Value of Antibiotic Prophylaxis for Percutaneous Gastrostomy: A Double-Blind Randomized Trial

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ABSTRACT

Purpose: To compare peristomal infection rates following percutaneous gastrostomy (PG) after a single dose of prophylactic antibiotics versus placebo and evaluate rates of peristomal infection in patients receiving concurrent antibiotics.

Materials and Methods: This single-center, randomized trial (2012–2016) enrolled 122 patients referred for image-guided PG; all enrolled patients completed the study. Of enrolled patients, 68 were randomly assigned to receive either antibiotics (n = 34) or placebo (n = 34) before PG placement. The remaining 54 patients were taking pre-existing antibiotics and were assigned to an observation arm. Stoma sites were assessed for signs of infection by a blinded evaluator at early (between 3–5 d and 7–10 d) and late (between 14–17 d and 28–30 d) time points after the procedure. The primary outcome was peristomal infection.

Results: Under intention-to-treat analysis, early infection rate was 11.8% (4/34 patients; 95% CI, 0.0%–9.4%) in the placebo arm and 0.0% (0/34 patients; 95% CI, 0.0%–8.4%) in the antibiotic arm ($P = .057$ for comparison of infections in the 2 arms). Under per-protocol analysis, early infection rate was 13.3% (4/30 patients; 95% CI, 4.4%–29.1%) in the placebo arm and 0.0% (0/32 patients; 95% CI, 0.0%–8.9%) in the antibiotic arm ($P = .049$). The number needed to treat to prevent 1 early infection was 8.5 and 7.5 from the 2 analyses, respectively.

Conclusions: There is a trend toward reduction in rate of peristomal infection after PG when prophylactic antibiotics are administered.

ABBREVIATIONS

CI = confidence interval, ITT = intention-to-treat, PEG = percutaneous endoscopic gastrostomy, PG = percutaneous gastrostomy, PP = per-protocol

There is a wide range of practice variability in the use of antibiotics before interventional radiology (IR) procedures. Guidelines published by the Society of Interventional Radiology (SIR) (1–3) recommend the routine use of prophylactic antibiotics before pull-through gastrostomy tube placement, but there is no consensus on the use of antibiotics for the push-type procedure (3). Prospective data to advise physicians on the appropriate use of antibiotics before this procedure are lacking. Owing to the nature of placing a catheter into a nonsterile organ (ie, the gastric lumen) via a percutaneous route, coupled with the potential long duration of catheter placement, the potential risk of skin infection is enough to consider antibiotic prophylaxis (3).

Prophylactic antibiotics before percutaneous gastrostomy (PG) tube placement (via a push technique) are not currently supported by prospective data (3). All existing studies in the IR literature regarding prophylactic antibiotic use before PG have been retrospective. One retrospective study (4) found that infection rates were 15% in patients not receiving prophylactic antibiotics. Another retrospective review (5) in which no patients received antibiotic prophylaxis demonstrated an infection rate of 3%. In a larger series (6) that included > 300 percutaneous gastrostomy tube placements,

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Appendix A and Table E1 are available online at *www.jvir.org*.

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an infection rate of < 1% was reported. Differences in infection rates may vary because of differences in patient population, technique, or use of prophylactic antibiotics, which was not uniform in these studies (3–6).

There have been several randomized controlled trials examining the use of prophylactic antibiotics before percutaneous endoscopic gastrostomy (PEG) catheter placement via a transoral or pull technique (during which the device traverses the oropharynx) (7,8). One well-designed study (7) showed a statistically significant difference in peristomal infection rates between patients receiving prophylactic antibiotics and patients receiving placebo (3% vs 18%). A different study (9) showed no difference in rates of infection between patients receiving antibiotics and patients receiving placebo. However, a modified introducer, endoscopic-assisted push type of PEG was used in this study compared with older PEG studies. The aim of the present study was to compare peristomal infection rates in patients undergoing PG who received a single dose of either antibiotic or placebo before the procedure and to examine peristomal infection rates in patients concurrently receiving antibiotics for the treatment of other infections at the time of PG placement.

MATERIALS AND METHODS

Patient Selection and Randomization

Institutional review board approval was obtained to conduct this single-center, double-blind, randomized controlled trial (ClinicalTrials.gov identifier: NCT01424085). Informed consent to participate in the trial was required of all patients, and the study complied with the Health Insurance Portability and Accountability Act guidelines. Randomization was performed by the pharmacy department using a random number generator to assign patients to treatment or placebo arms. The pharmacy department maintained a master log of enrolled patients, which was available to the study staff at the conclusion of the study. All patients, operators, nursing staff, and study staff were blinded to patient assignments in the randomization arm of the study.

