

Gastric Decompression and Enteral Feeding Through a Double-Lumen Gastrojejunostomy Tube Improves Outcomes After Pancreaticoduodenectomy

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Objective: The objective of this study was to assess the feasibility and safety of inserting a double-lumen gastrojejunostomy tube (GJT) after pancreaticoduodenectomy (PD) and to evaluate associated outcomes.

Background: Gastroparesis is a frequent postoperative event following PD. This often necessitates prolonged gastric decompression and nutritional support. A double-lumen GJT may be particularly useful in this situation: gastric decompression may be achieved through the gastric port without a nasogastric tube; enteral feeding may be administered through the jejunal port.

Methods: Thirty-six patients with periampullary tumors were randomized at the time of PD to insertion of GJT or to the routine care of the operating surgeon. Outcomes, including length of stay, complications, and costs, were followed prospectively.

Results: The 2 groups had similar characteristics. Prolonged gastroparesis occurred in 4 controls (25%) and in none of the patients who had a GJT ($P = 0.03$). Complication rates were similar in each group. Mean postoperative length of stay was significantly longer in controls compared with patients who had a GJT (15.8 ± 7.8 days versus 11.5 ± 2.9 days, respectively; $P = 0.01$). Hospital charges were $\$82,151 \pm 56,632$ in controls and $\$52,589 \pm 15,964$ in the GJT group ($P = 0.036$).

Conclusions: In patients undergoing PD, insertion of a GJT is safe. Moreover, insertion of a GJT improves average length of stay. At the time of resection of periampullary tumors, GJT insertion should be considered, especially given this is a patient population in which weight loss and cachexia are frequent.

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Delayed gastric emptying is 1 of the most frequent postoperative complications after pancreaticoduodenectomy (PD), reportedly occurring in 7% to 36% of patients.^{1–6} This is typically associated with a protracted hospitalization. Moreover, because patients with periampullary malignancies are frequently malnourished or cachectic,^{1,2,7–9} prolonged nutritional support is usually required in these circumstances. Unfortunately, when delayed gastric emptying occurs, it is very difficult to anticipate the need for nutritional support. Thus, patients who have this complication can be expected to suffer a considerable nutritional deficit over the months of convalescence after PD.

There are a number of options available for administering nutritional supplementation. Parenteral nutrition (TPN) can be administered when the gastrointestinal tract is inaccessible, but this route is relatively expensive and it is associated with increased infectious complications.^{10–13} Enteral nutrition has numerous potential advantages such as maintaining gut mass and absorption, limiting microbial translocation, fewer infectious complications, and reduced cost.^{11–16} However, with gastroparesis, feeds must be administered directly to the jejunum.⁸ This is difficult to access if this complication has not been anticipated, especially given the major anatomic alterations secondary to PD.

Percutaneous tubes have advantages over nasogastric (NG) tubes, particularly if prolonged gastric decompression is required, as is often the case after pancreaticoduodenectomy.^{1,2,7,17} Nasally placed tubes are uncomfortable, can be easily dislodged, and are associated with sinusitis, nasal trauma, gastroesophageal reflux, and respiratory complications.^{18–21} Indeed, a unique randomized study by Hoffman et al reaffirms that patients find NG tubes more inconvenient and uncomfortable than gastrostomy tubes, even though gastrostomy tubes are left in situ for up to 4 weeks.¹⁹ Double-lumen gastrojejunostomy tubes (GJT)^{22,23} may be particularly useful after PD given the problems outlined here. Prolonged gastric decompression can be effected through the

gastric port if necessary without the discomfort and complications associated with prolonged nasal intubation. Because feeding through a gastrostomy is not feasible until gastric motility has normalized,²³ enteral feeding may proceed through the jejunal port. We postulated that routine insertion of a GJT and administration of a standard enteral feeding protocol would reduce the impact of gastroparesis after PD, improving average length of stay. To investigate this hypothesis, we implemented a prospective, randomized, controlled study in which the study group had a double-lumen GJT inserted.

METHODS

Protocol Implementation

The study protocol was approved by the University of Miami Institutional Review Board and all patients who participated provided informed consent. All patients with a potentially resectable periampullary mass were screened for participation. Inclusion criteria were age greater than 18 years, Karnofsky performance score ≥ 70 , and normal organ function. Exclusion criteria included concurrent intraabdominal infection, prior abdominal radiation, and pregnancy or breast feeding. Patients receiving preoperative nutritional support and patients who required emergency surgery (eg, for bleeding, bowel obstruction, or cholangitis) were also excluded.

