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EFFICACY OF EARLY VERSUS LATE ENTERAL NUTRITION IN GASTROINTESTINAL SURGERY"DR. LUIS RAZETTI" UNIVERSITY HOSPITAL COMPLEX 2023-2024

PRESENTED BY

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RESEARCH PROJECT

ANZOATEGUI – VENEZUELA 2024

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CHAPTER I: STATEMENT OF THE PROBLEM

Problem Description

In a standardized manner, the management of the start of oral intake, after a gastrointestinal surgery that includes resection and anastomosis, primary closure of the small intestine and colon or closure due to gastric perforation, is reserved for 48 to 72 hours postoperatively, in order to allow healing of the manipulated tissues and prevent dehiscence (1).

However, currently, multiple clinical studies indicate that early enteral nutrition can be adequately tolerated and provide benefits such as decreasing the incidence of infectious complications, reducing the state of post-surgical protein hypercatabolism, promoting healing and shortening the length of hospital stay(1).

Enteral feeding is the most important form of ideal nutritional contribution for any individual: it provides adequate protein-calorie support, prevention of intestinal atrophy due to disuse, maintenance of immunocompetence, preservation of saprophytic flora and reduction of the inflammatory response in surgical trauma (2).

The initiation of enteral nutrition stimulates the production of enterotrophic hormones (enteroglucagon and gastrin), enhances the renewal of enterocytes, contributes to maintaining the quality of intestinal villi and their restoration in biological, metabolic, endocrine and structural functions (2).

After intestinal reconnection, the most feared complication for the surgeon is the presentation of dehiscence/fistula, which is still reported in 1 to 4%, followed by paralytic ileus and abdominal pain, which is why some surgical groups decide to postpone the start of nutrition to reduce the presence of these complications, based more on experience than on

medical evidence (2).

The General Surgery service of the “Dr. Luis Razetti” University Hospital Complex serves the population from Callao, who are between the ages of 16 and 75. It has 12 hospital beds and performs approximately 78 surgeries per month, both elective and emergency.

The most frequent gastrointestinal pathologies are: acute appendicitis, intestinal obstruction and abdominal trauma, for emergency surgeries, and cholecystitis, abdominal wall hernias and anorectal pathology, for elective surgeries.

The level of care is II-2, and it has an Intensive Care Unit with three hospital beds available for all medical and surgical specialties. The Surgery service occupies these beds on average two per month, for complicated surgical pathologies, which, it should be noted, are very frequent.

The General Surgery Department of the “Dr. Luis Razetti” University Hospital Complex performs the standardized practice of late enteral nutrition in all patients whose gastrointestinal surgery includes intestinal anastomosis or raffia.

Late enteral nutrition is the traditional practice that surgeons at this hospital follow as a guideline in the postoperative period due to fear of complications that early enteral nutrition could cause, such as anastomotic dehiscence or enteral fistula. This service does not have research that supports this behavior.

However, as mentioned above, current practice, based on international clinical studies with good evidence, encourages early initiation of enteral nutrition. The lack of this information or fear on the part of surgeons does not allow us to establish whether there is any difference, advantage or disadvantage in the initiation of early enteral nutrition

over late.

Late enteral nutrition leads to prolonged hospital stay and, in some cases,

As a consequence, certain complications such as hospital-acquired infections may arise.

Problem formulation

What is the effectiveness of early enteral nutrition versus late enteral nutrition in gastrointestinal surgery at the “Dr. Luis Razetti” University Hospital Complex 2023-2024?

Objectives

General

objective

To compare the efficacy of early enteral nutrition versus late enteral nutrition in gastrointestinal surgery at the “Dr. Luis Razetti” University Hospital Complex 2023-2024.

Specific objectives

Identify the benefits of early enteral nutrition.

Identify potential disadvantages or risks in starting early enteral nutrition.

To relate the effect of early enteral nutrition on the reduction in hospital stay time.

To compare the incidence of complications of early enteral nutrition compared to late enteral nutrition.

Justification

The importance of establishing the efficacy of early enteral nutrition over late enteral nutrition will bring about beneficial changes, both for the patient and for the hospital. These would be translated into the impact on the patient's health by enjoying the possible benefits provided by early enteral nutrition described in other studies, such as promoting healing, decreasing catabolism and weight loss in the postoperative period, as well as reducing hospital stay. This last aspect is also beneficial for the institution from an economic point of view. It is also worth highlighting the scientific impact that research of this type will have, both for the population of the area under study and for the institution, as it would provide data that could be used to generate a protocol for starting early enteral feeding, which according to the results may be findings that are disseminated with surgeons not only from this hospital, but from other hospitals through scientific meetings.