Between May 2012 and February 2016, 517 patients underwent PG tube placement. Indication for gastrostomy tube placement was inability to meet adequate nutritional needs by mouth (eg, neurologic causes, head and neck cancer). All nonpregnant, English-speaking patients ≥ 18 years old were eligible for the study. The institutional review board at the performing institution required in-person consent and English-speaking patients, which excluded many eligible patients. In addition, 24 eligible patients refused to participate in the study. Patients were eligible for randomization to antibiotic treatment or placebo only if they had not received antibiotics within 48 hours before PG placement. The remaining patients who were already receiving antibiotics at the time of enrollment for the treatment of other infections were assigned to the observation arm (**Fig**).

There were 34 randomly assigned patients in the placebo arm and 34 randomly assigned patients in the antibiotic arm included in the intention-to-treat (ITT) analysis. Two patients in the placebo arm, and 1 patient in the antibiotic arm were outpatients, and the remainder were inpatients. Separately, 54 patients already receiving antibiotics (all inpatients) were included in the observation arm. Indications for antibiotic therapy are listed in **Appendix A** (available online at *www.jvir.org*).

Baseline demographics of patients are summarized in the **Table**. There were no significant differences in baseline patient characteristics among the 3 study groups. Patients assigned to the antibiotics arm received a single dose of antibiotic 30 minutes before the procedure: cefazolin 1 g intravenously (n = 30) or clindamycin 600 mg intravenously (n = 4) if allergic to β-lactams. Patients assigned to the placebo arm received a similar volume of normal saline 30 minutes before the procedure. The specific antibiotics being administered routinely for patients in the observation arm are outlined in **Appendix A** (available online at *www.jvir.org*).

Gastrostomy Tube Placement

All patients had a 16-F Deutsch gastrostomy tube (Cook Medical, Bloomington, Indiana) placed, and 3 absorbable gastropexy sutures (SAF-T-PEXY T-fasteners; Halyard Health, Apharetta, Georgia) were placed surrounding the tube (all procedural details are outlined in **Appendix A** [available online at *www.jvir.org*]). Operators included 8 IR attending physicians (experience ranging from 4 to 25 y), 6 fellows under attending supervision, and 1 physician assistant (15 y of experience). All patients remained as inpatients for at least 1 night following the procedure. If there was no clinical concern for PG malposition or peritonitis by day 1 after the procedure, the tube was used for feeding. The dressing was changed daily, and nursing was instructed to alert the IR department if there were any signs or symptoms concerning for stoma site infection or tube malposition or malfunction. T-fasteners were routinely cut approximately 10 days after the procedure.

Outcomes and Patient Assessment

The stoma site was evaluated by a blinded evaluator (evaluators included 1 IR attending physician, 3 IR fellows under attending supervision, and 1 physician assistant) at 4 time points after the procedure (except in patients lost to follow-up during the follow-up period): 3–5 days, 7–10 days, 14–17 days, and 28–30 days. The appearance of the site was assessed using an established scoring system for categorizing stoma infections (7,10): presence of erythema (0, none; 1, ≤ 5 mm; 2, 6–10 mm; 3, 11–15 mm; 4, ≥ 15 mm), induration (0, none; 1, ≤ 10 mm; 2, 11–20 mm; 3, ≥ 20 mm), and exudate (0, none; 1, small serous; 2, moderate serous; 3, large serous ± sanguineous; 4, purulent). The stoma site was considered infected if the combined score at the time of evaluation was ≥ 8 or frank purulence was present.