All patients underwent exploratory laparotomy followed by standard PD as previously described.²⁴ Pancreaticojejunostomy was performed using a double-layer end-to-end technique. Closed suction drains were placed near the pancreaticojejunostomy and posterior to the hepaticojejunostomy.

Randomization occurred during surgery once it was determined that the tumor was resectable. Randomization was performed by drawing an envelope containing a group assignment. Patients in the GJT group had a GJT inserted. There were 3 approved tubes for the study: the COMPAT Surgical Gastrostomy/Jejunal Feeding Tube (Novartis Nutrition Corp., St. Louis Park, MN); a 2-tube system consisting of a COMPAT 22 Fr balloon gastrostomy tube and a COMPAT 9 Fr PEJ/J-line tube (Novartis); and a MIC gastrojejunostomy tube (MIC Global Resources Limited, London, UK). Enteral feeds (IMPACT, Novartis) were initiated at 24 to 48 hours after surgery, beginning at 20 mL/h. The infusion rate was increased at 20 mL/h each day as tolerated until a goal rate of 25 kcal/kg/d was achieved. Feeds were stopped when oral intake was sufficient. Patients in the control group were treated as per the operating surgeon's routine. This included insertion of an NG tube for gastric decompression. Nutritional support was administered if the surgeon felt it was indicated, and the route of administration was also dictated by the surgeon's routine practice.

Duration of NG tube or GJT drainage and progression to oral intake were directed at the discretion of the surgical

team. Discharge planning was similarly implemented at the discretion of the surgical team. All patients were followed for at least 90 days postoperatively to monitor for complications.

Data Analysis

The primary end point was length of stay. Secondary end points included costs, rates of gastroparesis, and complications. The bias at our institution was to administer TPN to all patients with significant weight loss (eg, $> 10\%$) or malnutrition. In view of this bias, TPN rates were not secondary end points in this trial. Gastroparesis was defined as an inability to tolerate oral intake on or after postoperative day 14.²⁵ Pancreatic fistula was defined as a radiographically detected leak or as drainage of greater than 50 mL of amylase-rich fluid on or after postoperative day 10.²⁶

Setting $\alpha = 0.05$, with a power of 80%, a sample size of 36 evaluable patients per group was required to show a difference in length of stay of 2 days, assuming a mean duration of hospitalization of 15 days and a standard deviation of 3 days. However, the study was terminated prematurely for administrative reasons, because the principal investigator moved to a new institution. All data were analyzed in an intent-to-treat fashion.

All values are expressed as mean \pm standard deviation unless otherwise specified. Statistical significance of differences between 2 means was tested by a 2-tailed *t* test for 2 independent samples or Wilcoxon signed rank tests. For categorical data, the Fisher exact test was used to compare groups. Length of stay was calculated as the number of days from the date of PD to the date of discharge. Length of stay was compared using log-rank comparisons for time-to-event data by the Kaplan-Meier method.²⁷

Cost Modeling

Hospital charges were in U.S. dollars. Given the small sample size and the limited ability to extrapolate from these data to determine the true cost effects of routine GJT insertion during PD, cost modeling was used to make more general predictions. In this way, the effects of potential confounding factors (eg, cost variations based on insurance coverage, operating surgeon, and so on) could be eliminated. Moreover, several assumptions could be tested to evaluate their effects on costs. Cost predictions for a hypothetical cohort of 100 patients were made. For the purpose of this analysis, the costs for PD, central line placement, and intensive-care unit stay were assumed to be the same in each group and were therefore excluded from analysis. Similarly, costs for intravenous lines, TPN bags, enteral feed tubing and bags were excluded from cost modeling.

Cost predictions for 100 model patients treated without a GJT were based on several variables: rate of gastroparesis, rate of TPN administration, and length of stay. Gastroparesis rates of 5%, 10%, and 15% were modeled. It was assumed

that average length of stay in patients with gastroparesis was 20 or 25 days. Moreover, it was assumed that TPN was administered for an average of 10 days in all patients with gastroparesis and in 20% to 40% of patients without gastroparesis. An average length of stay of 15 days was assumed for patients without gastroparesis. Similar cost predictions were made for 100 model patients treated with a GJT. The model was based on the same average length of stay as patients treated without a GJT uncomplicated by gastroparesis (ie, 15 days). Cost calculations were based on a group in which 0% or 10% of patients received TPN. The average duration of enteral feeding in patients was assumed to be 13 days.