Furthermore, it is important to mention that, currently, there are no studies in our setting that provide guidance on the potential benefits and risks of early enteral nutrition in patients from our population, with their respective ethnic implications, undergoing digestive surgeries. Research such as this and others that involve other methodological designs should be carried out in the search for the creation of protocols that benefit the health of our patients.

Viability and feasibility

The time, human and financial resources required to carry out this research have been evaluated and will be feasible and sufficient thanks to the institution where the study is being carried out, whose authorities,

when informed, will provide the necessary permits and facilities. Obtaining the appropriate number of eligible subjects in this research will not be an obstacle, given the

large number of patients seen daily in the Surgery Department of this hospital. Ethical aspects will be supported by the preparation of an informed consent, in addition to the confidential handling of the data obtained.

The research, being of the prospective cohort type, provides a scope on the population served in the service of the “Dr. Luis Razetti” University Hospital Complex, but will not provide generalizable results for the rest of the population.

The population under study will be the one that comes to the care at the “Dr. Luis Razetti” University Hospital Complex, from the province of Callao, socioeconomic class C: low, young people, adults and older adults, of both sexes. The data obtained could serve as a reference, but cannot be generalized to other groups such as other socioeconomic strata, since nutritional status plays an important role in the subject of study, and this is associated in some way with the subject's purchasing power.

The bibliography of authors worldwide is sufficient; however, there is no research of this type in Venezuela.

CHAPTER II: THEORETICAL FRAMEWORK

Background

In 2013,Zhuang C, et al., in China, conducted an investigation with a view to characterizing the safety and efficacy of early oral feeding after colorectal surgery. A meta-analysis was performed to evaluate surgical outcomes after early oral feeding compared with traditional oral feeding in patients undergoing elective colorectal surgery. Seven trials, involving a total of 587 patients, met the inclusion criteria.

Compared with traditional oral feeding, early oral feeding reduced the length of hospital stay (weighted mean difference - 1.58 days, 95% CI -2.77 to -0.39, p = 0.009) and total postoperative complications (relative risk 0.70, 95% CI 0.50 P = 0.04). There were no significant differences in the risk of anastomotic dehiscence, pneumonia, wound infection, nasogastric tube reinsertion rate, vomiting, or mortality. Early oral feeding is safe and effective in patients undergoing elective colorectal surgery (3).

In 2014, in Japan,Manba N, et al., conducted a study, which retrospectively examined whether initiation of enteral nutrition within 24 hours after esophagectomy improves the postoperative course. Among the
103 patients who underwent thoracic esophagectomy for esophageal cancer were enrolled, in whom enteral nutrition was started within 72 hours after surgery. Patients were divided into two groups: enteral nutrition started within 24 hours (group D1) and enteral nutrition started at 24 - 72 hours (group D2-3).

Clinical factors including days to first stool passage, postoperative albumin infusion dose, difference in serum albumin between pre- and postoperative, incidence of postoperative infection, and use of total parenteral nutrition were compared. Statistical analyses were performed

using the Mann-Whitney U test and the Chi-square test, with significance

defined as $P < 0.05$. There were no significant differences between groups in clinical factors. While pneumonia was significantly more frequent in Group D1 than in Group D2-3 ($P = 0.0308$), the frequency of infectious complications was comparable between groups (4).

Koretz R. et al., in Germany 2014, conducted a research with a view to assessing the potential effect of methodological bias. In randomised trials, they suggest that early enteral nutrition is beneficial in critically ill adults. Randomised trials identified in electronic searches of PUBMED, EMBASE and the Cochrane Library, and in several hand searches, were assessed. Primary (mortality, morbidity) and secondary (time on ventilator or intensive care unit/hospital, cost) outcomes were extracted from each identified trial comparing early enteral nutrition with no/delayed enteral nutrition.

Meta-analyses of trials with higher or lower risks were compared in the following ways: adequate methodology to deal with domains ≥3 or ≤2; Jadad scores ≥3 or ≤2; adequate versus not adequate for each domain. In the 15 trials identified, early enteral nutrition appeared to improve mortality and infectious morbidity. The mortality benefit was seen only in trials with higher risks of bias; an infectious morbidity benefit was seen in some analyses of trials with lower risks of bias (5).

