernutrition is a condition in which the human organism does not get enough nutrients to function properly, or when the human organism cannot utilize the ingested food due to illness.

Overnutrition is a condition when a person consumes too many calories. The term malnutrition is used synonymously with the term undernutrition, but strictly speaking it also refers to overnutrition, obesity, and both toxicity or imbalance of nutrients.

The historical importance of malnutrition goes back to the time of Hippocrates, as it was already known that thin people had poor recovery or survival rates when they encountered an illness. Regardless of the fact that malnutrition has been widely known since the distant past, to this day it still represents a great burden in all age groups (5).

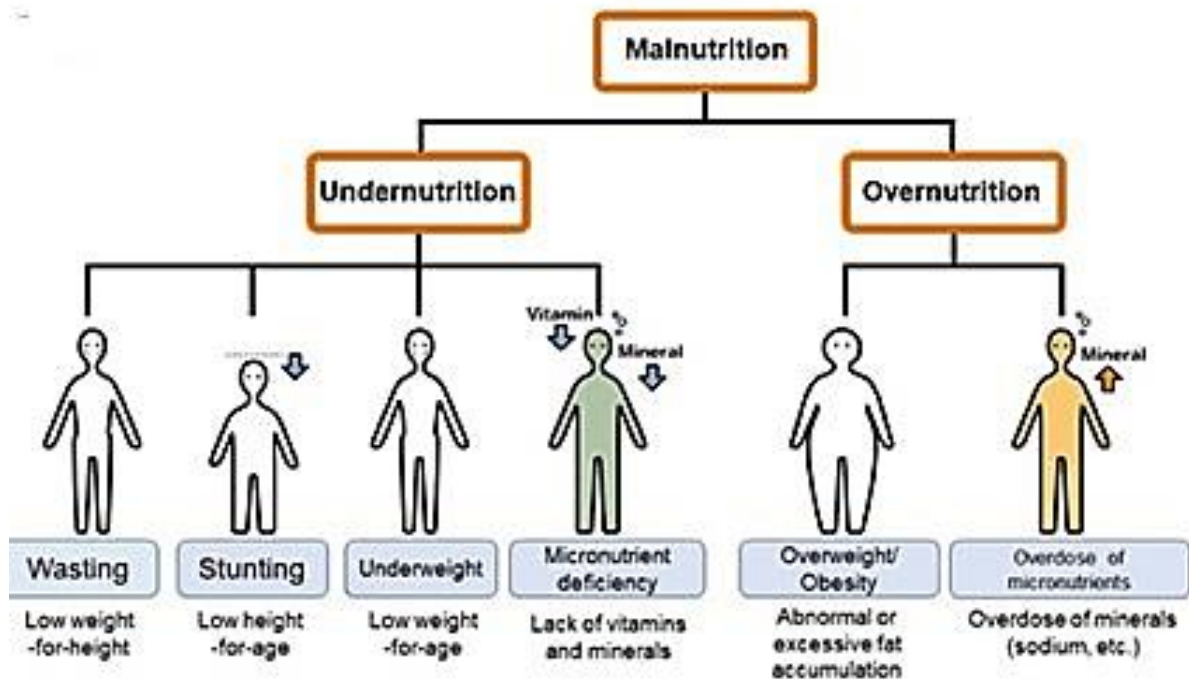


Figure 1. Types of malnutrition. Source: (6).

1.2.1 Epidemiology of malnutrition

Malnutrition is classified as the world's greatest threat to public health by the World Health Organization. About 20-60% of hospitalized patients in the world suffer from malnutrition (7). More than 900 million people in the world suffer from undernutrition (8). Around 45% of all child deaths under 5 years old worldwide are caused by undernutrition (9).

1.2.2. Undernutrition

Undernutrition is a common condition in clinical practice, and despite this fact, it is still a poorly recognized and poorly treated problem. Undernutrition can be the cause of disease, but it can also be the consequence of many different conditions (10).

It is a neutral term that encompasses many conditions such as marasmus and kwashiorkor, but also micronutrient deficiencies (11). The spectrum of abnormalities that fall under the concept of undernutrition is very diverse.

This spectrum includes imbalances between nutrients, deficiencies of combination of nutrients, deficiency of specific nutrient or even abnormal interaction between nutrients (5). Especially vulnerable groups are the elderly, individuals with chronic diseases, individuals living in institutional care, pregnant women, adolescents, and children during the first 5 years of life. Children are especially at risk because their nutrition is completely dependent on other people (10,11).

1.2.2.1. Risk factors for undernutrition

The most important risk factors for the development of undernutrition can be divided into three groups, and they include biological, behavioral and social factors. Biological risk factors basically refer to pathological conditions such as systemic diseases, malabsorptive conditions and infectious diseases. Many infectious diseases such as diarrhea, respiratory infections, human immunodeficiency virus or malaria increase the chance of developing undernutrition. HIV makes people susceptible to undernutrition through various pathological mechanisms, such as increased metabolic needs, but also immunosuppression, which predisposes the patient to opportunistic pathogens that can cause diarrhea, which, in and of itself is the cause of undernutrition (11). Cancer patients are at particular risk of undernutrition. Decreased appetite, other cancer-related symptoms, metabolic abnormalities, and the effects of antineoplastic therapy may all contribute to such risk in cancer patients. Cancers most often associated with undernutrition are head and neck cancers, upper digestive cancers, and lung cancer, while cancer symptoms most often associated with undernutrition are difficulty swallowing, anorexia, vomiting, nausea, and diarrhea (12). Another group of conditions often associated with undernutrition are neurological diseases. Symptoms of neurological diseases that can promote undernutrition are dysphagia, immobility and gastrointestinal dysfunction. Therefore, undernutrition can often be found in patients with certain neurological diseases such as Parkinson's disease, stroke or amyotrophic lateral sclerosis (13).

Behavioral risk factors are very important contributors to the occurrence of undernutrition in the world, although most of these risk factors can be prevented. Insufficient access to food as well as poor water and sanitation are common problems in this risk group. Inappropriate maternal and infant feeding practices together with poor child care can contribute to the development of undernutrition. Social risk factors are based on poverty, lack of proper education and politics (11).

1.2.2.2. Causes of undernutrition

Most cases of undernutrition in the adult population are related to diseases. Reduced dietary intake is the most important etiological factor for the development of diseases related to undernutrition. This mechanism of undernutrition is believed to result from reduced appetite, which is a consequence of changes in cytokines but also hormones such as insulin and glucocorticoids (10). Reduced nutrient intake due to dysphagia is another possible reason for this etiological factor (13). Another possible etiological explanation for undernutrition is malabsorption of any type of nutrients, which is often encountered after certain abdominal surgeries or in patients with intestinal failure (10). Celiac disease and pancreatic insufficiency are also common reasons for malabsorption, which can lead to undernutrition (14).

Undernutrition can also be the result of altered body requirements or increased body losses. Such problems are common in patients with burns or enterocutaneous fistulae. Increased energy expenditure is described as a possible cause of malnutrition and most often accompanies specific pathological conditions (10). Symptoms such as tremor, rigidity and dyskinesia increase energy expenditure in Parkinson's disease (13).

1.2.2.3. Consequences of undernutrition

Undernutrition has an effect on all organ systems in the body. Weight loss is the most prominent sign of undernutrition and occurs due to the depletion of fat and muscle mass. Muscle

function is particularly sensitive and begins to wane before changes in muscle mass develop. Cardiac muscle mass is not spared and eventually begins to decrease in undernourished individuals. Reduced cardiac muscle mass causes a decline in cardiac output, which consequently has an impact on kidney function by reducing kidney perfusion and glomerular filtration rate. Decreased respiratory muscle function can delay recovery from respiratory infections due to weak cough pressure and reduced expectoration of secretions. Preservation of the gastrointestinal system depends on adequate nutrition. Chronic undernutrition causes many gastrointestinal changes related to intestinal blood flow, intestinal permeability and villous architecture. Over time, the colon's inability to reabsorb electrolytes and water develops and leads to abnormal secretion of ions and fluid, which can result in diarrhea. Diarrhea in severely undernourished patients can be fatal and has a high mortality rate. Undernourished individuals have a higher risk of getting an infection because they have a weakened immune system due to impaired function of cell-mediated immunity, the complement system and phagocytes. Delayed wound healing, higher incidence of postoperative complications and longer hospital stays are also observed in malnourished surgical patients. Undernutrition is generally associated with psychosocial consequences that can manifest as anxiety, apathy, depression and self-neglect (10).

1.2.2.4. Nutritional screening and assessment tools

Screening tools for nutritional risk are used to detect potential or already manifested malnutrition. The goal of such screening tools is to accurately and quickly detect patients with malnutrition who should be referred for further assessment by a nutrition specialist. It is recommended that nutritional screening tests should be based on dynamic parameters such as current body mass index or current weight loss. Many screening tools have been established for use in various clinical scenarios. All patients at nutritional risk should undergo nutritional assessment. Data collected during nutritional screening in many cases overlaps with data obtained during nutritional assessment (15).

1.2.2.4.1. Clinical evaluation

1.2.2.4.1.1. Clinical history

The patient's clinical history is the starting point of the nutritional assessment. Symptoms that may cause malnutrition are discussed with the patient, such as loss of appetite, diarrhea, vomiting, weight loss, dysphagia, and pain. The patient's previous health conditions are another important part of the patient's clinical history for the purpose of assessing the nutritional status. Dietary history and dietary habits are extremely important to examine in patients with suspected nutritional imbalances (15).

1.2.2.4.1.2. Physical exam

Physical examination serves as a tool for detecting signs of nutritional deficiencies. Certain clinical signs are common with specific nutrient deficiencies, such as edema in the case of protein deficiency. Physical examination is useful in this group of patients because it can also be used to assess tolerance to nutritional support (15).

1.2.2.4.1.3. Physical function

Functional measurements are tools that can also be used for nutritional evaluation. Improper nutrition can cause energy deficiency, which can be translated into a decrease in muscle strength. Muscle function tests are used to obtain information about muscle strength, and such tests are considered to be very sensitive to nutritional deficiencies.

Hand dynamometry is a common test that can be used as a marker to assess nutritional status, as shown in Figure 2. Other tests that can be used are peak expiratory flow, knee extension, or hip flexion strength (15).



Figure 2. (A) Handgrip dynamometer; (B) Reference values for handgrip strength. Source: (16).

1.2.2.4.2. Anthropometric Measurements

1.2.2.4.2.1. Body height, weight, and calculated body mass index

Body height, weight, and calculated body mass index (BMI) are crucial parameters when assessing nutritional status. The purpose of the BMI is to serve as an indicator of chronic malnutrition. In the European population, individuals are considered undernourished when BMI is $< 18.5 \text{ kg/m}^2$, as demonstrated in Figure 3.

BMI values can be misleading in conditions characterized by edema or fluid overload, but also in very muscular people because BMI does not describe body composition, so such individuals can have a high BMI like obese individuals (15).

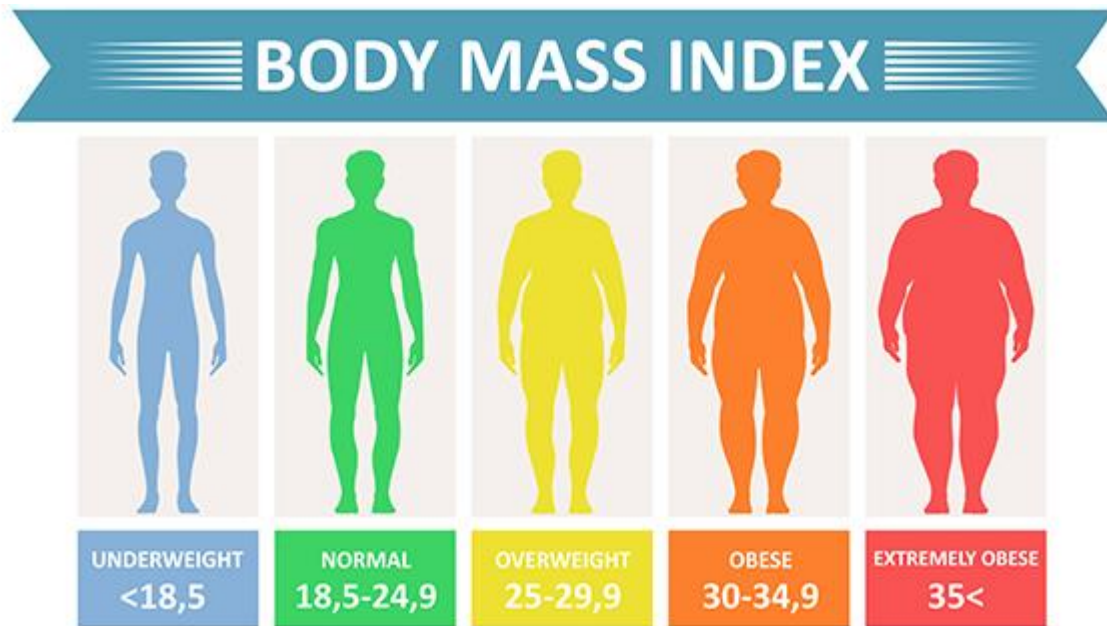


Figure 3. Adult Body Mass Index (BMI). Source: (17).