When in-person stoma site evaluation was not possible, such as when the patient had been discharged home or to a

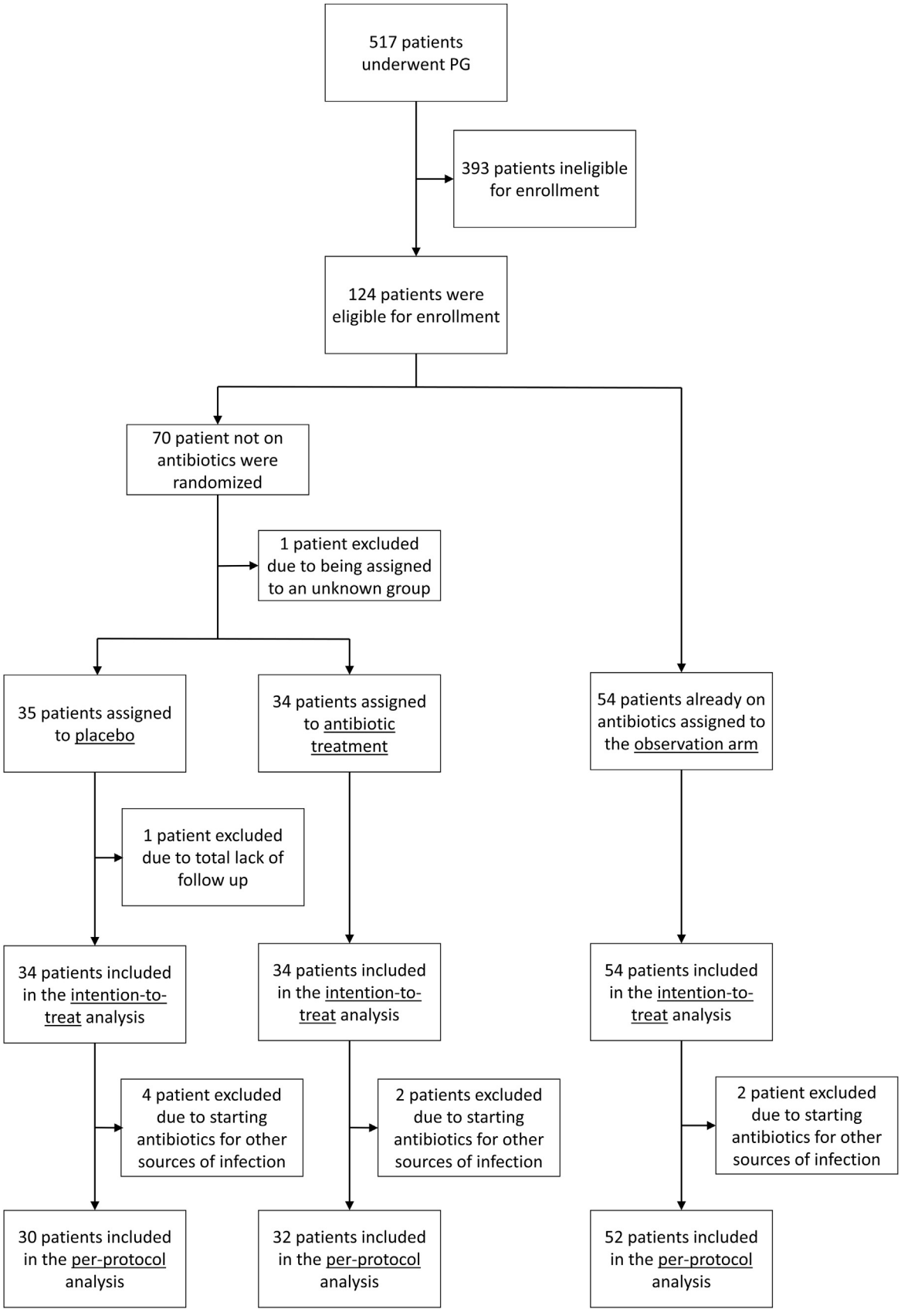

Figure. Flow chart showing how patients were assigned during the study.

Table. Patient Baseline Characteristics

Variable	Treatment Arm			*P* Value*
	Antibiotic (n = 34)	Placebo (n = 34)	Observation (n = 54)	
Sex				
Male	25 (73.5)	23 (67.7)	36 (66.7)	.83
Female	9 (26.5)	11 (32.4)	18 (33.3)	
Age, y	61.4 ± 14.1	64.3 ± 17.6	57.9 ± 17.7	.25
Indication for PG				
Neurologic	25 (73.5)	26 (76.5)	39 (72.2)	.96
Head and neck cancer	9 (26.5)	8 (23.5)	15 (27.8)	
WBC count	8.5 ± 2.6	9.2 ± 2.3	9.8 ± 3.8	.14
Albumin†	3.1 ± 0.7	3.1 ± 0.7	2.7 ± 0.8	.055
Comorbidities				
CAD	4 (11.8)	3 (8.8)	6 (11.1)	> .99
CHF	4 (11.8)	1 (2.9)	1 (1.9)	.12
COPD	2 (5.9)	4 (11.8)	9 (16.7)	.39
Chronic renal insufficiency	0 (0.0)	2 (5.9)	0 (0.0)	.15
Chronic liver disease/cirrhosis	0 (0.0)	1 (2.9)	2 (3.7)	.79
Diabetes†	7 (20.6)	9 (27.3)	10 (18.9)	.66
Current smoker†	9 (31.0)	7 (20.6)	17 (34.7)	.38
On steroids	3 (8.8)	2 (5.9)	4 (7.4)	> .99