Yin J et al., in China 2015, conducted a study that aimed to determine whether early enteral feeding could be safely implemented with the intended benefits in patients with abdominal trauma. A retrospective cohort study was conducted that included 88 adult patients with abdominal trauma. Patients who received enteral feeding within 72 h of surgical intensive care unit (SICU) admission (early initiation group, n = 28) were compared to those who received enteral feeding later (late initiation group, n = 60).

The two groups were comparable in terms of demographic characteristics and injury severity. There were no differences in feeding

intolerance (53.6 versus 43.3%, p = 0.37) and 28-day mortality (0 versus 5%, p = 0.55) between the

early initiation group and the late initiation group. However, patients in the early initiation group had fewer infectious complications (17.9 vs. 40%, p = 0.04) and shorter ICU and hospital stays (p <0.01)than patients in the late-onset group (6).

Dorai D et al., in 2016, conducted a randomized control study to compare the outcome of early versus delayed enteral feeding after gastrointestinal surgery, 60 patients were randomly selected and classified into two groups, early feeding group and delayed feeding group and the following were observed: anastomotic leak, infection (wound, intra-abdominal abscess, pulmonary complication, sepsis), length of hospital stay.

The mean length of hospital stay was 9.3 versus 10.90. The difference was 1.6 days (P value: 0.129). Wound infection was 20% versus 26.7%. 6.7% had intra-abdominal abscess in the early feeding group, which was statistically insignificant. There were two patients (6.7%) with sepsis in the late feeding group (p = 0.150). There was no anastomotic leak or death in both groups (7).

In 2016, in the United Kingdom, Perinel J, et al., with a view to comparing the effectiveness of early enteral nutrition versus late enteral nutrition, carried out a prospective cohort study that included 204 patients exposed to gastrointestinal surgery; they found that the frequency of postoperative complications in the group using early enteral nutrition was 28% while in the group using late enteral nutrition it was 48%; a difference that was significant (p<0.05) (22).

Zhu XH, et al., in China, in 2013, with the aim of verifying the effectiveness of early enteral nutrition compared to late enteral nutrition, conducted a prospective cohort study that included 174 patients exposed to abdominal surgery for pancreatic pathology; observing that the frequency of postoperative complications in the group

The percentage of early nutrition users was 39% while in the late nutrition user group it was up to 58%, a difference that was significant ($p<0.05$) (23).

In Canada, year 2015, Balayla J, et al., conducted a study to compare the effectiveness and complications between the strategy of early enteral nutrition versus late enteral nutrition. The prospective cohort study, which included 119 patients exposed to abdominal surgery, showed that the average hospital stay was significantly lower in the group of patients exposed to early enteral nutrition ($p<0.05$) (24).

Boelens PG, et al., conducted a study in 2014 in the United Kingdom, with the aim of identifying the effectiveness of early enteral nutrition in relation to late enteral nutrition in patients exposed to abdominal colon surgery, in which 123 patients were included through a prospective cohort design; observing that the hospital stay was significantly lower in the enteral nutrition user group, 13.4 ± 2.2 days versus 16.7 ± 2.3 ($P = 0.007$) (25).

In Holland, in 2016, Van Barneveld KW, et al., captured the objective of recognizing the effectiveness of early enteral nutrition compared to late enteral nutrition through a study that included patients exposed to rectal surgery using 125 patients as a reference and through a prospective cohort design; it was found that serum albumin levels were significantly higher in the group exposed to early nutrition compared to the group using late nutrition ($p<0.05$) (26).

Theoretical bases

Physiology of the digestive tract

The gastrointestinal tract includes the mouth, pharynx, esophagus, stomach, small intestine, large intestine, rectum, and associated glands.

Its function is based on the processing of nutrients, facilitating their entry into the internal environment and, through circulation, to each cell for its correct functioning. The structure varies from

according to the region, with the common mucosa, submucosa, muscular and serous

(27).

The mucosa contains the epithelium, lamina propria and muscularis mucosae. The submucosa is inferior to the mucosa and consists largely of loose connective tissue associated with collagen. The muscular layer differs and has specific characteristics at each level. The serosa or adventitia, in contact with the abdominal cavity.

The intrinsic innervation governed by the Meissner and Auerbech plexuses, located between the layers of the muscle layers, have sensory and motor/secretory neurons. The extrinsic innervation in charge of the autonomic nervous system in its two modalities, sympathetic, which generally has an inhibitory character of intestinal motility, and the parasympathetic, stimulates the motor and secretory function, a function antagonistic to the sympathetic (28).

