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Randomized Clinical Trial: Nasoenteric Tube or Jejunostomy as a Route for Nutrition After Major Upper Gastrointestinal Operations

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Abstract

Background Curative treatment of upper gastrointestinal tract neoplasms is complex and associated with high morbidity and mortality. In general, the patients are already malnourished, and early postoperative enteral nutrition is recommended. However, there is no consensus concerning the best enteral access route in these cases.

Methods A prospective randomized trial was performed from 2008 to 2012 with 59 patients who underwent esophagectomy, total gastrectomy, or pancreaticoduodenectomy. In all, 4 patients declined to participate, and 13 did not meet the inclusion criteria and were excluded. Of the 42 included patients, 21 had nasoenteric tubes, and 21 had a jejunostomy.

Results The two groups were similar in demographic and clinical aspects. The nasoenteric (NE) and jejunostomy groups underwent early enteral therapy in 71 and 62 % of cases ($p > 0.05$), respectively. The median length of enteral therapy use was less in the NE group (5.0 vs. 8.5 days), but the difference was not statistically significant. The NE group required introduction of parenteral therapy more frequently than the jejunostomy group ($p < 0.05$). Complications related to the enteral route occurred in 38.0 and 28.5 % of patients ($p > 0.05$) in the NE and jejunostomy groups, respectively. In the NE group, there were four losses and four tube obstructions. In the jejunostomy group, there were two losses, four obstructions, and two cases of leakage around the tube. In the latter group, patients who underwent therapy for a longer time had tubal complications ($p < 0.05$) and longer intensive care unit and hospital stays ($p < 0.05$).

Conclusion The two enteral routes were associated with the same number of complications. However, the presence of a jejunostomy allowed enteral therapy for longer periods, especially in patients with complications, thus avoiding the need for parenteral nutrition.

Introduction

Operations for curative treatment of upper gastrointestinal (GI) tract neoplasms, especially esophagectomy, total gastrectomy, and pancreaticoduodenectomy, are complex procedures with high surgical stress. They are associated with high morbidity and mortality, mainly in malnourished patients [1–4]. It is common to maintain "nil per os" during the first days after surgery. This approach is based on the supposed increased risk of gastrointestinal distension and associated fistulas [5, 6]. Furthermore, malnutrition has a high prevalence in oncologic patients and increases up to 15.7-fold when patients have GI tract neoplasms, affecting between 60 and 85 % of patients [7, 8]. As a result, postoperative enteral therapy after upper GI procedures is widely indicated [9–12] and has been shown to be superior to the parenteral route [13]. Patient benefits include reduced infection complications, lower cost, and shorter length of hospital stay [9, 10, 13, 14].

Essentially, there are two routes that can be used to administer enteral nutrition in these cases: a nasoenteric tube or enterostomy using a biocompatible catheter [15, 16]. However, there is no consensus in the literature

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regarding the best access point to the GI tract for postoperative feeding, and the ideal access route remains controversial. Generally, the enteral route is defined according to the surgeon's preference [7]. The objective of this study was to compare the incidence of complications between placing a nasoenteric catheter and performing a jejunostomy as enteral feeding routes after major upper GI cancer procedures.

Methods

A prospective randomized trial was conducted. Patients with neoplasms of the esophagus, stomach, or pancreatic head who were referred for tumor resection after preoperative clinical and radiologicstaging were invited to participate in the study after providing written informed consent. Sample size was determined with the use of Stata software, version 10 (Stata, College Station, TX, USA). It was based on a value of $p < 0.05$ and the power of the test of 0.8, considering complication rates for nasojejunal catheters of 40 %, and for jejunostomies of 60 %, as well as the number of patients who would be operated on per year. We concluded that 44 patients should be included in the study.

During the perioperative period, a random drawing to assign the enteral access route was conducted using sealed opaque envelopes containing either nasoenteric (NE) tube or jejunostomy group allocation, which were drawn by the anesthesiologist. The NE tube was introduced by an anesthesiologist through the nostril and positioned, with the surgeon's assistance, 20 cm distal to the last anastomosis. The guidewire was then withdrawn, and the catheter was attached to the nose wing with surgical silk thread (2.0) and tape. The jejunostomy was performed using Stamm's technique with a no. 16 or 18 latex catheter. It was positioned 20 cm after the last anastomosis following gastrectomy or pancreatoduodenectomy and in the case of esophagectomy after the Treitz ligament. Postoperatively, enteral feeding was initiated after orientation by the assistant surgeon at a rate of 30 ml/h, increasing the rate according to the patient's tolerance to meet nutritional requirements. Patients were followed until catheter removal, death, or discharge.

