Laparoscopic Gastrostomy and Jejunostomy

Safety and Cost With Local vs General Anesthesia

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Background and Hypothesis: General anesthesia is used for laparoscopic enteral access because pneumoperitoneum requires relaxation of the abdominal muscles. We wanted to determine whether these procedures could be performed with similar results and cost under local anesthesia.

Design: Randomized controlled study with 30-day follow-up including a cost-benefit analysis.

Setting: University-affiliated hospitals.

Patients: Forty-eight patients (32 men, 16 women; mean age, 67 years) undergoing laparoscopic gastrostomies (n = 32) and jejunostomies (n = 16).

Intervention: Twenty-four patients underwent laparoscopic gastrostomy (n = 15) and jejunostomy (n = 9) under local anesthesia with intravenous conscious sedation and monitored anesthesia care. Twenty-four patients had general anesthesia.

Main Outcome Measures: Conversion to general anesthesia, complications, and cost.

Results: Ten patients under local anesthesia had periods of deep sedation and 1 required conversion to general anesthesia. One patient under general anesthesia required conversion to open gastrostomy. No patients had intraoperative aspiration; however, 4 aspirated after the procedure. One patient died of myocardial infarction during the 30-day follow-up. We found no significant difference in the total mean cost and actual procedure time. The surgeon’s fee accounted for 31% of the total cost.

Conclusions: Some patients undergoing laparoscopic enteral access may require deep sedation and a rare patient may require general anesthesia. Clinical conditions and surgeon preference, therefore, should determine whether local anesthesia is suitable for laparoscopic gastrostomies and jejunostomies, and in what setting, since there is no difference in success rate or complications when compared with general anesthesia. Potential savings are possible from the operating room (26% of total cost) or anesthesiologist (12% of total cost) if these procedures are performed in an endoscopy suite without monitored anesthesia care.

Arch Surg. 1999;134:151-156

We and others have previously shown that gastrostomies and jejunostomies can be performed safely with laparoscopic techniques using the T fasteners to retract and anchor the bowel.1,4 Relaxation of the abdominal muscles is required for adequate pneumoperitoneum. Therefore, general anesthesia is used for most patients who undergo laparoscopic feeding tube placement.

Other techniques, such as open surgical gastrostomy or jejunostomy, percutaneous endoscopic gastrostomy10-12 or jejunostomy,13 and percutaneous feeding tube placement by interventional radiologists, can be performed in most patients under local anesthesia with conscious sedation. For laparoscopic techniques to be a true alternative for placing feeding tubes, local anesthesia with conscious sedation needs to be an option, especially for patients who are at very high risk for general anesthesia.

We therefore undertook a multiinstitutional prospective randomized study to determine whether laparoscopic gastrostomy or jejunostomy can be performed safely in most patients under local anesthesia with conscious sedation as compared with under general anesthesia. We studied how often local anesthesia is successful without the need to convert to general anesthesia, how often the laparoscopic cases required conversion to open procedures, and whether the rates of complications or costs differ between cases performed under local vs general anesthesia.
PATIENTS AND METHODS

PATIENTS AND RANDOMIZATION

The protocols were reviewed and approved by the institutional review boards of the 6 participating institutions (Veterans Affairs Medical Center, San Francisco, Calif; Duke Medical Center, Durham, NC; Creighton University, Omaha, Neb; University of California, San Francisco; University of Nebraska Medical Center, Omaha; and University of California, Davis). A signed informed consent was obtained from each patient.

All the participating surgeons were experienced laparoscopic surgeons who had participated in prior studies of laparoscopic feeding tube placement. Each surgeon was required to have performed at least 2 cases of laparoscopic gastrostomy or jejunostomy under local anesthesia and sedation before starting the study.

To achieve true randomization, the surgeon, anesthesiologist, and patient all had to agree to either general or local anesthesia before the patient was enrolled in the study. Thus, patients were excluded if they had other specific indications for general anesthesia (because of other concomitant operations or inability to cooperate) or local anesthesia (because the cardiopulmonary risk was too high for general anesthesia).

Patients were randomized to receive local or general anesthesia by a predetermined randomization schedule in sealed envelopes. The assignment to gastrostomy or jejunostomy, however, depended on the clinical indications. Jejunostomies were performed only when gastrostomies were contraindicated (gastroparesis, gastrectomy, or gastroesophageal reflux). Because of this, twice as many patients underwent gastrostomy as jejunostomy.

Forty-eight patients requiring 32 feeding gastrostomies and 16 jejunostomies were randomized to undergo the procedure laparoscopically under local anesthesia with intravenous conscious sedation (16 men, 8 women; mean age, 63 ± 4 years; range, 17-86 years) or under general anesthesia (16 men, 8 women; mean age, 69 ± 2 years; range, 47-89 years).