The first activity is mastication, followed by swallowing and peristalsis. Motility in the stomach allows food to be stored, mixed, reduced in size and emptied. The small intestine is characterized by postprandial and interdigestive motility. The first is characterized by the mixing of chyme with digestive secretions, facilitating the absorption and progression of chyme. Unlike esophageal and gastric motility, which is peristaltic, here they are mixing movements (28).

Interdigestive motility, which occurs after all nutrients have been absorbed, establishes a different pattern, migratory peristalsis, which carries away food remains and secretions from the previous ingestion. In the large intestine, motility in the proximal segment is mostly segmental with a mixing function rather than propulsion to distal segments (29).

Most foods contain macromolecules, which are broken down to smaller sizes so they can pass into the internal environment. Secretions along the

entire route contain enzymes such as salivary, gastric, intestinal, pancreatic and biliary enzymes, all of which are constantly secreted (29).

The mechanical and chemical processes to which macromolecules are subjected have the purpose of degrading and converting them into simple compounds. The absorption surface and the blood and lymphatic irrigation are the facilitators towards the internal environment. 95% of the water in the small intestine, plus that of gastrointestinal secretions, approximately 9 L/d is absorbed, only about 500 ml pass to the large intestine (29).

Postoperative intestinal motility

Gastrointestinal surgery causes a reflex decrease in intestinal motility, causing postoperative ileus. The duration of ileus varies in the different segments of the digestive tract. In the jejunum-ileus, motility recovers within 24 hours, while that of the colon does so later (29).

After abdominal surgery, a transient state of intestinal ileus occurs due to failure of the normal propulsive activity of the digestive tract. In most cases, it is not serious and usually resolves spontaneously within a few days. However, it has been shown that absorptive recovery of the small intestine occurs a few hours after surgery (30).

Reflex ileus is caused by the depolarization of the intestinal muscle cells by the manipulation and traction of the intestinal loops. Depolarization is due to the release of potassium and the entry of sodium into the cell, causing a change in transmembrane potential. The ion that diffuses most rapidly through the cell membrane is called the resting potential and normally corresponds to potassium, which indicates that at rest the equilibrium potential is potassium. For the cell to repolarize again, sodium must leave and potassium must enter again, requiring large amounts of energy, similar to what happens in the heart muscle when a heart attack occurs (29).

Perioperative nutritional status

There is a consistent correlation between nutritional status and surgical treatment outcomes. Nutritional deficiencies are associated with longer hospital stay, postoperative complications and mortality. In the perioperative period, nutritional therapy plays a key role in improving outcomes (8).

In particular, after gastrointestinal surgery, basal energy expenditure is high, so nutritional support is of considerable importance. The absence of food at the intestinal level, even for short periods of time, can cause a decrease in the height of the mucosal villi, hypoplasia and a decrease in the content of deoxyribonucleic acid, together with alterations in the enzymatic functions at the level of the villi and the secretion of immunoglobulin A (IgA).

Nutritional support plays an important role in wound healing and postoperative recovery, and poor nutritional status is strongly associated with delayed wound healing and longer hospital stays after surgery (15).

Early and late enteral nutrition

Early nutritional therapy is that which is started within 24 hours of hospital admission or surgery and can be administered by enteral route (enteral nutritional therapy - ENT), parenteral route (parenteral nutrition - PNT) or both. The choice of the best route, the perfect time to start, especially in seriously ill and potentially unstable patients, remains a matter of discussion (9).

In elective operations, early enteral nutrition offers advantages over parenteral nutrition because it is more physiological. These effects are mainly related to the modulation of the response and the maintenance of intestinal integrity (barrier), preventing bacterial translocation and overgrowth of pathogenic germs (10).

In recent decades, enteral nutrition has been preferred over total parenteral nutrition due to several advantages, including decreased mortality, infectious morbidity, and length of hospital stay. Nutritional support has been shown to improve clinical outcomes when initiated within 10 days after hospital admission or surgery in patients unable to eat (11).

Traditionally, enteral feeding after anastomosis has been delayed to prevent the development of complications. The reason for this is to prevent postoperative nausea and vomiting and also to protect the anastomosis site to allow time for healing. However, gastric juice, secretions from the intestine pass through the anastomotic site. If this transit occurs without leakage, there is no reason to delay oral feeding for fear of leakage (12).