Unintentional weight loss is considered to be of paramount importance for the assessment of nutritional status, since it is an indicator of a catabolic metabolic situation (15). Weight loss of 10% within six months is considered serious (18).

1.2.2.4.2.2. Skinfold Measurements

Skinfold measurements are very easy but also cheap methods of estimating the nutritional status. Such methods include measurement of the circumference of a limb and of skinfold thickness (SFT). Measurement of skinfold thickness provides information about the energy stores of the body, predominantly fat stores. In order to assess the total amount of body fat, it is necessary to measure 4 different skinfolds, namely the biceps, triceps, subscapular and suprailiac skinfolds. The main drawback of this is high interindividual variability, such as gender, age, and ethnicity (15).

1.2.2.4.2.3. Body composition analysis

Body composition measurement methods can be used to assess nutritional status. Many different methods can be used to determine body composition. Among them, the current gold standard is dual energy x-ray absorptiometry (DXA). DXA serves to indirectly measure bone mineral mass, fat mass, and fat-free mass. The disadvantage of this method is exposure to radiation. Other methods that can be used to measure body composition are bioelectrical impedance analysis (BIA), creatine height index (CHI), magnetic resonance tomography (MRT) and computed tomography (CT) (15).

1.2.2.4.3. Biochemical Analysis

Simple biochemical parameters are another tool used to assess nutritional status, but also to monitor the condition of patients. However, in clinical practice, these methods are rarely used, and additionally, they are not very useful for screening purposes (19). Plasma proteins are useful parameters for assessing nutritional status since they reflect the visceral protein condition. Most commonly used proteins for such nutritional assessments are albumin, transferrin, prealbumin and retinol binding protein. Prealbumin is considered to be the best protein marker of nutritional status. The biggest disadvantage of using plasma proteins for such assessments is the fact that they behave as acute phase reactants, which means that their concentrations can change regardless of nutritional status. Concentrations of serum vitamins and minerals should always be determined when certain nutritional deficiencies are suspected or in cases of moderate or severe undernutrition (18).

1.2.2.4.4. Questionnaires

Screening and assessment of nutritional status can be performed with many different questionnaires. There is still no consensus about a questionnaire that would be universally accepted as an optimal and reliable tool (20).

1.2.2.4.4.1. The Malnutrition Universal Screening Tool (MUST)

The Malnutrition Universal Screening Tool (MUST) is designed to identify adults, who are malnourished or obese, or to assess the overall risk of malnutrition in individuals in all care settings such as home care, nursing homes, or even hospitals (15). It is a very reliable tool, but at the same time it is also a very quick and simple method to perform. Assessment of the overall risk of malnutrition is obtained by incorporating body mass index, unplanned weight loss in the past 3-6 months, and acute disease score, as shown in Figure 4. Acute disease effect is a component which is unlikely to apply in care settings which are outside the hospital. Scores from individual components are inferior predictors of the outcome compared to the total MUST score (10).

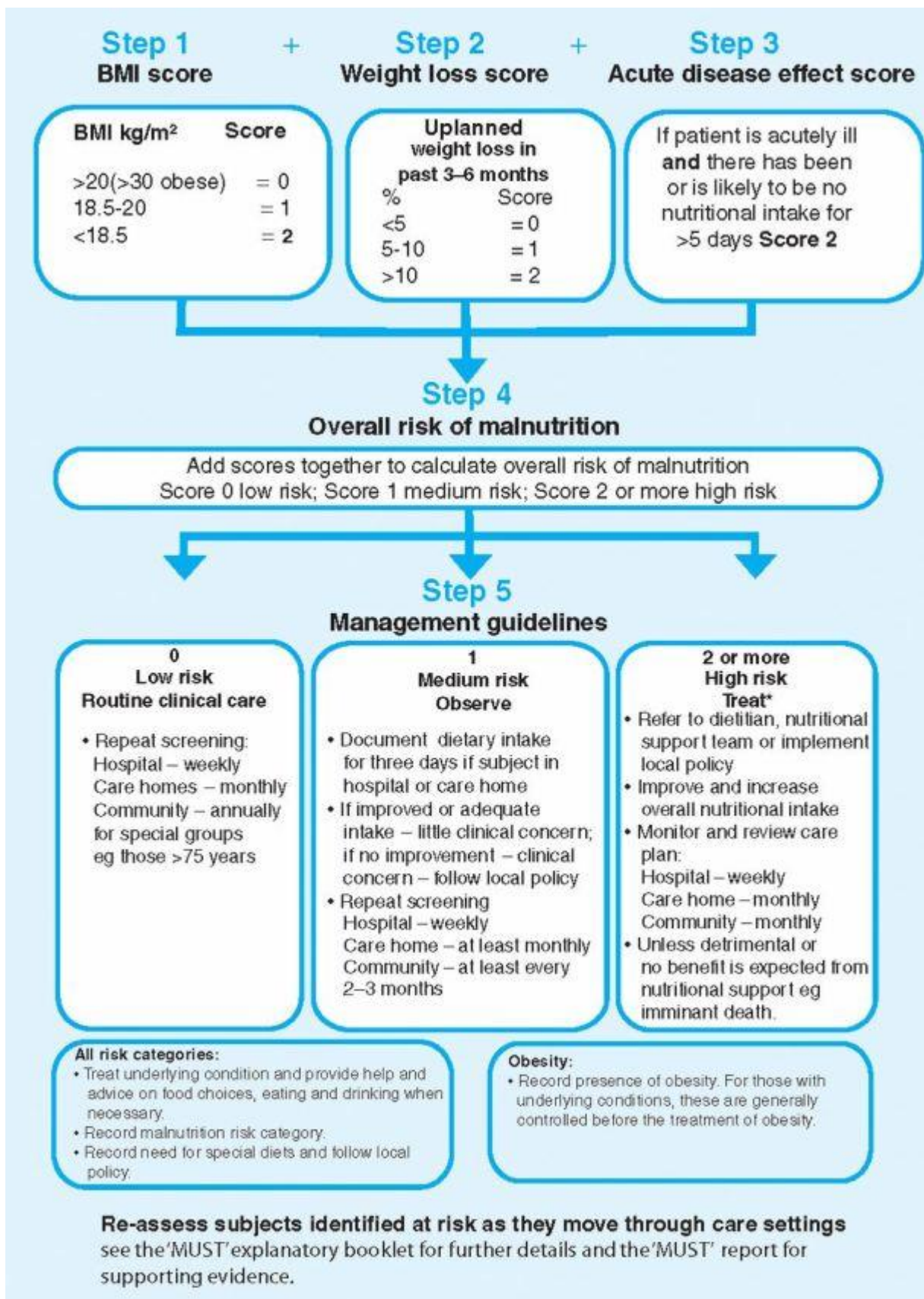


Figure 4. The Malnutrition Universal Screening Tool (MUST). Source: (10).

1.2.2.5. Treatment of undernutrition

The goal of undernutrition treatment is to provide optimal nutritional requirements of the body in order to reduce the negative effects of losing the body's protein content and also to reduce the negative effects of catabolism (21). Nutrition therapy is a therapeutic tool for the treatment of various conditions by using oral interventions, enteral nutrition or parenteral nutrition, as shown in Figure 5 (22).

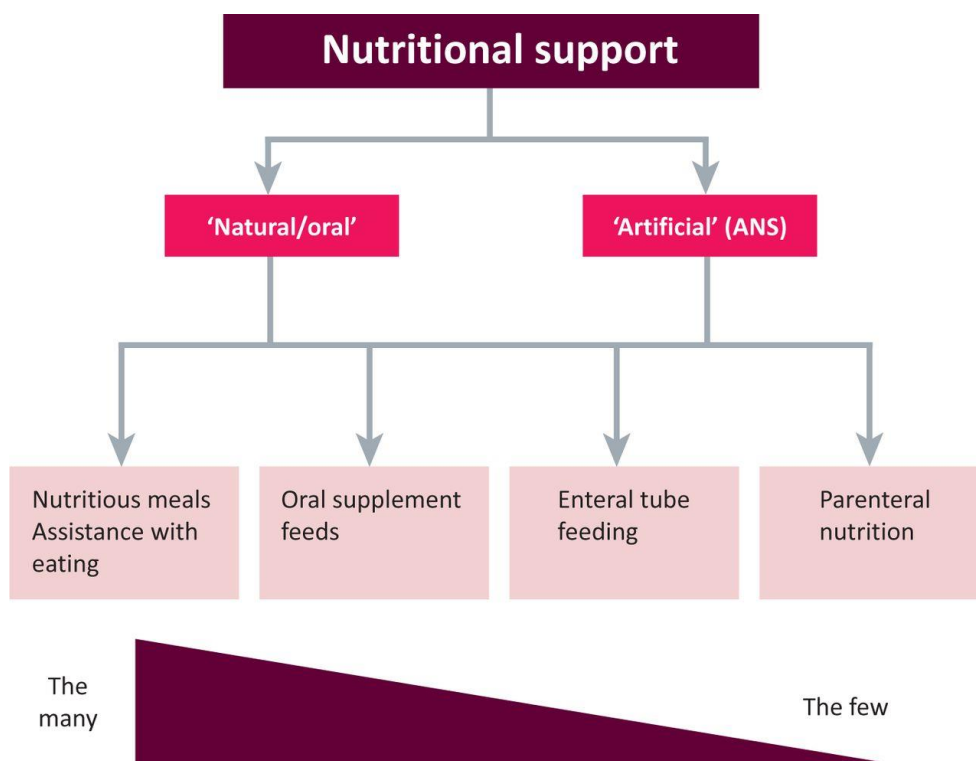


Figure 5. The spectrum of nutritional support. Source: (23).

Before starting any type of nutritional therapy, it is important to make the patient aware of his problem and provide him with useful dietary advice (24). Dietary advice provides the patient with information about appropriate food options, but also about healthy eating habits such as protected mealtimes and positive social atmosphere. Eating support is another important aspect in the treatment of malnourished patients and may include interventions such as physical assistance with feeding (25). The most acceptable diet is that which takes place naturally, through the mouth, and should be given priority if possible (26). Therapeutic options for oral

nutrition of malnourished patients include modified therapeutic diets and oral nutritional supplements (25,26). Oral nutrient supplements are most often multinutrient supplements that contain both macronutrients and micronutrients. Enteral tube feeding is indicated in individuals who are unable to consume food orally. It can also be implemented in conditions when oral intake is contraindicated, such as unsafe swallowing or unconsciousness. Enteral tube feeding can be administered via nasogastric tubes, gastrostomy tubes or jejunostomy tubes. Parenteral nutrition is used when oral nutrition or enteral nutrition has failed or is not possible and when partial or complete intestinal failure is present (26). If caloric requirements are not met after a week of enteral feeding, then the use of parenteral nutrition is considered (27).

In cases where undernutrition is the result of a disease, treatment of such disease or its symptoms can have a positive effect on the patient's nutritional status. Antiemetic drugs can be a tool used to combat reduced nutritional intake as a result of nausea and vomiting (25).

1.2.2.6. Prevention of undernutrition

Many social interventions are designed to prevent undernutrition, such as child growth monitoring, education, water supply and sanitation, as well as integrated nutrition programs. Female education is extremely important for prevention of undernutrition because it affects both the individual and her future children. The influence of education on the improvement in the social status of women seems to play a considerable role in this context. Improved water and sanitation may reduce the incidence of diarrheal diseases and thus indirectly reduce undernutrition as result of reduction in the number of infections and time spent being ill. Interventions to improve dietary intakes are another type of tool that can be used in the prevention of undernutrition. Food fortification is an example that can be applied at the national level and is based on the fortification of foodstuffs in order to achieve the correction of specific micronutrient deficiencies. Salt fortification is the most effective way to prevent iodine deficiency disorders. Supplementary feeding is one of the most common approaches for the prevention of undernutrition, which is also used for the purpose of treating undernutrition (11).