Note–Numbers in parentheses are percentages. Age, WBC count, and albumin values are expressed as mean ± SD.
CAD = coronary artery disease; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; PG = percutaneous gastrostomy; WBC = white blood cell.
*Fisher exact test (categorical variables) or Kruskal-Wallis test (continuous variables) comparing all 3 arms.
†Patients with missing values were excluded: albumin (n = 36), diabetes (n = 2), and current smoker (n = 10).

skilled nursing facility, 1 study member (either 1 attending IR physician [C.R.I.] or the physician assistant [E.L.A.]) contacted the patient or caregiver for evaluation. Generally, for patients in a skilled nursing facility, a nurse at the facility evaluated the patient with direct instruction from the study member by telephone. In-person follow-up was performed for 169 of 241 total evaluations (70.2%) up until the second time point and for 118 of 225 total evaluations (52.4%) for the third and fourth time points.

Study Outcomes

The primary study outcome was a peristomal wound infection during the first 30 days, divided into 2 time periods: early infections, defined as occurring by the second time point at 10 days after the procedure, and late infections, defined as occurring after the second time point up until the last time point at 28–30 days after the procedure. Other outcomes measured were complication rate and death during the 30-day study period. There were no technical failures.

Complications not related to stoma site infection were categorized into major and minor, based on standard SIR guidelines (11). Major complications included death, blood loss requiring transfusion, nontarget bowel transgression, septicemia, extraluminal tube placement, and peritonitis (11). Minor complications included minor bleeding not requiring transfusion and tube maintenance issues, such as tube dislodgment, kinking, clogging, or migration (12).

Sample Size

The planned sample size for the study was chosen based on reported rates of infection from previous studies estimated as 15%–30% when antibiotics are not given prophylactically and as 3% when antibiotics are given prophylactically (7,13,14). Therefore, this study aimed to randomly assign 128 subjects (64 per arm) to detect a difference of approximately 20% between the antibiotic and placebo groups. With this sample size, across a range of infection rates, differences in infection rates of 20% (placebo arm) versus 3.5% (antibiotic arm), 25% versus 6.3%, or 30% versus 9.4% would be detectable with 80% power (2-sided $\alpha \leq .05$).

Approximately 100 gastrostomy tube procedures are performed each year at the institution where the study was performed. The original study recruitment duration was expected to last approximately 2 years. Although the study originally planned to randomly assign 128 subjects, recruitment was substantially slower than expected owing to limitations of the patient population (eg, in-person consent and English-speaking patients only allowed) and the unexpectedly low rate of infection encountered. Therefore, the trial was stopped at 45 months after 70 patients were randomly assigned (approximately 19 per year—about 30% of the expected accrual rate).

Statistical Analysis

Comparison of patient baseline demographics among the 3 groups was performed using Fisher exact test (categorical

variables) or Kruskal-Wallis test (continuous variables). Infection rates and other outcomes were compared between study groups using the mid-*P* version of Fisher exact test (15). Infection rates were compared between the randomized placebo and antibiotic arms as the primary comparison. This comparison was performed as part of an ITT analysis and a per-protocol (PP) analysis. Under the ITT analysis, all randomly assigned patients except the patient with unknown treatment assignment and the patient with no follow up were included in the comparison of infection rates between the 2 arms (**Fig**). Under the PP analysis, the infection rates between the 2 arms were compared after excluding patients who received antibiotics for new sources of infection after enrollment unrelated to the PG placement (**Fig**). Those patients were excluded from the PP analysis, as the additional antibiotics may have reduced the infection rate relative to patients who received only prophylactic antibiotics or placebo according to the random assignment. Infection rates were also compared between the observation arm and the randomized arms as an exploratory analysis.