RESULTS

Patient Characteristics

Between April 1999 and January 2002, 59 patients consented. Eighteen patients were excluded during surgery: 13 had unresectable disease, 1 had a neuroendocrine tumor treated with enucleation, 1 had a choledochal cyst, 1 had a mass arising from the transverse colon mesentery, and 2 had a benign stricture treated with biliary reconstruction. Five patients were nonevaluable because of failure to randomize during surgery or because of a failure to implement the protocol. These 5 patients did not significantly differ from the randomized patients in terms of diagnoses, operative time, operative blood loss, or incidence of preoperative jaundice or weight loss. At the end, 36 patients with periampullary tumors were randomized to either insertion of a GJT (N = 20) or to the control group (N = 16).

The incidence of jaundice or significant weight loss was similar in each group. There were 12 individuals in the GJT group who had major comorbidities (60%) and 6 patients in the control group (38%) who had major comorbidities. This difference was not statistically significant. The patient characteristics of each group are summarized in Table 1.

Perioperative Outcomes

Operative details are summarized in Table 2. All patients had a PD. None of these was a pylorus-preserving procedure. One patient had a hemicolectomy and 2 patients had a hepatic wedge resection in addition to the PD. Five surgeons participated in this trial, and there was no significant difference in the distribution of surgeons in either treatment group or in outcomes by surgeon. Although 3 tube systems were approved for the trial, only 2 were used by participating surgeons according to personal preference: the COMPAT Surgical Gastrostomy/Jejunal Feeding Tube and the MIC gastrojejunostomy tube. There was no significant difference in outcomes between the different devices.

Operative time was significantly longer in the GJT group (416 ± 128 minutes versus 327 ± 55 minutes; $P = 0.01$). The distribution of operative times is depicted in detail

TABLE 1. Baseline Preoperative Patient Characteristics

	GJT Group	Control	Significance
Number	20	16	
Gender			
Male	17	9	0.07
Female	3	7	
Age	62 ± 10	5 ± 14	0.47
Weight loss >10%	11 (55%)	8 (50%)	1.0
Jaundice	11 (55%)	6 (34%)	0.72
Cormorbidities			
DM	4	1	
CAD	2	0	
Hypertension	3	3	
PUD	2	0	
Hypothyroid	1	1	
Asthma	1	0	
Prior malignancy	2 (1 MEN)	1	
No. of patients with major comorbidities	12 (60%)	6 (38%)	0.31
No. of comorbidities/patient	1.1 ± 1.1	0.8 ± 1.1	0.4

GJT, gastrojejunostomy group; DM, diabetes mellitus; CAD, coronary artery disease; PUD, peptic ulcer disease; MEN, multiple endocrine neoplasia.

TABLE 2. Operative Factors

	GJT Group	Control	Significance
Procedures			
Pancreaticoduodenectomy	20	16	
Additional features			
Pylorus-preserving	0	0	—
Hemicolectomy	1	0	1.0
Liver wedge resection	0	2	0.2
OR time (min)	416 ± 128	327 ± 55	0.01
EBL (mL)	610 ± 354	430 ± 366	0.17
Blood transfusions (units)	0.4 ± 0.9	0.5 ± 1.0	0.68
Pathologic diagnosis			
Adenocarcinoma			
Pancreas	9	9	0.73
Ampullary	5	4	1.0
Duodenum	0	0	—
Common bile duct	2	2	1.0
Other malignancies	1	1	1.0
Benign disease	3	0	0.16

OR, operating room; EBL, estimated blood loss.

in Figure 1. Differences in operating times could not be explained by surgeon factors or by any obvious patient factors. Estimated blood loss was 610 ± 354 mL in the GJT group compared with 430 ± 366 mL in the control group.

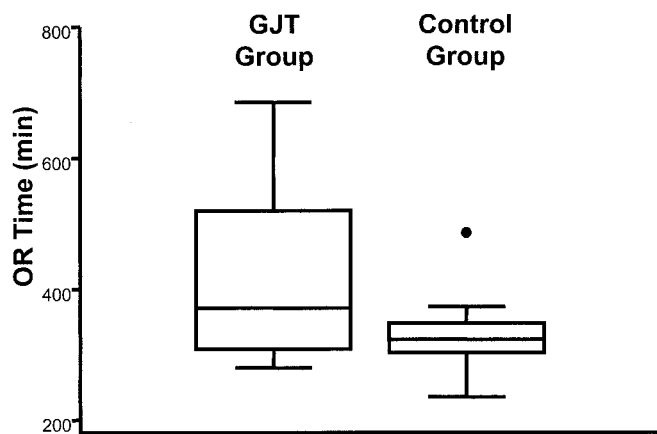


FIGURE 1. Box plot depicting operative times. The upper and lower lines comprising each box represent the 75th and 25th percentiles, respectively. The line in the middle of the box represents the median operative time.