Late postoperative oral intake has been called into question by evidence from several physiological studies of the digestive system that analyse the contractile activity of the intestine. Gastric emptying and small bowel absorptive capacity recover within the first postoperative day, although colonic activity returns to normal within 48 hours after surgery.

Several studies suggest that early enteral feeding is beneficial compared with delayed enteral feeding. Physiological studies show that postoperative dysmotility predominantly affects the stomach and colon with motility in the small intestine becoming normal within 4 to 8 hours after intestinal surgery (13).

Physiological studies demonstrating the presence of peristalsis and absorption of food further reinforce the fact that early feeding is well tolerated and leads to rapid wound healing and shorter length of hospital stay (14).

Several reports have emphasized that early enteral feeding should be started as soon as possible after resuscitation because the immunomodulatory effect of enteral feeding could aid recovery (16).

Patients undergoing emergency gastrointestinal surgery have an edematous or ischemic bowel, and are at high risk for postoperative complications such as ileus, obstruction, or anastomotic failure. (17).

There is recent evidence that nutritional support is beneficial during the metabolic and inflammatory phase, helping to improve a patient's outcomes after surgery. Early initiation of oral nutrition is promoted in most patients undergoing gastrointestinal surgery and is an important part of fast-track surgery protocols.

Early enteral nutrition is a viable option in patients undergoing intestinal anastomosis and is not associated with a high incidence of leaks, is well tolerated by patients, and has acceptable complications, with vomiting being more frequently associated. (18).

Postoperative ileus is a common complication in patients undergoing gastrointestinal surgery, accompanied by increased patient morbidity, increased use of prolonged parenteral nutrition, and increased costs. Data have indicated that the concept of postoperative ileus as paralysis of the entire bowel with complete absence of any functional contractile activity is erroneous. If postoperative ileus occurs, it is generally transient and of no clinical significance. Based on these findings, the concept of withholding oral intake until resolution of postoperative ileus does not appear reasonable.

There is also a psychological impact after surgery and an improvement in the sense of well-being was observed in patients who were fed earlier. The psychological aspect also plays a significant role in the whole postoperative recovery process. Cost savings, which seems to be an important aspect in many countries or healthcare systems, is another potential advantage of the early feeding scheme as patients in this group tend to have a shorter length of hospital stay.

Definition of basic terms

Nutritional support: Supply of nutrients by enteral or parenteral route with the purpose of achieving and/or maintaining an adequate nutritional status (3).

Enteral nutrition: Supply of nutrients through the digestive tract, using the oral route or means other than conventional feeding with the purpose of contributing to the total supply of nutritional requirements (3).

Early enteral nutrition: Oral food intake at 6 hours postoperatively before clinical signs of intestinal peristalsis appear, with or without the aid of gastric or jejunal tubes (3).

Late enteral nutrition: Oral intake of food or liquids after 18 postoperative hours and only after the appearance of clinical signs of resolution of postoperative ileus (3).

Gastrointestinal surgery: Surgical procedure that resolves problems of the digestive system; includes: primary closure of intestinal perforation; primary closure of gastric perforation; enteral anastomosis (4).

Postoperative Paralytic Ileus: Transient cessation of coordinated intestinal motility after surgery, which prevents effective transit of intestinal contents and/or tolerance to oral intake (5).

Nausea:imminent desire to vomit, referred to the epigastrium and oropharynx

(5).

Vomit:violent oral expulsion of gastric contents (5).

Oral tolerance:ability to ingest 300 mL of liquids 6 hours postoperatively through the mouth without nausea, vomiting and abdominal distension (5).

Postoperative complications: Complication that occurs on its own in the postoperative period; which includes the following: pneumonia, surgical wound infection, metabolic alterations, others (6).

Security: Absence of complications as a result of treatment (7).

CHAPTER III: HYPOTHESIS AND VARIABLES

Formulation of the hypothesis

Null hypothesis: Early enteral nutrition is less effective than late enteral nutrition in gastrointestinal surgery at the “Dr. Luis Razetti” University Hospital Complex 2023-2024.

Alternative hypothesis: Early enteral nutrition is more effective than late enteral nutrition in gastrointestinal surgery at the “Dr. Luis Razetti” University Hospital Complex 2023-2024.