Confidence intervals (CIs) for infection rates were calculated using the mid-*P* version of exact Clopper-Pearson intervals (16). CIs for the differences in infection rates between groups were calculated using an approximation based on the mid-*P* CIs from each group (17). The number needed to treat with antibiotics to prevent 1 infection was calculated as the inverse of the difference in infection rates between groups that did and did not receive antibiotics. All *P* values were 2-sided and $P < .05$ was considered statistically significant. All statistical calculations were conducted with R version 3.2.3 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Among the 122 patients included in the ITT analysis, all had completed follow-up at the first 2 time points (3–5 d after procedure and 7–10 d after procedure), which was sufficient to determine early infection. Of the 34 patients in the antibiotics arm, 3 (8.8%) were lost to follow-up after the second time point (during the late infection period); 1 patient was lost to follow-up between the second and third time points (by 14–17 d after procedure), and 2 patients were lost between the third and last time points (by 28–30 d after procedure). Of the 34 patients in the placebo arm, 2 (5.9%) were lost to follow-up after the second time point, both between the second and third time points. Of the 54 patients in the observation arm, 5 (9.3%) were lost to follow-up after the second time point; 2 (3.7%) patients were lost between the second and third time points, and 3 (5.6%) patients were lost between the third and last time points. Eight patients who received antibiotics for new sources of infection unrelated to the PG placement were excluded from the PP analysis across the 3 study arms by the second time point (**Fig**). An additional 2 patients (placebo arm), 5 patients (antibiotics arm), and 1 patient (observation arm) received antibiotics for new sources of infection after the second time point (during the late infection period).

ITT Analysis

Early infections occurred in 4 of 34 patients (rate 11.8%; 95% CI, 3.9%–26.0%) in the placebo arm and 0 of 34 patients (rate 0.0%; 95% CI, 0.0%–8.4%) in the antibiotics arm. The difference in the rate of infection between the antibiotics and placebo arms was found to be nonsignificant (difference 11.8%; 95% CI, 0.5%–25.1%; $P = .057$). This difference corresponded to a number needed to treat of 8.5 (95% CI, 4.0–203). No late infections were observed in either arm.

PP Analysis

Among the patients meeting the criteria for the PP analysis (**Fig**), early infections occurred in 4 of 30 patients (rate 13.3%; 95% CI, 4.4%–29.1%) in the placebo arm and 0 of 32 patients (rate 0.0%; 95% CI, 0.0%–8.9%) in the antibiotics arm. The antibiotics arm had a marginally significantly lower infection rate than the placebo arm (difference 13.3%; 95% CI, 1.0%–28.1%; $P = .049$). This difference corresponded to a number needed to treat of 7.5 (95% CI, 3.6–101). No late infections were observed in either arm.

Analysis of Observation Arm

Early infections occurred in 1 of 54 patients (rate 1.9%; 95% CI, 0.1%–8.8%) in the observation arm. This infection rate was numerically similar to the infection rate in the prophylactic antibiotic arm (1.9% vs 0.0%; $P = .61$) and tended to be lower than the infection rate in the placebo arm from the ITT analysis (1.9% vs 11.8%; $P = .078$), although this difference did not reach statistical significance. After excluding 2 patients in the observation arm who received an additional antibiotic for new sources of infection unrelated to the PG placement, early infections were observed in 1 of the remaining 52 patients (rate 1.9%; 95% CI, 0.1%–9.1%). This infection rate also tended to be lower than the infection rate in the placebo arm from the PP analysis (1.8% vs 13.3%; $P = .063$), although again not significantly. A single late infection (a peristomal infection) was observed in the observation arm between days 28 and 30. Further analysis of late infection rates could not be performed owing to the very low incidence of late infections, incomplete follow-up, and administration of antibiotics for unrelated infections during the late follow-up period.

Treatment of Infections

All infections that occurred during the study were peristomal infections. No cases of peritonitis were encountered. All peristomal infections were evaluated by a member of the IR research team (C.R.I., E.L.A.) and treated with a 10-day course of oral cephalexin with the exception of 3 patients, who required intravenous vancomycin for methicillin-resistant *Staphylococcus aureus* cultured from the stoma site (**Table E1** [available online at *www.jvir.org*]). One skin infection in the observation arm was significant enough to

necessitate tube removal in addition to intravenous antibiotic therapy (vancomycin) to allow the wound and surrounding cellulitis to heal. PG removal was not required to cure any other infection. All infections were verified by an IR research team member to have healed with medical therapy alone.