This difference was not statistically significant. Transfusion requirements were the same in each group. No intraoperative difficulties or excessive bleeding related to the GJT insertion were reported throughout the course of the study. Table 2 itemizes final pathologic diagnoses for each group. There was no significant difference in the types of diagnoses.

One patient had inadequate gastric decompression with the GJT and required insertion of a NG tube. However, in this patient, tube feeds were erroneously initiated at 80 mL/h on the first postoperative day. Other complications related to enteral feeding included hyperglycemia (N = 1) and bloating (N = 1). Table 3 summarizes postoperative outcomes. Mean length of GJT drainage was 5.3 ± 2.2 days (median, 5 days) and NG tube drainage lasted 9.5 ± 6.7 days (median, 6.5 days) ($P = 0.02$). Prolonged gastroparesis occurred in 4 controls (25%) and none of the patients who had a GJT ($P = 0.03$). Two patients (12.5%) in the control group eventually had a GJT inserted: 1 had prolonged gastroparesis and had the tube inserted percutaneously; the other had a GJT inserted at the time of reexploration (see subsequently). Enteral feeds in the GJT group provided 1010 ± 360 kcal per day (range,

379–1545 kcal/d). TPN was administered to 9 patients in the control group (56%) and 1 patient in the GJT group (5%). Three patients in the control group received TPN secondary to gastroparesis and 6 had TPN because of a documented preoperative weight loss of greater than 10%. In 1 patient in the GJT group, TPN was initiated in response to hyperglycemia secondary to enteral feeding; this represented a protocol violation.

When gastroparesis was excluded, the overall complication rates in the 2 groups were similar (Table 3). One pancreatic fistula occurred in each group. Two reexplorations were required in the control group. One was for intraperitoneal hemorrhage on postoperative day 1 and 1 patient was reexplored to address a fluid collection associated with sepsis. In this latter patient, a GJT was inserted at the time of reexploration, because the operating surgeon anticipated a protracted convalescence. One patient in the control group had an intraabdominal abscess drained percutaneously on the fifth postoperative day. Overall, 2 patients had a major complication (pancreatic fistula, reexploration for hemorrhage on postoperative day 1) in association with gastroparesis. Two additional patients in the control group had gastroparesis without any additional complications. There were no intraoperative or 30-day mortalities.

Mean length of stay after surgery was 15.8 ± 7.8 days in the control group (median, 14 days). In the GJT group, mean length of stay was 11.5 ± 2.9 days (median, 11.5 days). This was significantly different ($P = 0.01$; Fig. 2). Interestingly, the difference in average length of stay could not be explained only by the need for reexploration in some individuals in the control group, because their durations of hospitalization were 15 and 16 days.

Cost Analysis and Modeling

Hospital charges were $\$82,151 \pm 56,632$ in the control group and $\$52,589 \pm 15,964$ in the GJT group ($P = 0.036$; Table 3). Cost modeling projections in patients treated without a GJT given the parameters outlined in the “Methods” section are summarized in Table 4A. Cost projections in patients treated with a GJT under various assumptions are summarized in Table 4B. Costs for patients treated with a

TABLE 3. Postoperative Course

	GJT Group	Control	Significance
Major complications (excluding gastroparesis)	1 (5%)	4 (25%)	0.15
Minor complications	3 (15%)	0 (0%)	0.2
Duration of gastric decompression (days)	5.3 ± 2.2	9.5 ± 6.7	0.02
Gastroparesis	0 (0%)	4 (25%)	0.03
Overall cost (U.S.\$)	$52,589 \pm 15,964$	$82,151 \pm 56,632$	0.036

GJT, gastrojejunostomy tube.

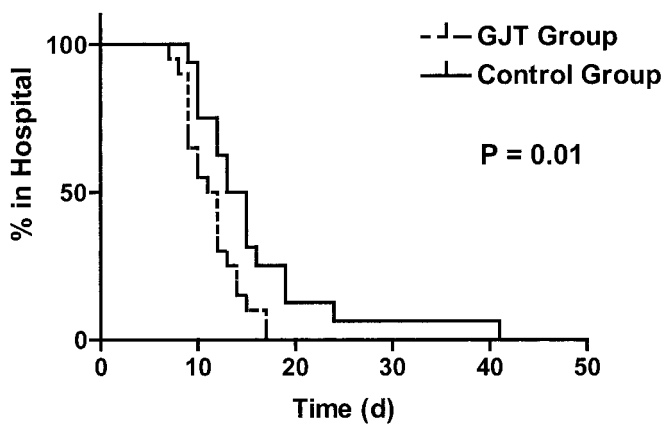


FIGURE 2. Kaplan-Meier curve illustrating postoperative length of stay.