1.3 Enteral nutrition

Enteral nutrition is a method of delivering nutrition through the gastrointestinal tract by means of either tube, catheter or stoma (28). Enteral nutrition is used for individuals who cannot maintain their nutritional requirements through oral intake but have a functional intestine. The concept of such nutrition is based on the fact that food or enteral formulas are given directly into the stomach or the small bowel (29). Enteral nutrition is applicable in different environments such as homes, home care settings or hospitals (30). In addition to feeding, it can serve as a mean for administering drugs to individuals who have problems with swallowing (31).

1.3.1. Routes of enteral feeding

Enteral nutrition can be applied through different feeding routes, as shown in Figure 6. Nasoenteric feeding tubes are inserted through the nostril all the way to the stomach or jejunum, so it is important to distinguish between a nasogastric tube and a nasojejunal tube. Percutaneous gastrostomy (PG) is a mode of feeding that is applied in the stomach, and can be performed by inserting a gastrostomy tube through the abdominal or oral route. Gastrostomy tube placement into stomach can be performed endoscopically, surgically or with image guidance. Percutaneous jejunostomy (PJ) is a mode of feeding that is applied to the jejunum through the abdominal wall. Gastrostomy tube placement into jejunum can be performed endoscopically or surgically (30).

Post pyloric sites for enteral feeding are duodenal or jejunal (32). Percutaneous gastrostomy with jejunal extension is a mode of nutrition in which a thin tube passes through the percutaneous gastrostomy tube in order to infuse a nutritional preparation into the jejunum (30).

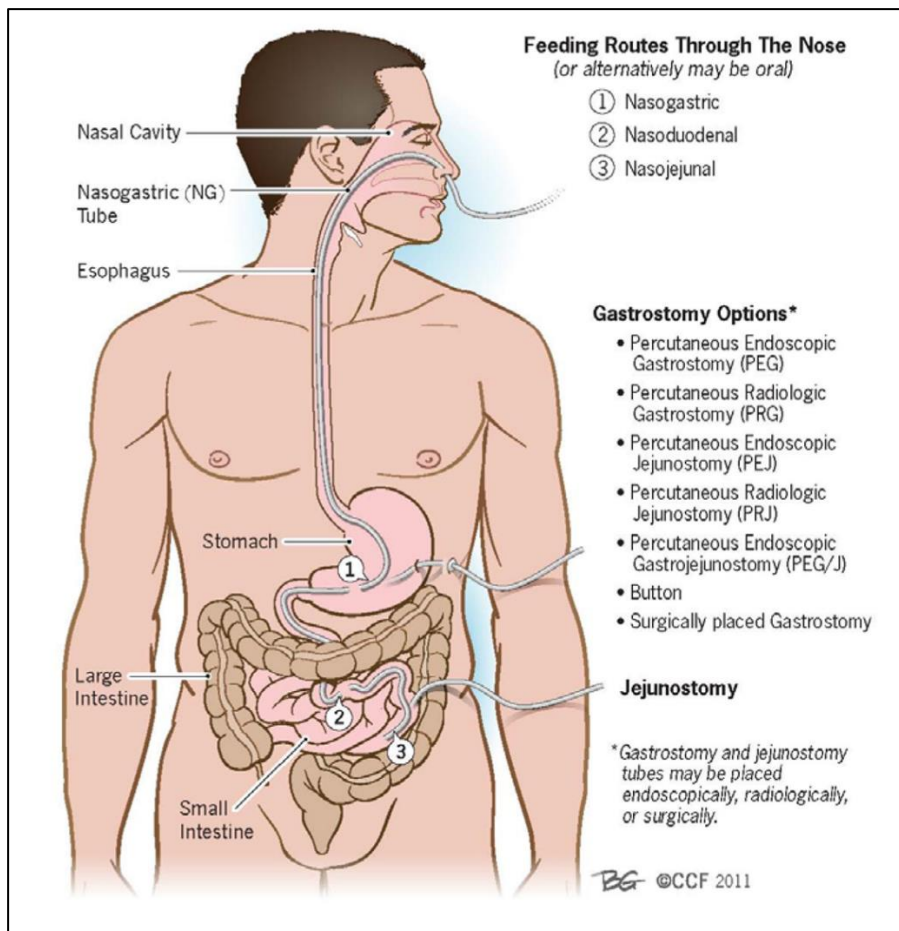


Figure 6. Enteral Access. Source: (33).

1.3.2. Short term and long term enteral nutrition

Enteral nutrition can be used for both short term and long term nutritional support (30). Nasogastric or nasojejunal tubes are the most frequently chosen methods in situations when short term feeding is expected for less than four weeks (34). The stomach is the preferred route for the administration of enteral nutrition, but occasionally a nasojejunal tube is preferred due to indications such as gastroparesis (35). Gastrostomy or jejunostomy are the preferred methods for long term enteral nutrition (30). Such tubes are used for long-term enteral nutrition because they can be left in place for months to years. If the patient recovers and regains the ability to feed by mouth, then the tubes can be removed and the hole usually heals and closes on its own (35).

1.3.3. Methods of enteral nutrition administration

Administration of enteral nutrition can be performed by bolus, intermittent, cyclic, and continuous techniques. These techniques can be used alone or in combination with each other. Continuous method of enteral feeding is based on hourly administration of nutrition by electric pump over 24 hours. This method is preferred in patients who are critically ill and is most often used in intensive care units.

Cyclic method of enteral feeding is also powered by an electric pump but in periods under 24 hours, and the goal infusion rate is determined. Intermittent administration technique is initiated via infusion pump or gravity drip method. Intermittent feeding takes place four to six times a day for twenty to sixty minutes. Bolus feeding technique is performed in a very short period and is given via gravity drip or syringe. Bolus feeding is performed about 3 to 6 times a day. Due to the rapid infusion, this method may lead to diarrhea or aspiration. The algorithm of nutritional supplementation is demonstrated in Figure 7 (36).

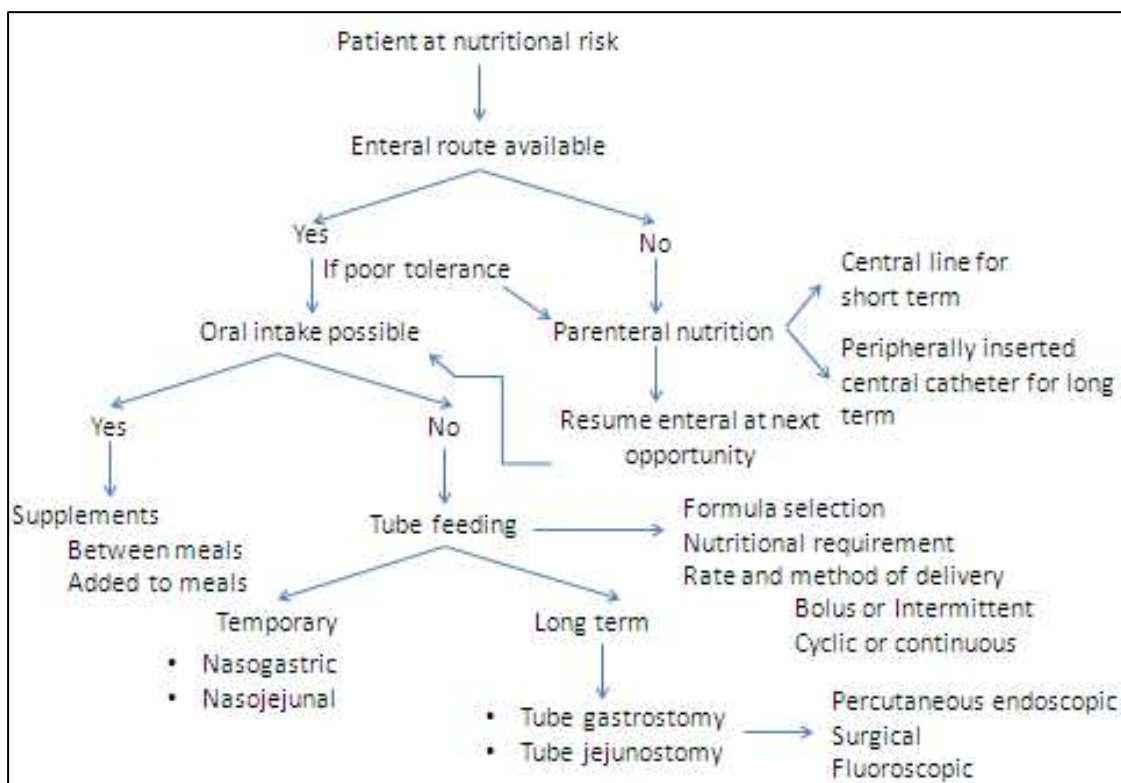


Figure 7. Algorithm of nutritional supplementation. Source: (37).

1.3.4. Enteral formulas

Enteral formulas can be classified as nutritionally complete or nutritionally incomplete. Nutritionally complete formulas can be used both as a sole source of nutrition or as a supplement. Nutritionally incomplete formulas can be used only as supplements (38). Enteral nutrition formulas can be standard formulas, peptide-based formulas, immune modulating formulas, disease specific formulas, and blenderized formulas.

Standard formulas contain intact nutrients and can be with or without fiber. Such formulas may be tolerated by most intensive care unit patients. Peptide-based formulas are used in malabsorption conditions, and are easier to digest as protein is already hydrolyzed. Immune enhancing or modulating formulas contain antioxidant components found in other peptide-based formulas but also contain glutamine and arginine (32).

1.3.5. Indications

The indications for enteral nutrition include malnutrition with insufficient oral intake due to different chronic conditions, dysphagia caused by head trauma or neurological conditions, luminal obstruction caused by head and neck cancers, luminal obstruction caused by esophageal or stomach cancer, post-operative fistulas located in the upper digestive tract, and hypercatabolic states such as extensive burn injuries (30). In general, enteral nutrition is most often indicated for neurological disorders associated with dysphagia, such as stroke, Parkinson's disease and amyotrophic lateral sclerosis (32). For most of these indications, gastric enteral nutrition is appropriate. Jejunal enteral feeding is an alternative that is indicated in cases such as severe gastroesophageal reflux disease, gastroparesis, gastric outlet obstruction, duodenal outlet obstruction, gastric fistula, and in case of gastrectomy due to altered anatomy that makes it impossible to insert a gastric enteral tube. In general, jejunal feeding is recommended for any patient who has severe reflux, an increased risk of aspiration or who does not tolerate gastric feeding. Jejunal access is also useful to avoid gastric stimulation in patients with severe acute pancreatitis (30).

1.3.6. Contraindications

Absolute contraindications to enteral nutrition are severe coagulopathy, intestinal ischemia, bowel occlusion and peritonitis. Certain nasal or facial injuries exclude the option of enteral nutrition via a nasogastric or nasojejunal tube. A relative contraindication for placing a percutaneous gastrostomy is active bleeding from a gastric or duodenal ulcer. The presence of a ventriculo-peritoneal shunt in a patient during the placement of a percutaneous gastrostomy tube may increase the risk of meningitis. The location for the insertion of the enteral tube can be changed due to the presence of anatomical alterations such as surgical scars, abdominal wall hernias or open abdomen (30).

1.3.7. Complications related to enteral nutrition

The most frequent complications related to enteral nutrition are diarrhea, aspiration, and metabolic abnormalities. Regarding diarrhea, the frequency may be due to the high osmolality that is present in enteral food formulations, but there are also patient related risk factors such as severe malnutrition, *Clostridium difficile* infection, and medications. Aspiration as a complication is common when neurological patients are unable to keep their airways protected.

Aspiration of large volumes can cause pneumonia, but it can lead to more severe consequences such as respiratory failure and death. Hyperglycemia, micronutrient deficiency and electrolytic disturbances are metabolic complications related to enteral nutrition. Refeeding syndrome is a particularly dangerous metabolic complication that can occur during administration of any type of oral, enteral, or parenteral feedings in malnourished patients. It is characterized by rapid changes in fluid and electrolyte levels, and is most often manifested as severe hypokalemia, hypomagnesemia, and hypophosphatemia (30). Mechanical complications related to enteral nutrition may include tube dislodgement, clogging or occlusion. Mechanical complications may lead to severe injury such as perforation of the esophagus or bowel (39).