Complications

No complications occurred within the first 24 hours of the observation period in any patient. Two major complications (1.6%) and 5 minor complications (4.1%) occurred in the 122 patients in the ITT analysis after 24 hours in the 3 study arms. The rate of complications did not differ significantly between the placebo and antibiotics arm ($P = .62$) or between all 3 study arms ($P = .88$). There were no complications related to the administration of the study antibiotic, and there were no cases of peritonitis in any patient. For additional discussion of complications, see **Appendix A** (available online at *www.jvir.org*) (11).

DISCUSSION

This study demonstrated a trend toward a reduction in the rate of early peristomal infection after PG placement when antibiotics are administered before the procedure. However, this conclusion is limited by the sample size of this study and an overall low infection rate in the study cohort. There is little evidence to support the routine administration of prophylactic antibiotics before most IR procedures (1,2). All previously published studies in the IR literature regarding antibiotic use before PG have been retrospective. In the PP cohort, the infection rates observed in this study of 0% in the prophylactic antibiotic group, 13% in the placebo group, and 2% in the concurrent antibiotic/observation group are consistent with infection rates in other studies reported in the literature (4,5,7). The PP analysis found a statistically significantly lower rate of peristomal infection after catheter placement when antibiotics are given prophylactically compared with placebo ($P = .049$). The ITT analysis, which included multiple patients in each group who started antibiotics during the follow-up period, demonstrated a marginally nonsignificant difference in infection rates between the placebo and antibiotic groups ($P = .057$). Given that patients newly started on antibiotics are included in the ITT analysis, potential infection could have been reduced in the placebo arm.

A recent Cochrane review (8) of 13 randomized controlled trials examining the use of prophylactic antibiotics before PEG demonstrated that prophylactic antibiotics are effective at reducing peristomal rates of infection after the procedure. However, 2 more recent studies in the PEG literature (18,19) demonstrated no difference in the rates of peristomal infection between patients given prophylactic antibiotics and patients given placebo. Given the differences between the pull and push techniques, the present study aimed to examine if antibiotic prophylaxis was necessary in a patient group undergoing PG, given the differences in technique between PG and PEG.

The decision to administer prophylactic antibiotics depends on comparing the cost and morbidity of treating an infection that could potentially develop with the cost and morbidity of administering antibiotic prophylaxis (20,21). Proper use of antibiotics for primary prophylaxis must provide adequate coverage of the organisms most likely to colonize the surgical site, be safe to the patient, and be administered for the least amount of time to be effective and prevent the development of resistant organisms (21). Given the relatively low incidence of infection after PG placement observed by this study and others and the low morbidity associated with a peristomal infection, one could argue that it is not necessary to treat all patients with prophylactic antibiotics. Should a peristomal infection develop, it could be easily treated with a short course of antibiotics. However, the infection rate in the placebo arm reached 13%, which supports the use of a prophylactic antibiotic.

This study has several limitations. Nearly 400 patients were excluded because of consent and language requirements of the study. Slow recruitment led to terminating the study before enrolling the projected number of subjects. Lower than expected infection rates in combination with a small sample size gave the study less power than originally planned. One consequence of the lower sample size is that CIs for the difference in infection rates between the antibiotic and placebo arms were relatively wide, indicating notable uncertainty of the magnitude of the clinical impact of antibiotic prophylaxis. Initiation of new antibiotics for the treatment of other infections during the follow-up period interfered with the comparison of the study arms (the ITT analysis did not reach significance, and the sample size thus became further reduced in the PP analysis). Patients in the observation arm were on several different antibiotic regimens for the treatment of different infections, creating variability in the coverage of skin flora. Patient follow-up after discharge from the hospital was sometimes challenging, as many patients were either outpatients or discharged from the hospital before 30 days. Even with a very thorough verbal description of the clinical findings that were being used for stoma evaluation, telephone follow-up was suboptimal compared with evaluation by someone on the research team. Many patients were discharged to skilled nursing facilities, and clinical and stoma site care after discharge was likely variable and inconsistent. Ten patients were lost to follow-up after day 10 of the follow-up period (5 in the randomized arm and 5 in the observation arm), and there is a potential for missed late infections in the patients lost to follow-up. Pigtail catheters were used for all feeding tubes, which may differ in complication rates from other types of feeding tubes, such as balloon-retention devices. Similarly, 3 T-fasteners were used in all cases, which may be considered excessive. This was done to keep the procedural technique consistent throughout the study period. Finally, this study included patients with cancer, and immune status as a potential risk factor for infection was not evaluated in a separate subgroup analysis.