Data were registered on specific forms and included the following variables: age, sex, weight, weight loss during the last 3 months before the operation, height, body mass index, indication for surgery, diseases, albumin, hemoglobin, and previous operations. In addition, postoperative data related to enteral nutrition were collected, including time to feeding onset, diet progression, duration of enteral nutrition use, need for parenteral therapy, intensive care unit (ICU) length of stay (LOS), hospital LOS, general complications, and catheter-related complications.

The general complications were classified according to the criteria defined by Clavien-Dindo in 2004 and were subdivided into mild (Clavien-Dindo I and II) and severe (Clavien-Dindo III, IV, and V) complications [17]. Complications related to the catheters were investigated and recorded separately. Those related to the NE tube were described as loss, obstruction, or displacement of the catheter. Nasopharyngeal infection was also recorded. Regarding the jejunostomy, the following conditions were considered complications: catheter loss or obstruction, fistula formation, or collapse of the jejunostomy with peritoneal contamination, leakage around the catheter insertion, site infection, and/or bowel obstruction.

The Research Ethics Committees of HGIP-IPSEMG and Luxemburgo's Hospital approved the project (CAE 0016.0.191.000-08). It was registered with the National Research Committee (CONEP) and with the Clinical Trials (NCT01894490).

The statistical analysis considered a significance level of 5 %. The χ^2 test, Fisher's exact test, Mann–Whitney test, or Kruskal–Wallis test was used to evaluate the two methods used (NE tube/jejunostomy) and the complications associated with each method [18]. The statistical analysis was conducted using SPSS 15.0 software (SPSS, Chicago, IL, USA).

Results

From June 2008 through September 2012, a total of 59 patients admitted to the HGIP-IPSEMG and Luxemburgo's Hospital in Belo Horizonte were eligible for the study. Among these patients, 4 did not consent to the randomization, and 13 patients were excluded because of signs of locally advanced disease or a change in diagnosis. Thus, 42 patients underwent the proposed surgical procedures and were randomized into an NE group and a jejunostomy group, with 21 patients per group (Fig. 1).

The percentage of men in the NE group was 62 %, and that of the jejunostomy group was 38 % ($p > 0.05$). The mean age of the NE group was 60 years, and that of the jejunostomy group was 65 years. The difference in the mean ages was not significant.

The two groups had similar clinical characteristics, as shown in Table 1. Associated diseases were identified in 52 % of patients in each group. Hypertension and diabetes mellitus were especially common (nine and six patients in the NE group versus eight and four patients in the jejunostomy group, respectively). Others, such as obesity (three patients in each group), mild renal failure (one in the NE group), coronary disease (one in each group), and chronic obstructive pulmonary disease (one in the jejunostomy group), were also present. The most common

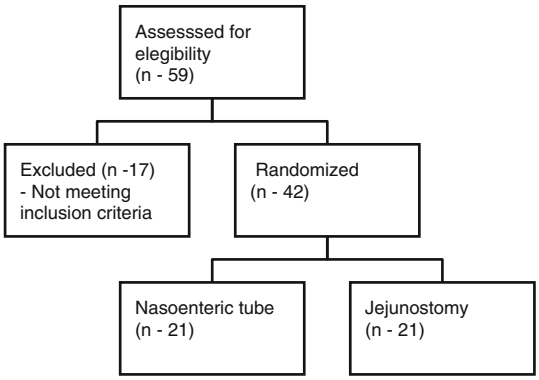

Fig. 1 Flowchart for patients, Belo Horizonte, 2013

Table 1 Clinical variables in nasoenteric tube and jejunostomy groups, Belo Horizonte, 2013 ($n = 42$)