TABLE 4. Cost Modeling for 100 Patients Treated in the Usual Fashion (A) and With the GJT (B)

A:) Controls						
TPN Rate	20-Day Stay			25-Day Stay		
	Gastroparesis Rate			Gastroparesis Rate		
	5%	10%	15%	5%	10%	15%
20%	1097	1129	1160	1114	1162	1211
30%	1127	1159	1190	1144	1192	1241
40%	1157	1189	1220	1174	1222	1271
B: GJT Group						
TPN Rate						
0%	1086					
10%	1116					

All costs are expressed as 1000s of \$ US.
TPN, parenteral nutrition; GJT, gastrojejunostomy tube.

GJT are less than those in patients treated without a GJT under most modeling assumptions, even though 100% of patients in the GJT group received nutritional supplementation compared with only 20% to 40% of the patients in the group treated by more standard methods. The only condition in which GJT insertion was not cost effective was under the assumptions that gastroparesis only occurs in $\leq 5\%$ of patients, patients with gastroparesis stay in the hospital for ≤ 20 days, and TPN is only required in $\leq 20\%$ of patients treated without a GJT.

DISCUSSION

After PD for periampullary tumors, gastroparesis is common. Unfortunately, this event is difficult to anticipate.¹⁻⁶ Delays in providing nutritional support are poten-

tially dangerous to the patient's long-term state of health, because many have already suffered significant weight loss and malabsorption before surgery. This may translate to prolonged hospitalization, prolonged convalescence, impaired quality of life, and a lesser likelihood of being fit for any adjuvant therapies available. Our intention was to evaluate whether duration of hospitalization could be impacted by insertion of a double-lumen GJT and administration of a standardized enteral feeding protocol. Indeed, insertion of a GJT and enteral feeding were associated with a shorter length of stay, a reduced incidence of gastroparesis, and cost savings. Moreover, this protocol was safe and feasible. As far as we are aware, this is the only series in the literature in which a GJT was used uniformly after PD.

Insertion of a GJT was found to be safe and feasible. Although operative time was longer in the GJT group, no major problems occurred during tube insertion. It is more likely that the longer operative times in this group reflected more difficult resections. Indeed, Gore and colleagues²³ observed that the GJT takes only 15 to 20 minutes on average to insert after a short learning curve. One patient in the GJT group required a NG tube, but this was associated with a major feeding protocol violation. In addition, it became apparent shortly after this event that the gastric port functions better on straight drainage than on suction.

Gastroparesis reportedly occurs in 7% to 36% of patients after PD in modern series.¹⁻⁶ The gastroparesis rate of 25% in our control group was consistent with these observed rates. It is unclear why patients with a NG tube should have a greater rate of gastroparesis or why they should require more prolonged gastric decompression on average. It is possible that this may reflect differences in breathing mechanics, because NG tubes impair breathing, predisposing to respiratory complications.¹⁸

The length of stay (LOS) in our control group was similar to those reported in large series from high-volume centers in the United States and Europe.^{24,25,28-32} In contrast, LOS in the GJT group compares favorably to lengths of stay reported by others.^{25,28-30} One notable exception is a series reported by Balcom et al, in which LOS was only 9.5 ± 0.4 days in 130 PD done between 1998 and 2002.⁶ They did not routinely administer perioperative enteral feeds. They attributed their recent improvements in LOS to a reduced complication rate, introduction of a clinical treatment pathway, as well as avoidance of pylorus-preserving procedures. Thus, the outcomes in the GJT group compare favorably to most series in the literature, which more closely reflect the outcome of our control group.