The indications for feeding tube placement were malnutrition and potential malnutrition, most commonly caused by cancer and neurologic disease. Twenty-three patients had neurologic dysfunction, such as stroke or Parkinson disease. Twenty-four patients had cancers of the head and neck or esophagus (including 3 patients who also had neurologic deficit). Four patients had other causes of malnutrition.

The mean serum albumin level was 30 g/L (reference range, 35-50 g/L) for both groups of patients (local anesthesia and general anesthesia). The mean serum prealbumin level was 119 g/L (reference range, 160-400 g/L) for patients randomized to local anesthesia and 161 g/L for those randomized to general anesthesia.

There were no differences between those randomized to local anesthesia vs those randomized to general anesthesia in age, sex, primary diagnosis, or American Society of Anesthesiologists (ASA) classification. Of the 24 patients who were randomized to local anesthesia, 17 were ASA class 3 and 7 were ASA class 4. Of the 24 patients who were randomized to general anesthesia, 18 were ASA class 3 and 6 were ASA class 4.

Surgical Techniques

Laparoscopic gastrostomy and jejunostomy were performed using the T-fastener techniques as previously described.1,2 These procedures were performed by experienced laparoscopic surgeons who had already performed at least 2 laparoscopic gastrostomies and 2 laparoscopic jejunostomies under local anesthesia.

Because the abdominal muscles need to be relaxed for adequate laparoscopy, the patient needs to be kept relatively pain-free and without anxiety. Shoulder pain from stomach wall, which was recognized intraoperatively. The procedure was converted to open gastrostomy and the perforation repaired.

Although 10 patients had a history of aspiration pneumonia before the procedure, none had intraoperative aspiration. There were no intraoperative complications.

PROCEDURE TIME

Table 2 summarizes the total procedure time (time in the operating room) and actual procedure time (skin incision to wound closure). The total procedure time included 8 concurrent procedures: 3 tracheostomies, 2 central line placements, and 1 each of lysis of adhesions, skin graft, and epigastric hernia repair. None of these procedures, by themselves, would have dictated general anesthesia.

POSTOPERATIVE COMPLICATIONS

Major postoperative complications occurred in 5 patients (11%). Four patients had aspiration pneumonia and 1 patient had bleeding.
diaphragmatic irritation by carbon dioxide is the most common discomfort that is felt by patients undergoing laparoscopic procedures under local anesthesia. This can be partially alleviated by decreasing the pneumoperitoneum pressure. Too low a pressure, however, makes laparoscopic visualization difficult. The optimal pneumoperitoneum pressure is usually 6 to 8 mm Hg, but needs to be adjusted according to the clinical situation.

ANESTHESIA

The protocols for anesthesia were prospectively reviewed by and agreed to by the anesthesiologists. All procedures were performed in the operating room with an anesthesiologist who administered either the general anesthesia or the intravenous sedation and monitored the patient throughout the procedure. Local anesthesia was administered by the surgeon. Patients who were randomized to local anesthesia received injection of lidocaine or bupivacaine without epinephrine, optional intravenous conscious sedation as per the individual institution’s protocol, and/or monitored anesthesia care. Patients who were randomized to general anesthesia received general anesthesia that is routine at each institution and endotracheal intubation. They also received injection of lidocaine or bupivacaine without epinephrine for the trocar sites and stoma sites. Patients were routinely monitored by continuous pulse oximetry.

For patients undergoing local anesthesia, the depth of sedation was controlled by the anesthesiologist using intravenous sedation and titrated to a level that was considered safe for the patient but sedated enough for the procedure. Sedation levels were classified according to the standard developed by the American Dental Association in 1984: level 1 (conscious sedation), level 2 (deep sedation), or level 3 (unconscious). Patients who could not tolerate the procedure under local anesthesia and intravenous sedation, or who could not protect their airway, were intubated and converted to general anesthesia.

Although 7 of 24 local anesthesia patients and 3 of 24 general anesthesia patients had a history of aspiration pneumonia, only 1 patient in the local anesthesia group and 3 patients in the general anesthesia group had aspiration pneumonia after the procedure. Three of the 4 patients with postoperative aspiration pneumonia did not have a history of aspiration before the procedure. These patients developed aspiration pneumonia 14 to 30 days after the procedure. One patient, who had a rectus abdominus flap to cover a surgical neck wound, required suture ligation for bleeding of his muscle flap near the gastrostomy site 30 days after the procedure. One patient, who had an ileostomy for cancer who died of perforation, required suture ligation for bleeding of his ileostomy site 30 days after the procedure. The other 10 patients died of underlying diseases.

There were no differences in the rate of major postoperative complications and 30-day mortality between the group randomized to local anesthesia and those randomized to general anesthesia.