Variables and their operationalization

Variables	Definition	Type by nature	Dimensions	Indicator or	Measuring scale	Categories	Values of the categories	Means of verification
Age	Time elapsed since birth an individual	Quantitative	-----	Years completed	Continue	-----	Time in years	Data recorded in clinical history
Sex	Gender identity	Qualitative	-----	Gender	Nominal	- Female - Male	-----	Recorded data in clinical history
Effectiveness of early enteral nutrition (NET)	Benefits of regular food intake 6 hours after surgery before there are clinical signs of intestinal peristalsis	Qualitative	- NET in primary closure of intestinal perforation - NET in primary closure of gastric perforation - NET in enteral anastomosis	Intake of liquids or food, whatever the formula, through the mouth, after the surgical procedure either.	Nominal	-----	-----	Medical record
Efficacy of late enteral nutrition (LETR)	Benefits of regular food or liquid intake after 18 hours postoperatively and only after the appearance of clinical signs of resolution of postoperative ileus.	Qualitative	- NETR in primary closure of intestinal perforation - NETR in primary closure of gastric perforation - NETR in anastomosisenteral	Intake of liquids or food, whatever the formula, through the mouth, after the surgical	Nominal	-----	-----	Medical record

postoperative in early enteral nutrition	which occurs in the postoperative period as a result of the initiation of early enteral nutrition		postoperative complication - Absence of postoperative complications			abdominal - Nausea and/or vomiting - Abdominal distension - Diarrhea - Adynamic ileus - Leakage or dehiscence of the anastomosis or closure primary.		clinic
Postoperative complications in late enteral nutrition	Complication that occurs in the postoperative period as a result of the late initiation of enteral nutrition	Qualitative	- Presence of postoperative complication - Absence of postoperative complications		Nominal	- Abdominal pain - Nausea and/or vomiting - Abdominal distension - Diarrhea - Adynamic ileus - Leakage or dehiscence of the anastomosis or closure primary.		Medical record
Days of hospital stay postoperatively	Time elapsed in the postoperative period that the patient remains in hospitaln	Quantitative		Length of stay in days	Continue		Time in days	Medical record
Surgical Time	Time elapsed during the surgical act.	Quantitative		Start from the incision to the closure of the incision.	Continue		Time in minutes	Medical record
Postoperative complications	Complication that occurs on its own in the postoperative period	Qualitative	- Presence of postoperative complication - Absence of postoperative complications		Nominal	- Pneumonia - Surgical wound infection - Alterations metabolic - Others		Medical record

CHAPTER IV: METHODOLOGY

Types and design

The study is prospective, observational, cross-sectional, analytical and responds to a prospective cohort design.