1.4 Percutaneous endoscopic gastrostomy (PEG)

1.4.1. Introduction

Percutaneous endoscopic gastrostomy (PEG) is one of the most frequent endoscopic procedures performed in the world. It is performed to provide route of feeding and nutritional support in patients with a functionally preserved gastrointestinal system who require long-term enteral nutrition support. It provides numerous advantages over parenteral nutrition, and in addition to that, it offers superior access to the gastrointestinal system compared to surgical methods. Enteral feeding together with stomach decompression constitute the main indications for percutaneous endoscopic gastrostomy procedure. Overall, it is considered to be a safe procedure. However, it is important to be aware of potential complications and contraindications associated with this procedure. Percutaneous endoscopic gastrostomy tube placement can be performed via different methods, among which the pull technique is most commonly used (40).

1.4.2. History

Percutaneous endoscopic gastrostomy was initially developed for pediatric patients with an inability to swallow. It was first presented in Florida in 1980, at the American Pediatric Surgical Association annual meeting. Soon afterward, percutaneous endoscopic gastrostomy was adopted for adult patients by both gastroenterologists and surgeons (41). Initially, the method was used to provide adequate nutrition in neurologically impaired patients while avoiding the need for more invasive approaches such as laparotomy, which was part of traditional gastrostomy. Over the years, many additional indications have been developed for percutaneous endoscopic gastrostomy (42).

1.4.3. Preparation of patients for PEG procedure

Preparation of patients for PEG procedure starts with obtaining informed consent from patients or legal caretakers. The purpose of informed consent is providing the patient with information regarding both benefits and potential complications associated with PEG procedure and enteral feeding. Patients are instructed to fast overnight or at least eight hours before the procedure. Antibiotic prophylaxis should be administered to the patient one hour before the procedure. According to Rahnemai-Azar et al., intravenous injection of 1-2 g cephazolin is the gold standard (40).

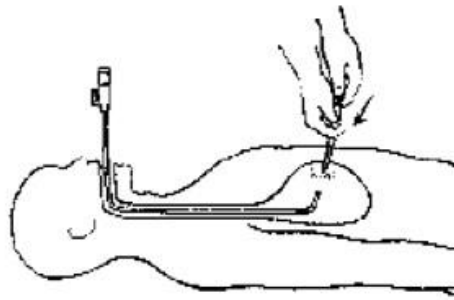
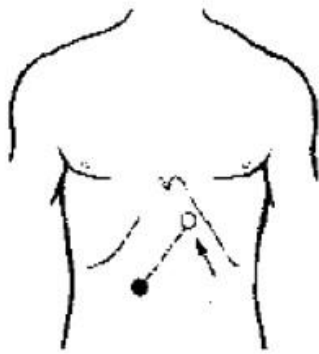
1.4.4. Techniques for PEG tube placement

PEG tube insertion can be achieved by different techniques. In all insertion techniques, the aim is to insert the PEG tube through the abdominal wall. Location of insertion is determined by finding a point on the abdominal wall where the stomach is in closest contact with the abdominal wall (40). For all four types of insertion, the PEG insertion site is defined with the assistance of endoscopic transillumination and finger indentation (40,43).

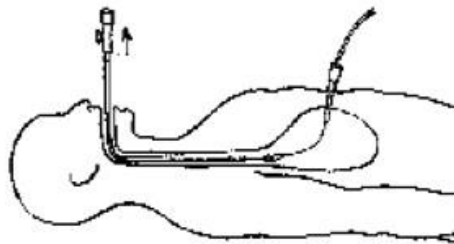
1.4.4.1. Pull method

The pull method is the most commonly used method for PEG tube placement in clinical practice. As shown in Figure 8 in this technique, the string is inserted through a needle that is placed in the abdominal wall. After the string enters the stomach, endoscopic biopsy forceps are used to extract the string first through the esophagus then through the mouth. The next step consists of attaching the string to the outside of the feeding tube. Finally, the feeding tube is pulled through the mouth, esophagus, stomach and eventually through the abdominal wall (40). This technique is also known as the Ponsky-Gauderer method (44).

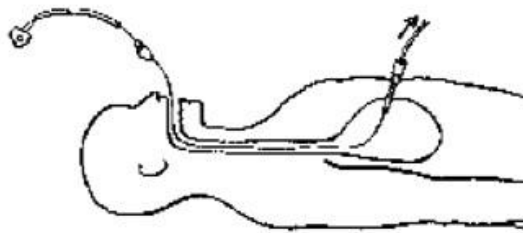
1. Puncture of the abdominal wall under endoscopic control and infiltration of 5-10 ml local anaesthesia.



2. Insertion of the intragastric catheter and the guidewire into the stomach. Removal of the guidewire with the endoscope through the mouth.



3. External fixation of the PEG-tube and pull it through the gastric and abdominal wall.



4. Fixation of the feeding-tube.

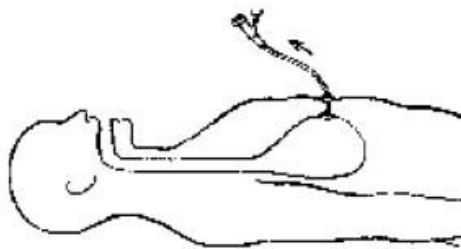


Figure 8. Percutaneous endoscopic gastrostomy (pull method). Source: (45).

1.4.4.2. Push method

The first step is to insert the guide wire into the stomach. After that, the guide wire is pulled out with an endoscope first through the esophagus and then the mouth. Finally, we use a guide wire to push the feeding tube back into the stomach and eventually through the puncture site (40). This technique is also known as Sacks-Vine method (44).

1.4.4.3. Introducer method

Under endoscopic view, this technique uses the Seldinger method to insert the guide wire into the lumen of the stomach. After that, a guide wire is used to pass the dilating catheter and sheath over it. The feeding tube is advanced through the peel-away sheath after the removal of the guide wire (40). Such an approach may reduce the risk to some extent regarding tumor metastasis and infection. This technique is recommended in cases where the introduction of a tube with the pull method is difficult to achieve, as in the case of severe esophageal stenosis.

The disadvantage of this technique is more complicated tube maintenance. The use of the trocar is responsible for the increased cost of the procedure and for the extended time of the procedure. This technique is also known as the Russell method (44). The introducer method can be performed with or without gastropexy (46).

1.4.4.4. Modified introducer method

This insertion technique starts with gastropexy in order to fix the abdominal wall together with the gastric wall as shown in Figure 9. This fixation is secured with stitches. Between sutures, a skin incision is performed which is followed by a puncture.

The next part of the procedure involves inserting a guide wire inside the stomach lumen. The insertion site is then percutaneously expanded with a 27-Fr dilator. Finally, the guidewire is used to implement the PEG catheter with the help of an obturator (43).

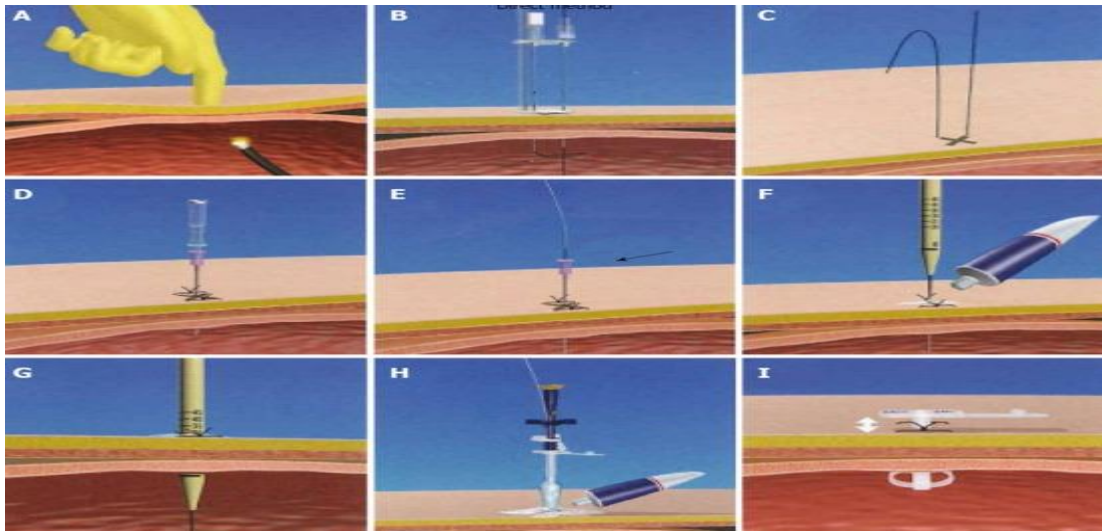


Figure 9. Percutaneous endoscopic gastrostomy (modified introducer method). Source: (47).

1.4.5. Initiation of feeding after PEG placement

The initiation of feeding is most often done around 12-24 hours after PEG tube insertion, although such practice is not based on findings from randomized controlled trials. Currently, early feeding is considered safe and has the potential to reduce healthcare costs as well as to achieve desired nutritional status in patients at an earlier time (48).

1.4.6. Indications

PEG is a tool that is implemented for the purpose of optimizing the nutritional status of patients. When nutritional support is needed for less than a month, the nasogastric tube is most often used as an instrument to provide such support.

It is recommended to consider the use of PEG when nutritional support is needed for a longer period, more specifically about a month or more. The period of four weeks or one month was chosen mostly for reasons to prevent many adverse effects associated directly with percutaneous access. Indications for PEG placement can be divided into benign and malignant diseases. Many diseases can be included in the benign category, but PEG is especially often used as a means of nutrition in patients with neurological conditions. Examples of such conditions are dementia, stroke, motor neuron diseases, Parkinson's disease and head injuries with neurological damage. Other indications that can be classified as benign are polytrauma, facial surgery, burns, prolonged coma, intensive care patients, benign esophageal strictures and short bowel syndrome. Indications that are specific to the pediatric population include cerebral palsy, cystic fibrosis, and congenital anomalies such as tracheoesophageal fistula. Malignant diseases for which PEG may be indicated are head and neck tumors, esophageal tumors, cerebral tumors, and any oncological disease associated with hypercatabolism that cannot be corrected by oral nutrient intake.

PEG is not used exclusively as a mean of nutritional support but has other indications such as gastric decompression. PEG related gastric decompression is used to achieve symptomatic relief in patients with gastric outlet obstruction or in cases of intestinal stricture (49).

The PEG tube can also be used for the administration of drugs. Before administration of drugs, it is very important to consider tube size because narrow-bore tubes increase the risk of clogging (40).

1.4.7. Contraindications

Contraindications related to PEG tube placement can be absolute and relative (49). Absolute contraindications include conditions such as sepsis, peritonitis, peritoneal carcinomatosis, history of total gastrectomy, interposed organs and abdominal wall infection at the selected site of placement (40,49). If PEG tubes are used for nutrition, then absolute contraindications additionally include gastric outlet obstruction and severe gastroparesis (40).

Given that PEG placement belongs to the group of procedures associated with a high risk of bleeding, blood findings such as partial thromboplastin time > 50 seconds, international normalized ratio > 1.5 and platelet count < 50000 mm³ are also considered as absolute contraindications for this procedure.

Relative contraindications include abdominal scars, peptic ulcer bleeding with high risk of rebleeding, ventriculoperitoneal shunts, ascites, large intrathoracic hiatal hernia, and hemodynamic and respiratory instability (49). PEG tubes are generally avoided during pregnancy due to the risk of uterine or fetal damage or the risk of infection, but there are cases when PEG tubes have been successfully implemented during pregnancy (48).

1.4.8. Complications

In general, PEG tube placement is considered a safe procedure. Complications related to PEG tube placement can be classified into two groups, more precisely as minor and major complications. In general, major complications are rare. Major complications include bleeding, internal organ injury, aspiration pneumonia, necrotizing fasciitis, metastatic seeding, and buried bumper syndrome. Buried bumper syndrome is a complication closely related to the use of PEG tubes with an internal bumper. The mechanism of this syndrome is ischemic necrosis affecting the gastric wall due to excessive tension between the external and internal bumpers. Consequently, the PEG tube becomes dislodged along the PEG tract. In such a condition, it is crucial to remove the PEG tube quickly to prevent perforation, peritonitis or even death. Minor complications include granuloma formation, local wound infection, peristomal leakage, tube dislodgement, gastric outlet obstruction and pneumoperitoneum. Local wound infection is the most common among the minor complications associated with PEG placement (40). Gastrocolocutaneous fistula is another complication that can occur in patients with a PEG tube. In most cases, the clinical presentation of such fistula develops gradually, but sometimes it can manifest acutely with peritonitis or intestinal obstruction. Depending on the clinical manifestation, it can be treated conservatively or with surgical or endoscopic procedures (48).