Variable	NE ($n = 21$)	Jejunostomy ($n = 21$)
Associated disease (*n*)	11	11
Indication (*n*)		
Esophageal cancer	4	3
Gastric cancer	9	10
Periampullary cancer	8	8
Body weight loss (*n*)		
≤10 %	14	15
>10 %	7	6
Albumin, g/dl (mean ± SD)	2.8 ± 1.1	3.4 ± 0.6
Hemoglobin, mg/dl (mean ± SD)	11.4 ± 3.2	11.4 ± 1.8

NE nasoenteric catheter

* $p < 0.05$>

indication for surgery was gastric neoplasms followed by periampullary and esophageal tumors. Weight loss varied widely in both groups. A loss of >10 % was identified in 33 % of the NE patients and in 29 % of the jejunostomy patients. Albumin and hemoglobin values were similar in the two groups ($p > 0.05$).

Data from postoperative nutritional therapy are shown in Table 2. It was noted that feeding was started within 48 h in 71 % of patients with the NE tube and in 62 % of those with a jejunostomy. This difference was not significant. Regarding the time of enteral feeding use, there was no significant difference between groups, although the median time was less among patients with NE tubes (5 days) compared to patients with jejunostomies (8.5 days) ($p > 0.05$). Overall, 38 % of patients in the NE group and 33 % of patients in the jejunostomy group received the target nutrition requirements on postoperative day (POD) 3 ($p > 0.05$).

Concerning parenteral therapy, eight patients in the NE group received parenteral nutrition (38 %), compared to only two patients in the jejunostomy group (10 %) ($p < 0.05$). Of the NE patients, three underwent parenteral therapy because of loss of the NE tube and oral intake being contraindicated (according to the surgeon's discretion). The other five NE patients were placed on parenteral therapy because of complications such as postoperative pancreatic fistulas and anastomotic esophageal-pleural fistulas. In the jejunostomy group, there were no changes to parenteral therapy because of problems with nutritional access. The average duration of parenteral feeding use was also longer in the NE group, but the difference was not statistically significant ($p > 0.05$).

Table 2 Nutritional therapy in postoperative NE and jejunostomy groups, Belo Horizonte, 2013 ($n = 42$)

Parameter	NE ($n = 21$)	Jejunostomy ($n = 21$)
Time to feeding onset (*n*)		
≤48 h	15	13
>48 h	6	8
Nutritional target on POD 3 (*n*)	8	7
Parenteral nutrition (*n*)	8	2*
Duration of PN (days), median (IQ 25–75)	10 (5–15)	5.5 (1–11)
Duration of EN (days), median (IQ 25–75)	5 (3.5–9.5)	8.5 (6–23)

IQ interquartile range, *POD* postoperative day, *PN* parenteral nutrition, *EN* enteral nutrition

* $p < 0.05$

In the NE group, 19 % of patients had complications classified as mild (Clavien-Dindo I–II), and 47 % had complications classified as severe (Clavien-Dindo >II). In the jejunostomy group, 33 % of patients had complications classified as mild, and 29 % had complications classified as severe ($p > 0.05$). There were no serious complications directly related to the enteral access route. There were also no differences between groups with regard to the hospital LOS stay or the postoperative LOS in the ICU (Table 3). There were five deaths, none of which was related to the nutritional access route.

Complications related to the enteral access route occurred in eight (38 %) patients in the NE group and six (28 %) patients in the jejunostomy group ($p > 0.05$) (Table 4). Some patients had more than one complication, including catheter obstruction and loss and leakage around the jejunostomy. There were no other complications associated with catheters. There were no serious complications related to the NE catheter such as intraabdominal leak.

Catheter obstruction occurred in four (19 %) patients in each group. In the NE group, obstructions occurred on PODs 8, 9, 10, and 14, respectively. Only one of these patient required parenteral therapy. In the jejunostomy

Table 3 General complications and hospital and ICU stays in NE and jejunostomy groups, Belo Horizonte, 2013 ($n = 42$)

Parameter	NE ($n = 21$)	Jejunostomy ($n = 21$)
General complications (n)		
None	7	8
Mild	4	7
Severe	10	6
Hospital stay (days), median (IQ 25–75)	15 (10.5–27.0)	15 (10–28)
ICU stay (days), median (IQ 25–75)	3 (1.5–11.0)	3 (2–15)
Deaths	4	1

ICU intensive care unit

* $p < 0.05$

Table 4 Complication details associated with nutritional access in NE and jejunostomy groups, Belo Horizonte, 2013 ($n = 42$)

Parameter	NE	Jejunostomy
NE/jejunostomy complications (n)	8	6
Type of complication (n)		
Obstruction	4	4
Leakage	–	4
Loss of catheter	4	2

* $p < 0.05$

group, obstructions occurred on PODs 7, 8, 10, and 16, respectively. In all cases, the catheters were exchanged, and enteral therapy was restarted.