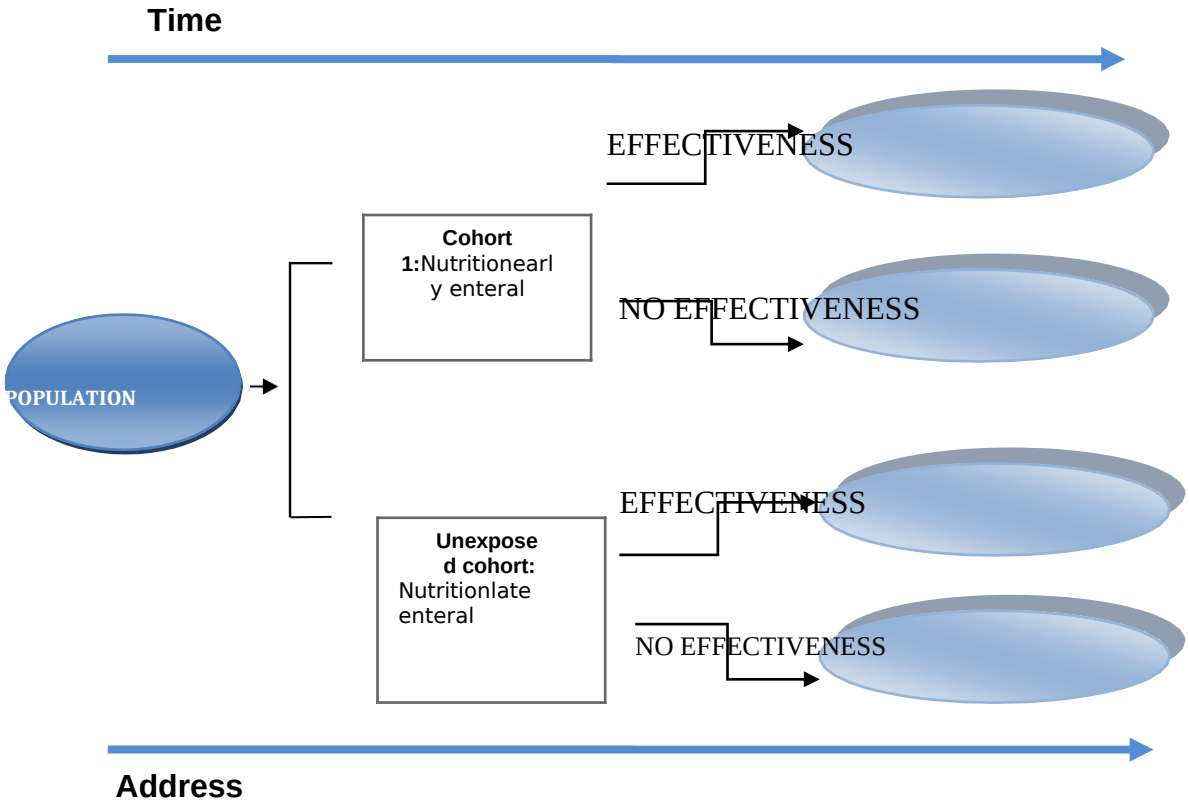
	G1	X1
P		
	G2	X1

Q: Population

G1 Early enteral nutrition G2:

Nutrition late enteral

X1: Effectiveness



Sample design

Universe population: patients undergoing gastrointestinal surgery including primary raffia or anastomosis, who are treated in the surgery service of the “Dr. Luis Razetti” University Hospital Complex 2023-2024.

Study population: patients undergoing gastrointestinal surgery including primary raffia or anastomosis, who are treated in the surgery service of the “Dr. Luis Razetti” University Hospital Complex 2023-2024.

Study population size: All patients undergoing gastrointestinal surgery including primary raffia or anastomosis, who are treated in the surgery service of the “Dr. Luis Razetti” University Hospital Complex 2023-2024.

Sampling: Simple random

Sample size:

To determine the sample size, the formula for cohorts (22) would be used:

$$n = \frac{(Z_{\alpha/2} + Z\,\beta)\,2\,(\,p1.q1 + p2.q2\,)}{(p1-p2)2}$$

Where:

p_1 = Proportion of the cohort exposed to early enteral nutrition who presented complications.

p_2 = Proportion of the cohort exposed to late enteral nutrition who presented complications.

n = Number of patients per
group Z α/2 = 1.96 for α = 0.05
Z_{β} = 0.84 for β = 0.20 P1 =
0.18 (Ref 6)
P2 = 0.40 (Ref 6)

Yin J*et al. and*They found that patients in the early initiation group had fewer infectious complications (17.9 vs. 40%, p = 0.04) (6).

n = 56

COHORT 1: (Early enteral nutrition) = 56 patients
COHORT 2: (Late enteral nutrition) = 56 patients.

Selection criteria

Inclusion criteria

Patients undergoing gastrointestinal surgery including primary raffia or anastomosis

Patients of both sexes over 18 years of age and under 65 years of age.

Exclusion criteria

Patients who do not wish to sign the informed consent

Patients undergoing gastrointestinal surgery including primary raffia or anastomosis under 18 years of age or over 65 years of age.

Patients with alterations in the upper gastrointestinal tract (mouth, pharynx, esophagus) that prevent the initiation of postoperative enteral feeding.

Patients with neurological disorders that prevent the initiation of postoperative enteral feeding.

Patients with metabolic disorders that prevent the initiation of postoperative enteral feeding.

Data collection techniques and procedures

The study will be carried out in the General Surgery Department of the "Dr. Luis Razetti" University Hospital Complex, over a period of one year, between August 2023 and August 2024, based on a data collection form, in which the data recorded in the medical history and operative report of each patient are recorded, as well as the post-surgical evaluation, after the start of enteral nutrition, of all selected patients undergoing gastrointestinal surgery that includes primary raffia or anastomosis (annex 1). The opening of the data collection form will require the prior approval of each patient with the signature of the informed consent (annex 2).

Technique:

Obtaining informed consent.

Random formation of two groups: A and B.

Collection of patient affiliation data and type of surgery performed that appear in the medical history

Group A will be prescribed early enteral nutrition, which consists of ingestion of clear liquids in a volume of 300cc at 6 hours postoperatively within a period of 6 hours.

Within 6 hours of starting enteral nutrition, the patient's signs and symptoms will be assessed and recorded.

Group B will be prescribed late enteral nutrition, which consists of ingestion of clear liquids in a volume of 300 cc after 24 hours of the postoperative period within a period of 6 hours.