1.4.9. Post-insertion care

Given that many patients complain of abdominal discomfort after PEG tube insertion, it is recommended that adequate pain relief should be achieved. Feeding can begin and is considered safe 4 hours after PEG placement. Part of the post-insertion care is an examination of the stoma and the purpose of such an investigation is to note any suspicious signs such as pain, discoloration or pus. The stoma should be cleaned every day. After the stoma is completely healed, the PEG tube should be rotated and moved up and down every day. Rotational movements are limited to 180 degrees, while up and down movements should not exceed 1 to 2 cm in the stoma site. Before and after each feeding or drug administration, flushing of the PEG tube should be done to prevent clogging and subsequent blockage of the tube (40).

1.4.10. Removal of PEG

PEG is removed when it is no longer indicated or when certain serious complications appear, such as buried bumper syndrome or persistent leakage.

In adult patients, the technique that can be used for PEG removal is the "cut and push" technique, but due to life-threatening complications, endoscopic PEG removal is still preferred. PEG is always removed by an endoscopic procedure in children due to the high risk of complications. The PEG tract is expected to heal and close a few days after the PEG is removed. In some cases, gastrocutaneous fistula persists (40).

1.5 1.5. Quality of life

Many different definitions exist to describe the quality of life (QoL) and there is no universal consensus on this topic.

One of the definitions describes the quality of life as a personal perception of one's own position in life in the context of the cultural environment and value systems in which one lives. Subjective judgment is the basis of many definitions of quality of life, but many experts believe that objective factors should be additionally considered when describing quality of life (50). Quality of life includes many factors that are related to each other, such as values, satisfaction, accomplishments, perspectives, functionality, spirituality and culture (51). Quality of life became more important in medical care as treatments progressed and consequently length of life extended for many medical conditions (50). Consequently, the trend in medicine is to increasingly consider the quality of life of patients. Information obtained from quality of life assessments are used to improve medical care, symptomatic relief and patient rehabilitation. Quality of life can be used as a predictor of both treatment success and survival (52). There is also no consensus on the definition of health-related quality of life (HRQoL). Health-related quality of life can be defined as aspects of self-perceived health status that are affected by illness or treatment. HRQoL is an important indicator of how general health affects the quality of life. HRQoL questionnaires are designed to measure self-perceived health status. The terms quality of life and health-related quality of life are used interchangeably (50).

1.5.1. Quality of life in percutaneous endoscopic gastrostomy patients

The quality of life of enterally feeding patients is very important because the enteral feeding method can be long-lasting and life sustaining (53). Although PEG is considered a harmless procedure and many patients are satisfied with its application, there are characteristics related to the application of such a feeding technique that can reduce the quality of life (54). Many negative impacts associated with percutaneous endoscopic gastrostomy feeding have been described in the available literature. Such disturbances can be present in everyday life and significantly affect the quality of life. Unwanted events such as disturbed sleep or interferences with social life or with everyday activities can be present as a consequence of such a feeding method (53).

Although the focus is mostly on problems related to social life, it must also be taken into account that the unwanted effects of PEG tube placement, such as pain and infections, can reduce the quality of life in this group of patients as well. Mechanical problems related to the use of a PEG tube is another concern that patients may face. Examples of possible technical problems are blockage and leakage. With the enteral type of feeding, patients can lose all pleasure related to mealtime.

Considering the fact that many patients are feeding through a PEG tube in the home environment, they or their caregivers must be motivated and have knowledge in order to prevent and also solve everyday problems related to such feeding technique. Personal characteristics and preferences of patients can influence the quality of life and satisfaction related to the use of PEG. Although PEG can greatly affect the patients themselves, it can also affect the lives of family members or caregivers, who in many cases are the main individuals who take care of feeding through PEG in the home environment (54).

2. OBJECTIVES

1.6 2.1. Aim of the study

This study has the following aims:

1. To assess the nutritional status of patients who are enterally feeding via percutaneous endoscopic gastrostomy tube in the home environment.
2. To assess the quality of life of patients who are enterally feeding via percutaneous endoscopic gastrostomy tube in the home environment.

Hypothesis:

1. The high overall risk for malnutrition will be lower compared to the combined low and moderate risks among patients who are enterally feeding via percutaneous endoscopic gastrostomy tube in the home environment.
2. Patients who are enterally feeding via percutaneous endoscopic gastrostomy tube in the home environment will report that PEG does not reduce their quality of life.

3. SUBJECTS AND METHODS

3.1. Study design and participants

This cross-sectional study included a total of 31 participants who were recruited from the Department of Gastroenterology at the University Hospital of Split. All participants were 18 years or older. The study included patients who have been feeding via percutaneous endoscopic gastrostomy for a period of at least 3 months in the home environment. The study was conducted in the form of three different questionnaires that were answered over the phone. Telephone interviews were conducted during the months of June and July 2022. At the beginning of each telephone conversation, patients were informed about the goals of the research, and they were asked if they would participate in the research. The participant's consent to continue the interview was considered as informed consent. If the patients were unable to answer the questions by themselves due to their health condition, their family members or caregivers assisted or answered the questions for them. The study protocol was approved by the Ethics Committee of the University Hospital of Split (No: 500-03/22-01/109).

3.2. Methods

In order to assess the nutritional status and quality of life of the subjects, three different questionnaires were used. Additionally, the age, gender and referral diagnosis of each subject was recorded.

3.2.1. Nutritional status

The Malnutrition Universal Screening Tool (MUST) questionnaire was used to assess nutritional status. The MUST questionnaire is used for the purpose of detecting patients who are malnourished or are at risk of malnutrition. MUST relies on three criteria to determine the overall risk for malnutrition.

These criteria include body mass index (BMI), unplanned weight loss, and acute disease associated with no nutritional intake for more than five days. Each criterion can be rated as 0, 1, or 2. Overall risk of malnutrition is determined by the sum of the scores for all three criteria. Low, moderate and high risks of malnutrition correspond to an overall score of 0, 1, and ≥ 2 , respectively (21).

3.2.2. Health-related quality of life (HRQoL) assessment

Health-related quality of life (HRQoL) was assessed by EQ-5D-3L questionnaire and Liverpool PEG questionnaire.

The EQ-5D-3L questionnaire contains five dimensions. Dimensions include mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension can be graded by three response levels that correspond to no problems, some problems, and extreme problems (55).

The second part of the EQ-5D-3L questionnaire consists of the EuroQol-Visual Analogue Scale (EQ-VAS). The EuroQol-Visual Analogue Scale (EQ-VAS) is a tool used for patients to self-assess their health state. Worst imaginable health and best imaginable health are rated as 0 and 100, respectively (56).

The Liverpool PEG questionnaire was created on the basis of certain complications related to the placement of a percutaneous endoscopic gastrostomy tube. The questionnaire inquiries about duration of PEG use, problems related to PEG use, how often it was used and how many times their PEG needed replacing. At the same time, the questionnaire inquiries about how much patients think about the PEG and how much they want the PEG to be removed. Not at all, a little, quite a bit and very much are offered answers for most of the questions in this questionnaire (57).

3.3. Statistical analysis

Statistical data analysis was done by Statistical software MedCalc (Ostend, Belgium; version 11.5.1.0) for Windows. Kolmogorov–Smirnov test was used to assess normality of data distribution. Continuous variables were presented as means \pm SD or as median (Q1-Q3; min-max). Categorical variables were presented as numbers and percentages. Analysis of statistical significance of differences in EQ VAS score among three groups was performed by the Kruskal–Wallis test. Analysis of statistical significance of differences in EQ VAS score between 2 groups was performed by the Mann–Whitney U test. The comparison of two categorical variables was performed with the chi-square test. Correlation between two continuous variables was performed by Spearman's correlation test. Statistical significance of differences in categorical characteristics was calculated by Fisher's exact test. Statistical significance was set at $P < 0.05$.

4. RESULTS

In this study, a total of 31 participants were enrolled, of which 21 (68%) were men and 10 (32%) were women. The median age of the participants was 66 years (Q1-Q3: 53-73; min-max: 21-85). The median age of male participants was 66 years (Q1-Q3: 54-73; min-max: 21-78), while the median age of female participants was 62.5 years (Q1-Q3: 51-77; min-max: 50-85). There was no statistically significant difference in age between men and women ($Z = 0.127$; $P = 0.899$) – Mann–Whitney U test.

Table 1. Number (%) of patients according to indication for PEG.

Indication for PEG	N (%)
Head and neck cancer (HNC)	6 (19.4)
Esophageal cancer	4 (12.9)
Stomach cancer	1 (3.2)
Stroke	8 (25.8)
Coma	2 (6.5)
Parkinsonism	1 (3.2)
Amyotrophic lateral sclerosis (ALS)	2 (6.5)
Progressive supranuclear palsy (PSP)	2 (6.5)
Alzheimer's disease	1 (3.2)
Cerebral Palsy	3 (9.7)
Poliomyelitis	1 (3.2)

In Table 1 we concluded that the most frequent indication was stroke, followed by head and neck cancer (HNC) and esophageal cancer.

All participants were enterally feeding via percutaneous endoscopic gastrostomy tube in a home environment. The mean duration of PEG use was 2.5 ± 2.7 years. The median duration was 1 year (Q1-Q3: 0.42-4.6; min-max: 0.25-8.5).

In this group of patients (n = 31) it was found that:

1. 5 (16%) patients used PEG very occasionally for feeding
2. 8 (26%) patients used PEG often for feeding
3. 4 (13%) patients used PEG frequently for feeding
4. 14 (45%) patients used PEG all the time for feeding

PEG tube needed to be replaced in:

1. 3 (10%) patients once
2. 2 (6.5%) patients twice
3. 2 (6.5%) patients three times
4. 10 (32%) patients four or more times
5. 14 (45%) patients never

The mean body mass index (BMI) was $21.3 \pm 4.2 \text{ kg/m}^2$. The median body mass index (BMI) was 22.5 kg/m^2 (Q1-Q3: 18.6-24.4; min-max: 12.1-30.7).

Table 2. Number (%) of participants according to BMI categories.

Categories of BMI (kg/m^2)	N (%)
Underweight (< 18.5)	7 (23)
Normal weight (18.5-24.9)	20 (64)
Overweight (> 25)	4 (13)

In Table 2 the participants are categorized according to body mass index (BMI) into 3 categories:

1. Underweight (BMI $< 18.5 \text{ kg/m}^2$)
2. Normal weight (BMI: 18.5-24.9 kg/m^2)
3. Overweight (BMI $> 25 \text{ kg/m}^2$)

There was one patient with BMI = 30.7 kg/m^2 and three patients with BMI: 26.1-26.3 kg/m^2 in category of overweight patients in Table 2. There was one patient with BMI = 12.1 kg/m^2 and six patients with BMI: 13.6-18.3 kg/m^2 in category of underweight patients in Table 2.

Table 3. Number (%) of participants according to the results of the MUST questionnaire

	N (%)	
Unplanned weight loss in last 3-6 months	<5%	24 (77)
	5-10%	5 (16)
	>10%	2 (7)
Overall risk of malnutrition	Low risk	16 (52)
	Medium risk	6 (19)
	High risk	9 (29)

In Table 3 the results of the MUST questionnaire are presented.

In category < 5% for unplanned weight loss in last 3-6 months 22 patients didn't lose their weight and only 2 lost less than 5%.

The number of patients with unplanned weight loss \geq 5% was 7 in last 3-6 months.

There were no participants that fit into category „If patient is acutely ill and there has been or is likely to be no nutritional intake for > 5 days.