LENGTH OF HOSPITAL STAY

Length of postoperative hospital stay, from the day of feeding tube placement to the day of discharge, did not differ for those randomized to local anesthesia (6 ± 1 days) and those randomized to general anesthesia (8 ± 2 days). As expected, the length of hospitalization was mainly due to the underlying diseases and not due to the procedure or anesthesia.

COST OF PROCEDURES

Analysis of the cost for the procedure showed that major components were the surgeon (31%), operating room (26%), and anesthesiologist (12%) (Figure 1). There

Total procedure time (from the time patient arrived in the operating room to the time the patient left, including the time required for concurrent procedures) and actual procedure time (from skin incision to wound closure) were recorded. Patients were reevaluated at 24 hours, 2 weeks, and 30 days after the procedure for postoperative complications and outcomes. Length of hospitalization after the procedure was also recorded.

STATISTICAL ANALYSIS

Analysis of variance (ANOVA) was used to compare patient groups. Differences are considered significant if P < 0.05. The comparison between the local anesthesia group and the general anesthesia group was made on the basis of initial randomization (intent). Thus, the patient who was converted from local to general anesthesia was included in the local anesthesia group for data analysis. Unless otherwise indicated, data are presented as mean ± SEM.

COST ANALYSIS

We prospectively collected hospital and professional charges and other billing information. These charges were converted to cost and then analyzed by Vector Research Inc, Ann Arbor, Mich. The hospital charges were converted to cost, using institution-specific cost-to-charge ratios calculated by Hospital Cost Investment Analysis Inc, Baltimore, Md. Professional charges for the surgeon, anesthesiologist, and nurse anesthetist, were converted to cost, using national-level data from the American Medical Association, Chicago, Ill, and Medical Group Management Association, Englewood, Colo. We only calculated the cost for the procedure and not that for total hospitalization. The cost was analyzed from the perspective of the hospital.

Because the Veterans Affairs Medical Center does not charge patients or provide cost information, the cases from that institution were excluded from cost analysis.

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were marked variations in total cost and its components among the 5 hospitals studied (Figure 2). The cost of procedures as calculated using the charge-to-cost ratios is summarized in Table 3. The cost for laparoscopic jejunostomy was higher than for laparoscopic gastrostomy. This was primarily due to the higher professional cost for jejunostomy. There was no difference between the cost of cases performed under local anesthesia and those performed under general anesthesia (power \(0.80\) [type II error \(0.20\), type I error \(0.05\)] to detect a 20% difference.

**Comment**

Laparoscopic gastrostomies and jejunostomies have been shown by multiple studies to be safe and effective. In this prospective randomized study, we found that these procedures can be performed as safely under local anesthesia as under general anesthesia, and for similar cost. We did not choose regional anesthesia as an option in this randomized study. Regional anesthesia is very rarely used in laparoscopic procedures because it has the disadvantage of not completely relaxing the abdominal wall without the advantage of minimal anesthesia of local anesthesia with sedation. Also, one of the purposes of the study was to prepare for a comparative study between...
laparoscopic gastrostomy and jejunostomy vs percutaneous endoscopic gastrostomy, which is performed under local anesthesia and sedation.

The finding that no clinically or statistically significant difference was found between the local anesthesia and general anesthesia groups for laparoscopic feeding tube placement is not surprising, since these procedures are relatively simple in the spectrum of laparoscopic operations and we and others have successfully used local anesthesia previously in selected cases. In addition, many laparoscopic gynecological procedures are routinely performed under local anesthesia and laparoscopic hernia repair has been performed successfully under local anesthesia.

Technical advances simplify laparoscopic feeding tube placement. T fasteners, for example, obviated the need for laparoscopic suturing and shortened the procedure time. Other advances, such as small-bore needle-trocars used with microendoscopes and micrograspers, could also decrease patient discomfort. The main source of patient discomfort while under local anesthesia, however, seemed to be the diaphragmatic irritation due to carbon dioxide pneumoperitoneum. Using nitrous oxide pneumoperitoneum or the gasless technique may decrease the amount of intravenous sedation required and may have avoided the deeper (level 2) sedation that occurred in 10 of our patients.

In this study, the cost of procedures under local anesthesia was not different from the cost of procedures under general anesthesia. Other randomized studies of simple laparoscopic procedures have found local anesthesia to be less expensive. For example, a randomized study of laparoscopic sterilization found the local anesthesia group to have a shorter operating time, less discomfort, and lower cost than the general anesthesia group. Our study has a greater than 80% chance of detecting a 20% difference in cost.