Within 6 hours of starting enteral nutrition, the patient's signs and symptoms will be assessed and recorded.

After the first evaluation, each patient will be re-evaluated every six hours for three more times, noting symptoms and signs such as abdominal pain, vomiting, abdominal distension, intestinal noises, and flatus.

The data obtained will be tabulated.

Data processing and analysis

In data processing, once collected, the variables will be coded and entered into a database in SPSS version 15 and Microsoft EXCEL 2016, to later be tabulated and presented in tables: baseline and results. Univariate analysis will be performed using frequencies and percentages. To determine the risk between the types of feeding and complications, the relative risk will be determined, with confidence interval. Likewise, the average length of hospital stay in the two groups will be compared using ANOVA analysis. Values of $p < 0.05$ will be considered statistically significant.

Ethical aspects

Each individual who will be part of the study will authorize their inclusion through an informed consent prepared under the Helsinki criteria. No

The patient will be required to take part in the study and may be withdrawn from it at any time. The anonymity of the population will be respected and the data will be handled confidentially for the purposes of this thesis project only. As this is an experimental study, approval will be required from the ethics committee of the Hospital Complejo Hospitalario Universitario “Dr. Luis Razetti” and the Postgraduate Unit of the Universidad de Oriente.

SCHEDULE

	2023				2024				
MONTH	**SET**	**OCT**	**NOV**	**DEC**	**JAN**	**FEB**	**SEA**	**APR**	**MAY**
Project presentation	x	x							
Bibliographic research	x	x							
Project structuring		x	x						
Procedure				x	x				
Recording information on cards				x	x				
Information analysis						x	x		
Review of results						x	x		
Preparation of the final report								x	
Presentation of research paper									X

BUDGET

To carry out this research work, the implementation of the following resources will be necessary:

Concept	Estimated amount (Bolivars)
Stationery	300.00
Software Acquisition	800.00
Internet	300.00
Impressions	350.00
Logistics	300.00
Transfers	1200.00
TOTAL	**3250.00**

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ANNEXES

1. Consistency matrix

Qualification	Research Question	Goals	Hypothesis	Type and design of study	Study population and processing of data	Collection instrument
EFFICACY OF EARLY VERSUS LATE ENTERAL NUTRITION IN GASTROINTESTINAL SURGERY" DR. LUIS RAZETTI" UNIVERSITY HOSPITAL COMPLEX 2023-2024.	What is the effectiveness of early enteral nutrition versus nutritionLate enteral in gastrointestinal surgery at the "Dr. Luis Razetti" University Hospital Complex 2023-2024	General objective Compare the effectivenessof early enteral nutrition versus the nutritionLate enteral in gastrointestinal surgery at the "Dr. Luis Razetti" University Hospital Complex 2023-2024 Specific objectives Identify thebenefits of early enteral nutrition Determine thePossible disadvantages eitherrisks in hestart of early enteral nutrition Relate heeffect of theearly enteral nutrition on the decreasein the length of hospital stay Compare the incidence ofComplications of early enteral nutrition in relation to	Null hypothesis: TheEarly enteral nutrition is less effective than late enteral nutrition in surgery gastrointestinal in he"Dr. Luis Razetti" University Hospital Complex 2023-2024. Alternative hypothesis: TheEarly enteral nutrition results further effective than late enteral nutrition in surgery gastrointestinal in he"Dr. Luis Razetti" University Hospital Complex	The study will be analytical, observational, prospective, of cohorts.	Patients undergoing gastrointestinal surgery that includes primary raffia or anastomosis, who are treated in the surgery service of the "Dr. Luis Razetti" University Hospital Complex The variables will be coded and entered into a database in SPSS version 15 and Microsoft EXCEL 2016, to later be tabulated and presented in tables: baseline and results.	Data collection form

		late.				

2. Data collection instrument

DATA COLLECTION FORM

Cluster	
Medical Record No.	
Age	
Sex	
Size	
Weight	
BMI	
Gastrointestinal surgery	
Surgical time	
Symptoms and signs at 6 hours after the start of enteral nutrition	
Symptoms and signs at 12 hours after the start of enteral nutrition	
Symptoms and signs at 18 hours after the start of enteral nutrition	
Symptoms and signs at 24 hours after the start of enteral nutrition	
Postoperative complications related to the start of enteral nutrition	
General postoperative complications, not related to the onset enteral nutrition	
Days of hospital stay	