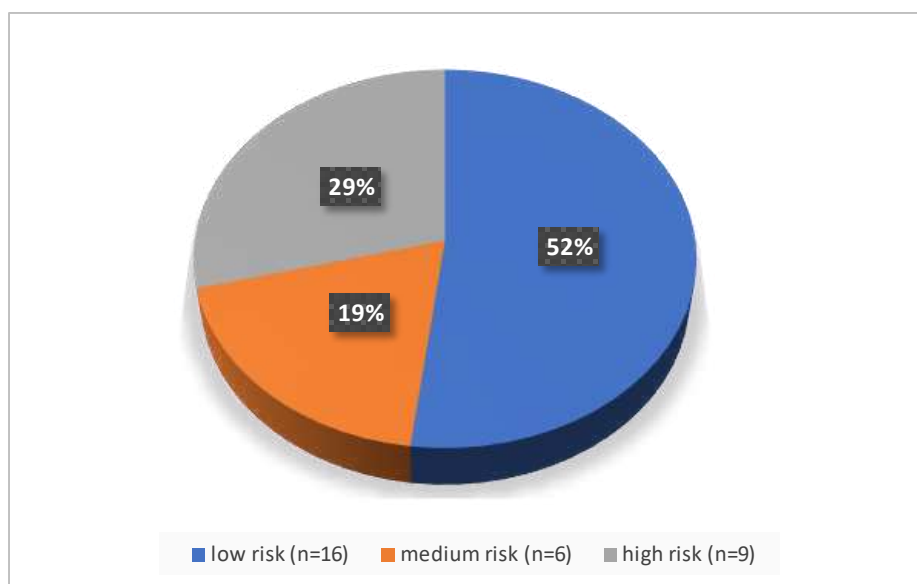


Figure 10. Distribution of the overall risk of malnutrition in 31 participants who are feeding via PEG in the home environment.

The distribution of the overall risk of malnutrition was not statistically different in comparison to uniform distribution with expected frequency $n = 10$ ($\chi^2 = 5.3$; $P = 0.071$). If the high risk of malnutrition is compared to the other risks (merged low and medium risks), it turns out that the high risk is 2.44 times lower than the other risks ($\chi^2 = 5.7$, $P = 0.017$)

Table 4. EQ-5D-3L frequencies reported by dimension and levels of perceived problems.

Level (answer)	Mobility n (%)	Self-care n (%)	Usual activities n (%)	Pain/discomfort n (%)	Anxiety/depression n (%)
Level 1	9 (29)	7 (22.6)	4 (13)	14 (45)	6 (19)
Level 2	5 (16)	7 (22.6)	10 (32)	10 (32)	9 (29)
Level 3	17 (55)	17 (54.8)	17 (55)	7 (23)	16 (52)
Total	31 (100)	31 (100)	31 (100)	31 (100)	31 (100)

In Table 4 the domains (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and levels of perceived problems (level 1, level 2, level 3) are shown. Level 1, level 2 and level 3 correspond to no problems, some problems, and extreme problems, respectively.

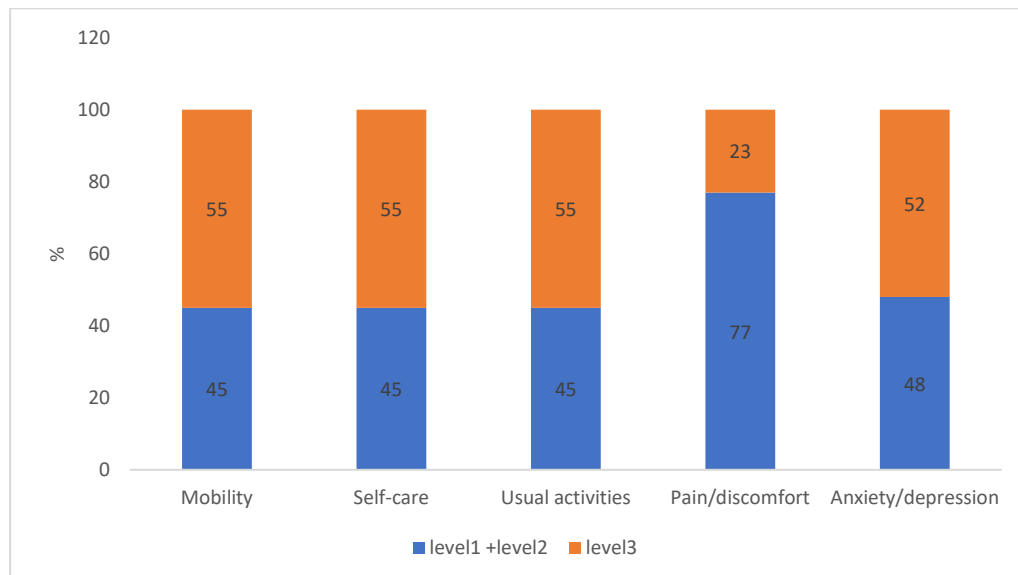


Figure 11. Distribution of levels of perceived problems (merged level 1 and 2; level 3) according to domains from EQ-5D-3L questionnaire in 31 participants who are feeding via PEG in the home environment.

It is clear from Figure 11 that 55% of patients were confined to their bed, unable to wash or dress themselves, and to perform their usual activities; 52% of patients were extremely anxious or depressed, but only 23% of patients had extreme pain or discomfort.

The mean value of the EQ-VAS score was 37.3 ± 29 ; the median value was 30 (Q1-Q3: 10-50; min-max: 1-99) (95% CI: 20-50). In this study, the median quality of life according to the EQ VAS score is 30 (95% CI: 20-50), which means that based on this study we can conclude that in the population of such patients who are enterally feeding via PEG in the home environment, median quality of life according to the EQ VAS score is from 20 to 50 with a probability of 95%.

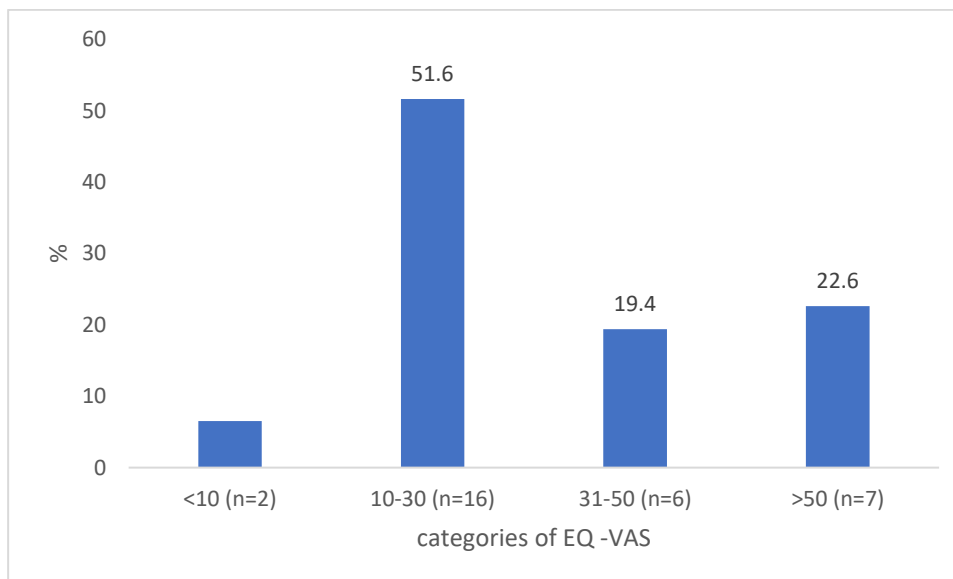


Figure 12. Frequency distribution of EQ VAS score according to median and quartiles in 31 participants who are feeding via PEG in the home environment.

The highest frequency of EQ VAS score (51.6%) was between 10 and 30. One patient in the category of EQ VAS score < 10 had a value of EQ VAS score = 1. In the group of EQ VAS score > 50, one patient had EQ VAS score = 99 and two of them had EQ VAS score = 90.

Table 5. Comparison of EQ VAS scores between two categorical groups according to age, BMI and total duration of PEG use.

		EQ VAS score Median (Q1-Q3; min- max)	<i>P</i> *
BMI (kg/m ²)	<18.5	50 (20-90; 10-99)	0.190
	≥18.5	27.5 (10-50; 1-90)	
Age (year)	≤ 66	30 (10-72; 1-99)	1.0
	>66	30 (10-50; 10-90)	
Total duration of PEG use (year)	≤1	30 (22.5-50;1-99)	0.193
	>1	15 (10-65; 1-90)	

* Mann–Whitney U test

In Table 5, EQ VAS score was compared with age, BMI and total duration of PEG use. Participants were categorized into two groups according to median age (≤ 66 ; > 66), BMI (< 18.5 ; ≥ 18.5) and median total duration of PEG use (≤ 1 ; > 1).

There was no statistically significant difference in EQ VAS scores between age groups (≤ 66 ; > 66) ($Z = 0$; $P = 1$).

There was no statistically significant difference in EQ VAS scores between BMI groups (< 18.5 ; ≥ 18.5) ($Z = 1.3$; $P = 0.190$)

There was no statistically significant difference in EQ VAS scores between groups of total duration of PEG use (≤ 1 ; > 1) ($Z = 1.3$; $P = 0.193$).

Spearman rank correlation coefficient between EQ VAS score and age of patients ($\rho = -0.036$; $P = 0.848$) was not statistically significant.

Spearman rank correlation coefficient between EQ VAS score and BMI ($\rho = 0.013$; $P = 0.945$) was not statistically significant.

Spearman rank correlation coefficient between EQ VAS score and total duration of PEG use ($\rho = -0.288$; $P = 0.116$) was not statistically significant.

Table 6. Median (Q1-Q3; min-max) EQ VAS scores according to levels of perceived problems.

		EQ VAS score Median (Q1-Q3; min- max)	<i>P</i> *
Mobility	No problems in walking about + some problems in walking about	45 (24-80; 10-99)	0.025*
	Confined to bed	20 (10-45;1-90)	
Self-care	No problems with self-care + some problems washing or dressing myself	45 (24-80; 10-99)	0.025*
	Unable to wash or dress myself	20 (10-45;1-90)	
Usual activities	No problems with performing my usual activities + some problems with performing my usual activities	45 (24-80; 10-99)	0.025*
	Unable to perform my usual activities	20 (10-45; 1-90)	
Pain/discomfort	No pain or discomfort	30 (17-80;1-99)	0.574 [†]
	Moderate pain or discomfort	17.5 (10-57;1-90)	
	Extreme pain or discomfort	30 (20-50; 10-50)	
Anxiety/depression	Not anxious or depressed	35 (27-92; 20-99)	0.098 [†]
	Moderately anxious or depressed	50 (17-80; 10-80)	
	Extremely anxious or depressed	20 (10-48; 1-90)	

* Mann–Whitney U test; [†] Kruskal–Wallis test

Remark: In the analysis, levels 1 and 2 were combined for the domains of mobility, self-care and usual activities. There was no statistically significant difference in the EQ VAS scores between levels 1 and 2 for the domains of mobility, self-care and usual activities ($P > 0.05$).

Median EQ VAS score was greater by 25 at level 1 + 2 than at level 3 in the mobility domain ($Z = 2.24$; $P = 0.025$).

Median EQ VAS score was greater by 25 at level 1 + 2 than at level 3 in the self-care domain ($Z = 2.24$; $P = 0.025$).

Median EQ VAS score was greater by 25 at level 1 + 2 than at level 3 in the usual activities domain ($Z = 2.24$; $P = 0.025$).

There was no statistically significant difference in the EQ VAS score between the three levels of the pain/discomfort domain ($\chi^2 = 1.11$; $P = 0.574$).

There was no statistically significant difference in the EQ VAS score between the three levels of the anxiety/depression domain ($\chi^2 = 4.65$; $P = 0.098$).

Table 7. Association of Liverpool PEG questionnaire answers with EQ VAS score categories (≤ 30 ; > 30).