One reason for finding no difference in cost between the local and general anesthesia groups is the requirement of our protocol to perform the procedures in the operating room (accounting for 26% of total cost) and to have an anesthesiologist for monitoring (accounting for 12% of total cost). These are areas of potential savings if laparoscopic feeding tubes can be safely placed in an endoscopy suite with a nurse as is usually done for percutaneous endoscopic gastrostomy. These potential savings will not be realized, however, if the rate of conversion from local to general anesthesia or from laparoscopic to open is too high and therefore unsafe for outside the operating room. Our study did not address whether it is safe to place laparoscopic feeding tubes in patients outside the operating room without the help of an anesthesiologist.

We also confirmed prior findings that laparoscopic feeding tube placement is relatively safe and associated with acceptable morbidity and mortality rates. The 30-day postoperative mortality rate is high (23%) in this study, but it is not unexpected for similar patients who require feeding tube placement. All our patients were relatively high risk, at least ASA class 3, and many were ASA class 4. All the deaths can be attributed to underlying diseases.

Although we found no difference in procedure time between local anesthesia and general anesthesia groups, the procedures were technically more challenging when performed under local anesthesia. It is more difficult to perform a thorough diagnostic laparoscopy because of a more limited exposure under local anesthesia. Some patients were unable to relax the abdominal muscles because of discomfort from carbon dioxide pneumoperitoneum, and some would only tolerate a lower pneumoperitoneum pressure (4-6 mm Hg). The requirement for deeper sedation in 10 of our patients reflects the inadequacy of conscious sedation in this group of patients.

We conclude that laparoscopic gastrostomy or jejunostomy can be performed with the patient under local anesthesia and intravenous conscious sedation with similar success as under general anesthesia and for similar cost. There may be potential savings by eliminating the cost of the operating room or the anesthesiologist. Some patients, however, may require deep sedation and rare cases may need to be converted to general anesthesia or to an open procedure. Clinical conditions and surgeon preference, therefore, should determine whether local anesthesia is used and in what setting, since there is no observed difference in success rate or complications when compared with general anesthesia.

This study was supported in part by the Medical Research Service of the Veterans Affairs Medical Center, San Francisco, Calif, and the Ross Product Division, Abbott Laboratories, Columbus, Ohio.

Drs Duh and Way developed the procedure for creating laparoscopic enterostomies using the T-fastener technique. The Regents of the University of California, San Francisco, hold the patent to this technique (US Patent No. 5 151 086). The Regents of the University of California have licensed Abbott Laboratories to use this patent for laparoscopic enterostomy kits. Drs Duh and Way may be entitled to a share of the royalties. Ms Senokozlieff-Englehart, Mr Choe, and Ms Rowland are employees of Abbott Laboratories.

Special thanks to the following investigators for their participation in this project: John P. Grant, MD, Duke Medical Center, Durham, NC; Robert J. Fitzgibbons Jr, MD, Creighton University, Omaha, Neb; Kenric M. Murayama, MD, University of Nebraska Medical Center, Omaha; and Bruce M. Wolfe, MD, University of California, Davis.

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REFERENCES


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Familial Transmission of Substance Dependence: Alcohol, Marijuana, Cocaine, and Habitual Smoking: A Report From the Collaborative Study on the Genetics of Alcoholism
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Background: Alcoholism and substance dependence frequently co-occur. Accordingly, we evaluated the familial transmission of alcohol, marijuana, and cocaine dependence and habitual smoking in the Collaborative Study on the Genetics of Alcoholism.

Methods: Subjects (n = 1212) who met criteria for both DSM-III-R alcohol dependence and Feighner definite alcoholism and their siblings (n = 2755) were recruited for study. A comparison sample was also recruited (probands, n = 217; siblings, n = 254).

Subjects were interviewed with the Semi-Structured Assessment for the Genetics of Alcoholism. The familial aggregation of drug dependence and habitual smoking in siblings of alcohol-dependent and non–alcohol-dependent probands was measured by means of the Cox proportional hazards model.

Results: Rates of alcohol, marijuana, and cocaine dependence and habitual smoking were increased in siblings of alcohol-dependent probands compared with siblings of controls. For siblings of alcohol-dependent probands, 49.3% to 50.1% of brothers and 22.4% to 25.0% of sisters were alcohol dependent (lifetime diagnosis), but this elevated risk was not further increased by comorbid substance dependence in probands. Siblings of marijuana-dependent probands had an elevated risk of developing marijuana dependence (relative risk [RR], 1.78) and siblings of cocaine-dependent probands had an elevated risk of developing cocaine dependence (RR, 1.71). There was a similar finding for habitual smoking (RR, 1.77 in siblings of habitual-smoking probands).

Conclusions: Alcohol, marijuana, and cocaine dependence and habitual smoking are all familial, and there is evidence of both common and specific addictive factors transmitted in families. This specificity suggests independent causative factors in the development of each type of substance dependence. (1998;55:982-988)

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