Although the baseline characteristics of our control group and the GJT group were comparable, several postoperative events in the control group could have potentially skewed our results. Specifically, 2 patients in the control group required reexploration, 1 developed a pancreatic fis-

tula, and 1 required percutaneous abscess drainage. After gastric surgery, impaired gastric emptying often heralds other major complications.¹⁷ Similarly, after PD, gastroparesis is particularly prevalent in patients who have experienced any major intraabdominal complication, occurring in up to 65% of such cases.² Another subgroup at risk for gastric dysmotility consists of patients who have leaks of the pancreaticojejunal anastomosis.⁴ In our series, 2 patients in the control group with major complications (fistula, hemorrhage) experienced gastroparesis, although an additional 2 had prolonged gastroparesis and LOS in the absence of other complications. One of the patients requiring reexploration had a GJT inserted at the time of reexploration and did not develop postoperative gastroparesis. It is conceivable that this may have averted a much more protracted recovery. Thus, although patients with a major complication may have potentially affected the results of this trial, these individuals were not the major source of the prolonged hospitalizations in the control group.

Randomized trials have shown the benefits of enteral nutrition compared with parenteral nutrition in terms of septic complications, cost, and overall outcomes in malignancy, pancreatitis, and trauma.^{8,14,15,16,33,34} Improvements in outcomes, including reduced overall and septic complications and diminished LOS, have also been reported when enteral nutrition is administered after PD.^{35,36} Gianotti et al³⁶ compared outcomes after PD in a 3-arm randomized trial of 212 patients. The first arm received standard enteral formula through jejunostomy; the second received an enteral diet enriched with arginine, omega-3 fatty acids, and RNA; and the third arm received TPN. Overall and septic complications were significantly fewer in both enterally fed groups.

The question remains whether the effects seen in our study were secondary to the tube itself or the result of the salutary effects of the enteral nutrition. Our trial differs substantially from other enteral feeding trials in that our regimen provided an average of only 1010 kcal/d for a mean of 6 days, compared with 1538 to 1847 kcal/d for a mean of 10 to 11.5 days.^{15,35,36} Therefore, in comparison to other enteral feeding trials, the degree of nutritional support administered was less. Our study was underpowered to demonstrate improvements in outcomes typically studied in enteral feeding trials. Despite this, our trial demonstrates that enteral feeding through the GJT is safe, feasible, and it impacts on LOS. We believe that improvements in LOS, gastroparesis rate, and cost reflect the multiple functions of the GJT. That is, the GJT provides gastric decompression without the potential respiratory and sinus complications of a NG tube; it decreases patient discomfort; and it represents an easily accessible port for feeding *should it be needed*. Thus, it is our belief that the improvements in outcomes observed in this study were not a function of the enteral feeding per se. Rather, the avoidance of a NG tube was also pivotal.

Since this study, the corresponding author has routinely used the GJT after PD in more than 35 patients. It has been observed that overly aggressive enteral feeding has delayed discharge in some individuals as a result of significant bloating. Martignoni et al¹ reported a similar experience in patients who had a PD. In a retrospective review, patients who were selected to receive enteral nutrition through a jejunostomy tube had a gastroparesis rate of 57% compared with 16% in patients who were not selected by their surgeon to receive enteral feeds. This translated to a prolonged average LOS (30.6 vs. 18.8 days). In view of our own observations, we see the role of the GJT as an adjunctive measure to provide gastric decompression without nasally placed tubes and to deliver enteral nutrition, if needed. It is unlikely to improve outcomes through aggressive enteral feeding strategies alone.

In addition to clinical outcomes, cost is an important consideration in deciding on whether insertion of a GJT is advantageous over the present standard of care. It is well established that enteral nutrition is less costly than TPN.^{13,14,37,38} Our own data plus the cost modeling in the current study confirm that feeding through the GJT is cost effective in most situations. Cost estimates for TPN and enteral feeding in this study are comparable to a recent review of costs in the U.S. healthcare system.³⁷ Cost savings may be considerably greater if enteral feeds are administered more selectively. That is, if feeds were only administered in patients who were initially malnourished or in those who experienced a major complication, greater cost savings could be realized, perhaps with little risk to clinical outcome.

In summary, insertion of a GJT during PD is safe and feasible, and it appears to reduce *average* hospital stay. This intervention is also cost effective. Although not all individuals will benefit in terms of LOS, insertion of a GJT does reduce the impact of those patients with gastroparesis or other major problems on hospital resources. The interpretation of the results of this trial is admittedly limited by the small numbers of evaluable patients. Therefore, larger confirmatory trials are required to demonstrate whether postoperative and long-term quality of life is better and whether nutritional outcomes are improved. Also, it would be interesting to determine whether more patients with a GJT have a sufficient performance status to proceed with adjuvant therapies within the 8- to 10-week window typical for most adjuvant protocols. It is our impression that initiating enteral feeds early in the postoperative period is not integral to the success of this strategy, although larger trials could address this issue as well.

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