	EQ VAS values	How much of a problem has the PEG been to you				% with any Problem	P*
		1. Not at all	2. A little	3. Quite a bit	4. Very much		
Pain/Discomfort	≤ 30	9	6	2	1	50	1.0
	> 30	7	4	2	0	46	
	Total	16	10	4	1	48	
Leakage	≤ 30	6	8	3	1	67	1.0
	> 30	5	4	3	1	62	
	Total	11	12	6	2	65	
Dirtying of clothes by leakage	≤ 30	12	6	0	0	33	0.157
	> 30	5	6	2	0	62	
	Total	17	12	2	0	45	
Redness/irritation	≤ 30	9	6	3	0	50	0.717
	> 30	5	4	4	0	62	
	Total	14	10	7	0	55	
Blockage	≤ 30	9	8	0	1	50	0.717
	> 30	8	1	3	1	39	
	Total	17	9	3	2	45	
Bleeding	≤ 30	16	2	0	0	11	
	> 30	11	2	0	0	15	
	Total	27	4	0	0	13	
Infection	≤ 30	12	6	0	0	33	
	> 30	11	1	1	0	15	
	Total	23	7	1	0	26	
Tube splitting	≤ 30	12	4	2	0	33	1.0
	> 30	8	4	1	0	39	
	Total	20	8	3	0	36	
Falling out	≤ 30	15	3	0	0	17	
	> 30	11	2	0	0	15	
	Total	26	5	0	0	16	

*Table 7
continued*

Keeping the PEG and PEG site clean	≤30	17	1	0	0	6	
	>30	8	4	1	0	39	
	Total	25	5	1	0	19	
Appearance	≤30	12	5	1	0	33	1.0
	>30	8	4	1	0	39	
	Total	20	9	2	0	36	
Types of clothes worn	≤30	15	3	0	0	17	
	>30	12	1	0	0	8	
	Total	27	4	0	0	13	
Difficulties using the PEG tube	≤30	13	5	0	0	28	
	>30	12	1	0	0	8	
	Total	25	6	0	0	19	
Interference with family life	≤30	15	2	1	0	17	
	>30	11	2	0	0	15	
	Total	26	4	1	0	16	
Interference with intimate relationships	≤30	17	1	0	0	6	
	>30	13	0	0	0	0	
	Total	30	1	0	0	3	
Interference with social activities	≤30	14	4	0	0	22	0.433
	>30	8	5	0	0	38	
	Total	22	9	0	0	29	
Interference with hobbies or leisure time	≤30	15	2	1	0	17	0.228
	>30	8	5	0	0	19	
	Total	23	7	1	0	26	
How much PEG tube affected overall quality of life	≤30	16	2	0	0	11	0.208
	>30	9	3	1	0	31	
	Total	25	5	1	0	19	
How much do you think about your PEG	≤30	7	2	5	4	61	0.718
	>30	4	4	3	2	69	
	Total	11	6	8	6	65	

*Table 7
continued*

Do you wish the PEG could be removed	≤30	16	0	0	2	11	0.006
	>30	5	2	4	2	62	
	Total	21	2	4	4	32	

* Fisher's exact test

Fisher's exact test was used to find the association between answers from the Liverpool PEG questionnaire (not at all; any problem) and EQ VAS score (≤ 30 ; > 30).

Table 7 shows the results of the Liverpool PEG questionnaire in relation to health-related quality of life, which was assessed with the EQ-5D-3L questionnaire. Participants were divided into two groups with regard to health-related quality of life based on the median of the obtained EQ-VAS score values (≤ 30 ; > 30). There were 18 subjects in the EQ VAS score ≤ 30 group, and 13 subjects in the > 30 group.

There was no statistically significant association between the answers to the "pain/discomfort" question (not at all; any problem) ($P = 1.0$); "leakage" question (not at all; any problem) ($P = 1.0$); "dirtying of clothes by leakage" question (not at all; any problem) ($P = 0.157$); "redness/irritation" question (not at all; any problem) ($P = 0.717$); "blockage" question (not at all; any problem) ($P = 0.717$); "tube splitting" question (not at all; any problem) ($P = 1.0$); "appearance" question (not at all; any problem) ($P = 1.0$); "interference with social activities" question (not at all; any problem) ($P = 0.433$); "interference with hobbies or leisure time" question (not at all; any problem) ($P = 0.228$); "how much PEG tube affected overall quality of life" question (not at all; any problem) ($P = 0.208$); "how much do you think about your PEG" question (not at all; any problem) ($P = 0.718$) and values of EQ VAS score (≤ 30 ; > 30).

Due to small number of patients with bleeding (n = 4), infection (n = 8), falling out (n = 5), keeping the PEG and PEG site clean (n = 6), types of clothes worn (n = 4), difficulties using the PEG tube (n = 6), interference with family life (n = 5), and interference with intimate relationships (n = 1), associations between questions of "bleeding", "infection", "falling out", "keeping the PEG and PEG site clean", "types of clothes worn", "difficulties using the PEG tube", "interference with family life", "interference with intimate relationships" with EQ VAS score (≤ 30 ; > 30) were not analyzed.

The percentage of patients who wanted to remove PEG in the group with EQ VAS score > 30 was 61% (n = 8). This was 5.5 times more than the percentage of patients (11%; n = 2) who wanted to remove PEG in the group with EQ VAS score ≤ 30 ($P = 0.006$).

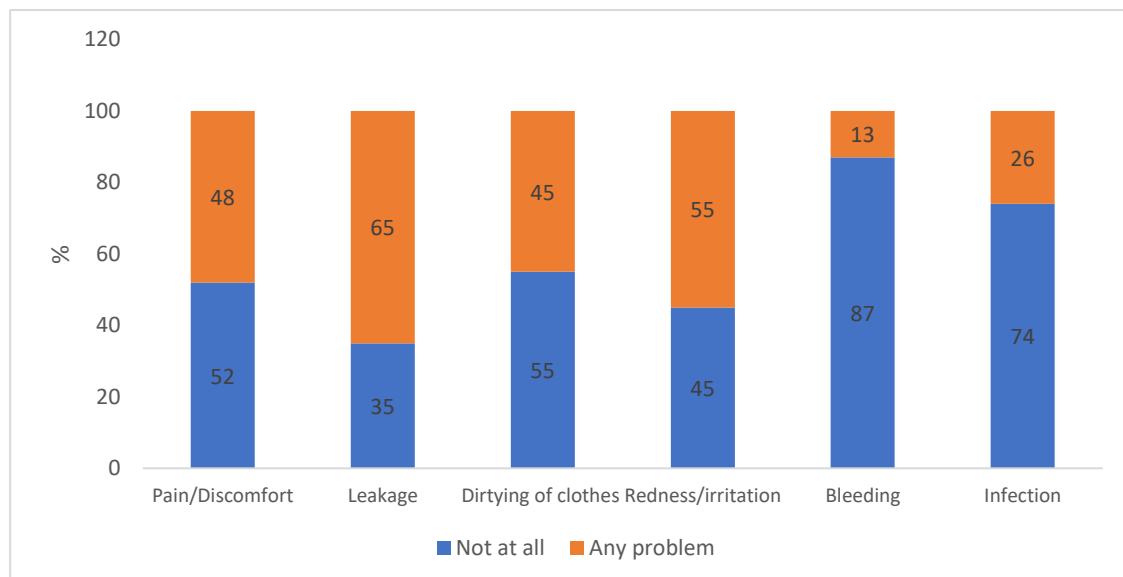


Figure 13. Frequency distribution of answers (not at all; any problem) according to six questions of Liverpool PEG questionnaire in 31 participants who are feeding via PEG in the home environment.

Bleeding was not found in 87% of patients. That is 6.7 times more than the percentage of patients with bleeding. Infection was not found in 74% of patients. That is 2.8 times more than the percentage of patients with infection. It was found that the percentage of patients with leakage was 1.9 times more than the percentage of patients without leakage.

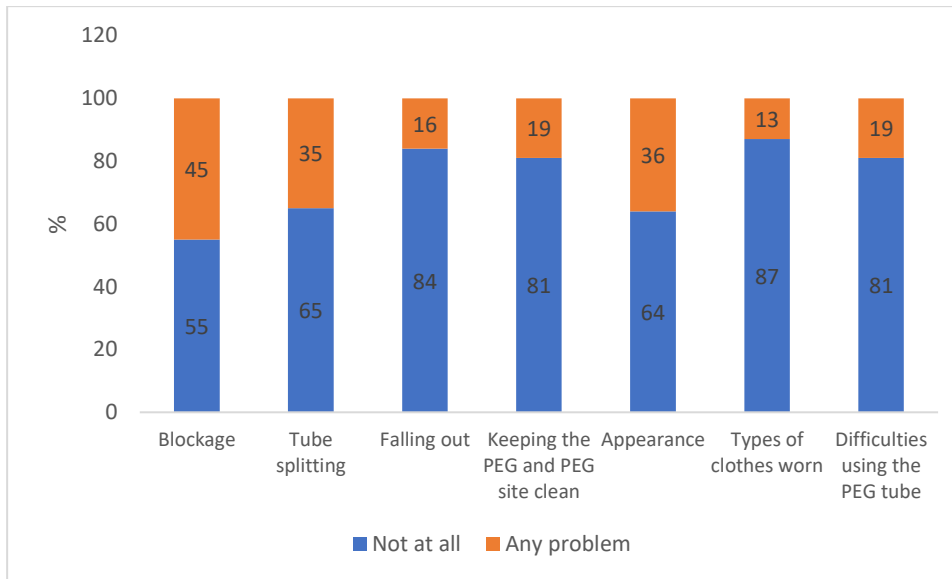


Figure 14. Frequency of distribution of answers (not at all; any problem) according to seven questions of Liverpool PEG questionnaire in 31 participants who are feeding via PEG in the home environment.

Percentage of patients without difficulties related to using the PEG tube was 4.3 times more than percentage of patients who had difficulties using PEG. This correlated to the fact that percentage of patients without falling out of PEG was 84%, percentage of patients with no problem regarding keeping the PEG and PEG site clean was 81%, and percentage of patients in whom PEG did not affect types of clothes worn was 87%.

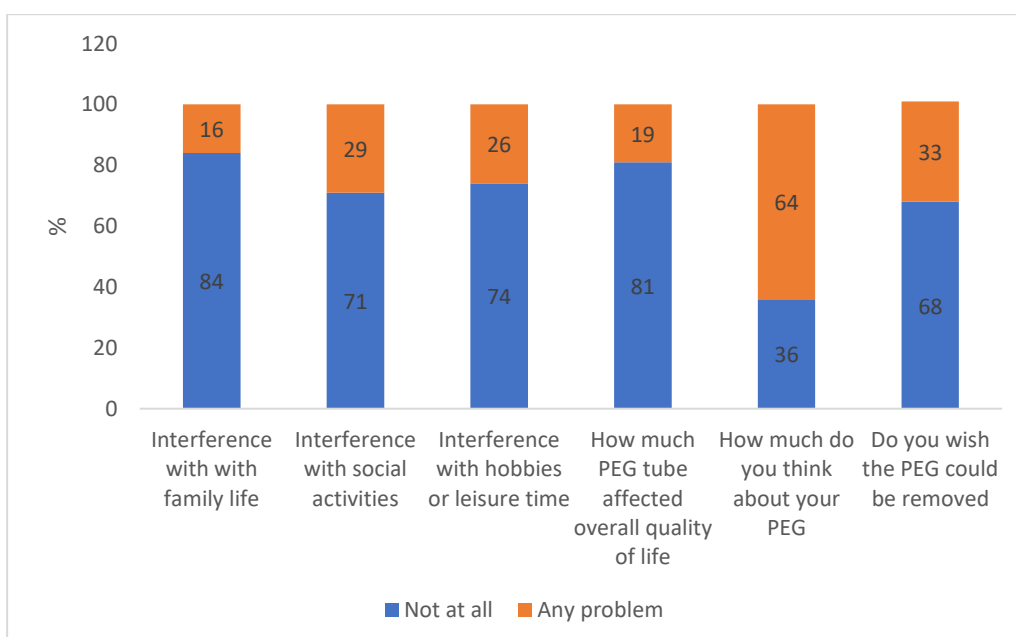


Figure 15. Frequency of distribution of answers (not at all; any problem) according to six questions of Liverpool PEG questionnaire in 31 participants who are feeding via PEG in the home environment.

The percentage of patients who were thinking about PEG was 1.8 times more than the percentage of patients who were not thinking about PEG. It seems that PEG did not affect family life, social activities and hobbies to a great extent. The percentage of patients who were thinking that PEG did not affect family life, social activities and hobbies was greater than 70%. Percentage of patients who were thinking that PEG did not affect their overall quality of life was 4.3 times higher. The proportion of patients who were thinking that PEG does not affect their overall quality of life is 81% (95% CI: 63-95).

5. DISCUSSION

Percutaneous endoscopic gastrostomy (PEG) is a type of enteral nutrition that is applied with increased frequency in the world. The benefits of PEG have been confirmed for some groups of patients, but there is still uncertainty about the long-term effects of this type of nutritional application on certain groups of patients (58). This study was designed to assess certain aspects of PEG application in the home environment, more precisely nutritional status and quality of life. Determination of the most common problems in the study sample is another important part of this study.