Catheter loss occurred in four (19 %) patients in the NE group and in two (10 %) patients in the jejunostomy group. The difference between the groups was not significant. In the NE group, there were two catheter losses in patients who pulled the tube on PODs 1 and 4, respectively, and two other accidental losses on PODs 2 and 4, respectively. Of the four, two required parenteral therapy. In the jejunostomy group, two catheter losses occurred on PODs 3 and 20, respectively. The catheters were reintroduced, and nutrition was restarted in both cases.

Four patients in the jejunostomy group had leakage around the catheter. They were treated with local wound care and either a reduced infusion rate or temporary interruption of enteral feeding.

The factors associated with enteral access route complications in the jejunostomy and NE groups were investigated. The duration of enteral feeding use was longer in patients who had complications with the jejunostomy ($p < 0.05$). The median duration for patients with complications was 26.5 days compared to 6.5 days for patients without complications. The opposite occurred in the NE group: Patients without complications used the enteral feeding for 6 days, and those with complications used it for 4 days, with no significant difference (Table 5).

Table 5 Factors associated with catheter complications in NE and jejunostomy groups, Belo Horizonte, 2013 ($n = 42$)

Factor	NE complications ($n = 21$)		Jejunostomy complications ($n = 21$)	
	No	Yes	No	Yes
Enteral therapy within 48 h	8	7	9	4
Enteral stay duration (days, median)	6.0	4.0	6.5	26.5*
Nutritional target on POD 3	5	3	4	3
Parenteral therapy (n)	4	4	2	0
PN duration (days, median)	15.0	6.5	5.5	NA
General complications (n)				
None	3	4	7	1
Mild	2	2	4	3
Severe	8	2	4	2
ICU stay (days, median)	3.0	4.5	2.0	13.5*
Hospital stay (days, median)	18.5	14.0	12.5	30.5

NA not applicable

Unless otherwise stated, the results are the number of patients or the median value

* $p < 0.05$

Enteral access route complications did not significantly influence the use of parenteral therapy. When the parenteral therapy usage during for the NE group was analyzed, there was a median of 15 days for patients without catheter complications and 6.5 days for those who had complications, with no significant difference.

General complication severity was not associated with the incidence of catheter complications. The median ICU LOS and postoperative LOS were higher among patients who had any catheter complications in the jejunostomy group ($p < 0.05$) (Table 5).

Discussion

The present study is one of a few that aimed to investigate the efficacy and complications related to the access route for enteral therapy on postoperative recovery from upper GI procedures, both prospectively and randomly. Our results show that the two enteral accesses are associated with similar numbers of catheter-related complications. However, jejunostomy can maintain enteral therapy for longer periods, even when catheter-related complications are present. Jejunostomy certainly facilitates treatment of patients who have complications, thereby avoiding the need for parenteral nutrition. Our study groups showed

homogeneous clinical and demographic characteristics, comparable to other publications on this patient group [19, 20].

The operations performed in the current study reflected the profile of the study institution. HGIP-IPSEMG and Luxemburgo's Hospital in Belo Horizonte is known predominantly for performing gastrectomy and pancreaticoduodenectomy. These operations, together with esophagectomy, represent the most common postoperative indications for catheter placement worldwide and were equally distributed in our study groups. The initiation of enteral feeding occurred within 48 h in the majority of patients in the NE and jejunostomy groups. Importantly, it was the assistant surgeon who made the decision about when to initiate the diet. Nonetheless, our data show a trend indicating early enteral therapy in clinical practice, which is consistent with the benefits previously demonstrated in the literature [8, 12, 21]. However, most patients did not receive their nutritional requirements on POD 3, a factor that should be reassessed in the future. This was related to the late start of the enteral infusion in some cases, slow progression, or suspension in patients who presented any complication.

Enteral nutritional therapy was used longer in the jejunostomy group, although the difference was not statistically significant. A similar study also showed this trend [20]. The time difference could be explained based on the type of access used. The NE tube triggers discomfort in the nasopharynx and oropharynx, causing patients to intentionally pull the tube to relieve discomfort, which occurred in two cases in this study. The incidence of NE catheter loss shows enormous variation in the reported literature (4.7–34.0 %) [16, 20]. Additionally, the discomfort may induce doctors to perform early removal. Furthermore, in patients with complications, such as loss or obstruction of the NE tube, the impossibility of repositioning the tube has interrupted enteral therapy. Nausea and vomiting favor displacement, and the catheter's attachment is another factor. Various methods are used to fix the catheter, such as dressing the dorsum and fixation points to the nose. Recently, a technique to create a nasopharyngeal handle was found to reduce the risk of loss—but at the expense of complications including infection, bleeding, and discomfort [22].

By contrast, jejunostomy triggers less discomfort and does not interfere with ingestion. Moreover, with jejunostomy performed by Stamm's technique, the catheter may be passed again in cases of obstruction or loss, allowing for resumption of the diet infusion, which occurred in six cases in this study. The NE patients required parenteral nutrition more often ($p < 0.05$) than the jejunostomy patients. This may have occurred for the same reasons already mentioned regarding prolonged use of enteral feeding in the jejunostomy group: mainly catheter displacement and loss. Nonetheless, complications of the enteral access route were not different in the NE and jejunostomy groups, in agreement with data from other studies (Table 6) [16, 19, 20].

Table 6 Comparative studies on complication rates between NE tube and jejunostomy for postoperative nutritional therapy during upper gastrointestinal tract procedures

Study	No. of patients	NE (%)	Jejunostomy (%)	*p*
Han-Geurts [19][a]	150	21	35	0.48
Abu-Hilal [16]	68	11	24	0.06
Gerritsen [20]	92	41	23	0.06
Torres 2013[a]	42	38	28	0.50

[a] Randomized studies

We observed no serious complications related to the enteral access routes in this study. In contrast, Han-Geurts et al. [23] described complications with jejunostomies in 1.1 % of their cases. In the studies presented in Table 6, two patients underwent reoperation for jejunostomy leaks, and one death was reported due to this complication. None of these studies reported serious complications related to the NE catheter. However, rare but fatal complications have been described resulting from improper positioning of the NE catheter in clinical patients [24].

In the current study, patients who experienced complications in the jejunostomy group were those who used enteral feeding for a longer time and had longer ICU and hospital LOS. Therefore, catheter usage time may be a predisposing factor for complications related to such usage. It is interesting to note that the complications were properly treated in these cases without changing the diet infusion. Thus, the jejunostomy technique is practical and efficient for providing enteral nutrition postoperatively. This is especially true for patients with general complications and who require prolonged enteral therapy [25–27].

Jejunostomy can be performed by various surgical techniques, each of which has modifications that hinder their comparison, and each has specific complications. Stamm's jejunostomy was the standard technique for the present study because it is preferred by most surgeons at the institution where this study was conducted. Unlike Witzel's jejunostomy, Stamm's has the advantage of allowing repositioning in the case of loss or obstruction.

This study may have some limitations, including the unblinded use of the enteral route, which is difficult to conceal considering the jejunostomy and nasojejunal catheters. Moreover, the relative small sample size might have affected the results as a type two error might have occurred. Another important potential drawback is that the latex catheter used to perform the jejunostomies was not ideal for this procedure. This catheter was chosen because

the main research institution for this study did not have the ideal silicone or polyurethane catheter in stock. Such substitution may have affected the results for this procedure, leading to reduced quality of the final results.

Conclusions

Our results permit us to conclude that the two enteral access approaches are associated with similar numbers of catheter-related complications. However, jejunostomy provides enteral nutrition for longer periods. This is especially true when an enteral diet is necessary in patients who have both procedure and catheter-related complications, thereby avoiding the need for parenteral nutrition.

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