Undernutrition is often overlooked in clinical practice and is unfortunately associated with increased health care costs but also with increased rates of morbidity and mortality (10). A study from 2017 claims that the nutritional benefits associated with gastrostomy feeding are not fully established, but also the assessment of nutritional status is highly versatile (59). A different study from 2019 describes BMI as an indicator of chronic malnutrition but also as an important parameter for nutritional assessment. The same study considers all Europeans with $\text{BMI} < 18.5 \text{ kg/m}^2$ as underweight (15). In the present study, 23% of the participants were in the underweight category, while 77% of the participants had a BMI of 18.5 kg/m^2 or more. Given that this study does not include data on the BMI status of the participants before the placement of the PEG, the study cannot provide additional information on the influence of PEG on the BMI of the participants, but it can show that there were 3.4 times more participants with $\text{BMI} \geq 18.5 \text{ kg/m}^2$ compared to $\text{BMI} < 18.5 \text{ kg/m}^2$. In order to avoid confusion, it is important to emphasize that this study cannot draw any conclusions about PEG based on BMI. Regardless of that, a recent study from 2022 compared BMI values before and after PEG placement and observed significantly increased BMI values after PEG utilization (60). In the present study, the share of participants with a high risk of malnutrition was 29%. High risk of malnutrition was 2.44 times statistically significantly lower compared to the combined low and medium risks in this study among participants. This result is important because risk of malnutrition, but especially a high risk of malnutrition, is definitely undesirable in patients who are enterally feeding via PEG in the home environment. Another study from 2019 reported that 68.4% of patients were severely malnourished before PEG was implemented. The same study found that it is very important to routinely screen the nutritional risk and assess the nutritional status in clinical practice (61). In a different study, high nutritional risk prior to PEG placement was found to be associated with PEG utilization in patients with head and neck cancer (62). The nutritional status of critically ill patients improves significantly after the application of PEG, according to a 2017 study (63). Interesting findings were reported in one study that showed that

when home hospitalization units take care of the treatment and monitoring of patients who are feeding via PEG at home, it leads to improvement in nutritional parameters and quality of life (64). Such findings in different studies point to the importance of evaluating the nutritional status when using PEG, but also that PEG has a positive effect on the nutritional status in certain malnourished conditions. Based on these different studies, it can be noted that the assessment of nutritional risk and status can be carried out before and during the administration of PEG and can have the purpose of selecting patients, monitoring the patient's condition, but can also provide additional information about the effectiveness of PEG in various diseases. This will perhaps lead to a trend in the future where more importance will be placed on nutritional assessment in the daily work of medical professionals.

In this study, self-assessment of health-related quality of life was presented by using the EQ VAS score, and the range of EQ VAS score is from 0 to 100, which represented the worst and best health state, respectively. The median EQ VAS score in our subjects was 30 (Q1-Q3: 10-50; min-max: 1-99) (95% CI: 20-50), and the highest frequency of EQ VAS score was ≤ 30 because this is how 18 (58%) participants rated their health-related quality of life. It is important to understand that the EQ VAS score refers to the patient's current general health condition and that it can be affected by both diseases and treatments.

Although this study cannot determine what is the reason behind the EQ VAS score in our participants, it is important to explain that 55% of patients were confined to their bed, unable to wash or dress themselves, and to perform their usual activities; 52% of patients were extremely anxious or depressed, but only 23% of patients had extreme pain or discomfort.

Considering such findings, we can argue that difficulties related to the general health state of our patients are serious and can certainly have a negative impact on the quality of life. To put the value of the EQ VAS score from our study into context, a study from 2021 reported a median EQ VAS score of 70 in patients with lower limb amputation (65). Another study showed that the median EQ VAS score in patients with amyotrophic lateral sclerosis was 70 as well (66). In the present study, it is visible that the percentage of patients who were thinking that PEG did not affect their overall quality of life is 4.3 times higher.

The proportion of patients who were thinking that PEG does not affect their overall quality of life is 81% (95% CI: 63-95), which means that based on this study we can conclude that in the population of such patients who are enterally feeding via PEG in the home environment, we expect that such a proportion will be between 63-95% with a probability of

95%. This result is a very important finding in relation to the assessment of the quality of life with the EQ VAS score. A similar study that evaluated the quality of life of patients with PEG concluded that the use of PEG can at least maintain the quality of life of the patient (67). A systematic review from 2019 even claims that most of the studies analyzed in this review show an improvement in the quality of life of patients who are under enteral tube feeding (68). In the present study, the most common PEG related problems that the participants reported were problems with leakage, redness/irritation and pain/discomfort. Similar results were observed in a similar study that analyzed PEG related problems with the same questionnaire in patients following primary surgery for oral and oropharyngeal cancer (57). Patients who had a better overall health-related quality of life according to the EQ VAS score were more in favor of the PEG removal option, and it is clear from table 6 that patients with higher EQ VAS score values had better mobility and abilities for performing usual activities and self-care. This finding could be explained by the fact that patients with a better health condition and daily activity are more burdened by the presence of PEG than those patients with a limiting health condition that does not allow them to be very active and engage in normal daily activities. It would be interesting for future studies to distinguish between different groups of patients with different levels of activity and consequently the difference between their satisfaction and problems related to the use of PEG.

This study has limitations. First, regarding the number of participants. A larger sample size would have been desirable as the smaller sample size probably affected whether the results were statistically significant in this study. Therefore, a larger sample size is needed in order to obtain more accurate results, but also to have greater credibility. The gender distribution was not equally divided in this study. The study included patients only from the region covered by the University Hospital of Split. In this study, a certain number of participants answered the questions themselves, and in the case when they could not do it themselves, family members or caregivers assisted them or answered instead of them. It is possible that the results would have been different if all the patients had answered completely for themselves without any help.

Future studies could separate such patients into those who can answer on their own and those who need help answering or are unable to give answers, and then compare whether there are differences between such groups of subjects. This study included all patients who met the inclusion criteria and the study did not limit the inclusion of patients based on their primary diagnosis or diagnoses. Patients with different clinical conditions were analyzed as one group. Assessment of the nutritional status and quality of life of patients with PEG could be determined

for each diagnosis separately, and on account of this, more precise data could be obtained, as well as reasons for different results between different medical conditions. Another limitation of the study is that the interviews were conducted over the phone. Due to this fact, this study relies on measurements performed by the subjects or their caregivers and not by medical professionals. It is important to emphasize that this study cannot establish causality between the results because it is a cross-sectional study. Due to the listed limitations, further research on this topic is recommended.

6. CONCLUSION

1. The high overall risk of malnutrition is statistically significantly lower compared to the combined low and medium overall risks of malnutrition among patients who are enterally feeding via percutaneous endoscopic gastrostomy tube in the home environment.
2. Based on this research, it could be concluded that the population of patients who are enterally feeding via PEG in the home environment estimate the median health-related quality of life between 20 and 50 according to EQ VAS score with 95% probability.
3. Patients who had a better overall health-related quality of life according to the EQ VAS score were more prone to the option of removing the PEG.
4. The majority of patients who are enterally feeding via PEG in the home environment report that PEG does not affect their overall quality of life.

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8. SUMMARY

Objectives : The main objectives of this study were to assess nutritional status and quality of life of patients who are enterally feeding via percutaneous endoscopic gastrostomy for a period of at least 3 months in the home environment.

Materials and methods: This study included a total of 31 participants, aged between 21 and 85 years, who have been feeding via percutaneous endoscopic gastrostomy for a period of at least 3 months in the home environment. Quality of life was assessed by EQ-5D-3L questionnaire and Liverpool PEG questionnaire, while nutritional status was assessed with the Malnutrition Universal Screening Tool (MUST). Statistical data analysis was done by statistical software MedCalc (Ostend, Belgium; version 11.5.1.0) for Windows.

Results: The study included 21 male and 10 female patients who are enterally feeding via percutaneous endoscopic gastrostomy tube in the home environment. The median body mass index (BMI) was 22.5 kg/m² (Q1-Q3: 18.6-24.4; min-max: 12.1-30.7). Low, medium and high risks of malnutrition among participants were 52%, 19% and 29%, respectively. If the high risk of malnutrition is compared with the other combined risks of malnutrition (combined low and medium risks), it turns out that the high risk is 2.44 times lower than the other risks ($x_2 = 5.7$, $P = 0.017$). The mean value of the EQ-VAS score was 37.3 ± 29 ; the median value was 30 (Q1-Q3: 10-50; min-max: 1-99) (95% CI: 20-50). The percentage of patients who wanted to remove PEG in the group with EQ VAS score > 30 was 61% ($n = 8$). This was 5.5 times more than the percentage of patients (11%; $n = 2$) who wanted to remove PEG in the group with EQ VAS score ≤ 30 ($P = 0.006$). Percentage of patients who were thinking that PEG did not affect their overall quality of life was 4.3 times higher. The proportion of patients who were thinking that PEG does not affect their overall quality of life is 81% (95% CI: 63-95).

Conclusion: The high overall risk of malnutrition is statistically significantly lower compared to the combined low and medium overall risks of malnutrition among patients who are enterally feeding via percutaneous endoscopic gastrostomy tube in the home environment. Based on this research, it could be concluded that the population of patients who are enterally feeding via PEG in the home environment estimate the median health-related quality of life between 20 and 50 according to EQ VAS score with 95% probability. Patients who had a better overall health-related quality of life according to the EQ VAS score were more prone to the option of removing the PEG. The majority of patients who are enterally feeding via PEG in the home environment report that PEG does not affect their overall quality of life.

9. CROATIAN SUMMARY

Naslov: Procjena nutritivnog statusa i kvalitete života pacijenata s perkutanom endoskopskom gastrostomijom.

Ciljevi: Procijeniti nutritivni status i kvalitetu života bolesnika koji se enteralno hrane putem perkutane endoskopske gastrostome u razdoblju od najmanje 3 mjeseca u kućnom okruženju.

Materijali i metode: Ovo istraživanje obuhvatilo je ukupno 31 sudionika, u dobi od 21 do 85 godina, koji su se hranili putem perkutane endoskopske gastrostome u razdoblju od najmanje 3 mjeseca u kućnom okruženju. Kvaliteta života procijenjena je sa EQ-5D-3L upitnikom i Liverpool PEG upitnikom, dok je nutritivni status procijenjen sa Malnutrition Universal Screening Tool (MUST) upitnikom. Statistička analiza podataka napravljena je statističkim softverom MedCalc (Ostend, Belgija; verzija 11.5.1.0) za Windows.

Rezultati: Istraživanje je obuhvatilo 21 muškog i 10 ženskih bolesnika koji se enteralno hrane putem perkutane endoskopske gastrostome u kućnim uvjetima. Medijan indeksa tjelesne mase (BMI) bio je 22,5 kg/m² (Q1-Q3: 18,6-24,4; min-max: 12,1-30,7). Niski, srednji i visoki rizici od pothranjenosti među sudionicima bili su 52%, 19% i 29%. Ako se visoki rizik od pothranjenosti usporedi s ostalim kombiniranim rizicima pothranjenosti (kombinirani niski i srednji rizici), uočava se da je visoki rizik 2,44 puta manji od ostalih rizika ($x_2 = 5,7, P = 0,017$). Srednja vrijednost EQ-VAS rezultata bila je $37,3 \pm 29$; medijan je bio 30 (Q1-Q3: 10-50; min-max: 1-99) (95% CI: 20-50). Postotak pacijenata koji su htjeli ukloniti PEG u skupini s EQ VAS rezultatom > 30 bio je 61% ($n = 8$). To je bilo 5,5 puta više od postotka pacijenata (11%; $n = 2$) koji su željeli ukloniti PEG u skupini s EQ VAS rezultatom ≤ 30 ($P = 0,006$). Postotak pacijenata koji su smatrali da PEG ne utječe na njihovu ukupnu kvalitetu života bio je 4,3 puta veći. Udio pacijenata koji su mislili da PEG ne utječe na njihovu ukupnu kvalitetu života je 81% (95% CI: 63-95).

Zaključci: Visoki ukupni rizik od pothranjenosti statistički je značajno niži u usporedbi s kombiniranim niskim i srednjim ukupnim rizikom od pothranjenosti pacijenata koji se enteralno hrane putem perkutane endoskopske gastrostome u kućnom okruženju. Na temelju ovog istraživanja može se zaključiti da populacija pacijenata koji se enteralno hrane putem PEG-a u kućnom okruženju procjenjuju medijan kvalitete života povezane sa zdravljem između 20 i 50 prema EQ VAS rezultatu s 95% vjerojatnosti. Pacijenti koji su imali bolju ukupnu kvalitetu života povezanu sa zdravljem prema EQ VAS rezultatu bili su skloniji opciji uklanjanja PEG-a. Većina pacijenata koji se enteralno hrane preko PEG-a u kućnom okruženju navodi da PEG ne utječe na njihovu ukupnu kvalitetu života.

10. CURRICULUM VITAE

PERSONAL INFORMATION:

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