In conclusion, this study demonstrates a trend toward reducing the rate of peristomal infection following percutaneous gastrostomy placement after administration of a single dose of antibiotic given as prophylaxis before the procedure.

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APPENDIX A.

Observation Group Indications for Antibiotics and Types of Antibiotics

Indications. Indications for antibiotic therapy included pneumonia (19 patients), urinary tract infection (18 patients), wound or surgical bed infection (15 patients), bacteremia/sepsis (9 patients), abscess (3 patients), *Clostridium difficile* colitis (3 patients), cellulitis (1 patient), empyema (1 patient), and otitis media (1 patient). There were 16 patients being treated for 2 different infections.

Antibiotic Regimen. Antibiotics included the following: vancomycin (13 patients), trimethoprim-sulfamethoxazole (9 patients), ciprofloxacin (7 patients), meropenem (6 patients), cefazolin (6 patients), levofloxacin (5 patients), ampicillin-sulbactam (5 patients), piperacillin-tazobactam (4 patients), cefepime (2 patients), ertapenem (1 patient), clindamycin (1 patient), gentamicin (1 patient), amoxicillin-clavulanate (1 patient), moxifloxacin (1 patient), doxycycline (1 patient), nafcillin (1 patient), metronidazole (1 patient), ceftriaxone (1 patient), rifampicin (1 patient), nitrofurantoin (1 patient).

Details of Gastrostomy Tube Placement

All patients undergoing PG placement had a nasogastric tube placed before the procedure. All patients underwent sterile preparation of the abdomen consisting of chlorhexidine 2%–isopropyl alcohol or povidone-iodine (Becton, Dickinson and Company, Franklin Lakes, New Jersey). All patients underwent PG by push technique performed by an attending physician and fellow trainee in the IR department. All patients received either moderate or deep sedation for the procedure. Glucagon 1 mg (Boehringer Ingelheim, Ingelheim, Germany) was administered intravenously before stomach insufflation. After insufflation of the stomach with air via the nasogastric tube and administration of 1% lidocaine for local anesthesia in the chosen gastrostomy tube site, 3 absorbable gastropexy sutures (SAF-T-PEXY T-fasteners) were placed. Centered within the gastropexy sutures, an 18-gauge needle was inserted into the gastric lumen under fluoroscopic guidance. Over a stiff wire (Amplatz Super Stiff Guidewire; Boston Scientific, Marlborough, Massachusetts), a 16-F Deutsch Gastrostomy Catheter (Cook Medical) was placed over the wire. The pigtail was formed in the gastric fundus. A Molnar Retention Disc (Cook Medical) was sutured to the abdominal wall using a nonabsorbable suture to secure the tube. A 4 cm × 4 cm split dry gauze sterile dressing was placed underneath the Molnar disc adjacent to the skin on completion of the procedure. Cloth tape (3M Medipore; 3M, St. Paul, Minnesota) was then used to secure the edges of the dressing to skin. The tube was connected to gravity drainage, and the patient was given nothing by mouth until after evaluation the following morning.

Additional Complications Data

One major complication occurred in the placebo arm after 24 hours. The patient experienced tracheal aspiration during tube feeding on day 7 after the procedure and died on day 10 after the procedure from overwhelming pneumonia. One minor complication occurred in the placebo group when a patient's tube was unintentionally pulled out on day 10 after the procedure and required replacement the next day.

One minor complication occurred in the antibiotics arm after 24 hours; the patient experienced minor bleeding at the stoma site on day 4 after the procedure, which resolved on its own and required no further intervention. One major and 3 minor complications occurred in the observation arm after 24 hours. The major complication was a significant bleed in the gastric fundus on day 2 after the procedure, thought to be secondary to the pigtail of the tube eroding the surrounding gastric mucosa. This patient required endoscopic intervention and surgical replacement of the tube. The patient had a myocardial infarction on day 5 after the procedure. The patient ultimately died 17 days after the procedure from multiorgan failure. The 3 minor complications consisted of catheter replacements in 2 patients (1 catheter was obstructed and 1 catheter was pulled out) and a tube in 1 patient that eroded the surrounding skin and had become dislodged, requiring replacement.

During the 30-day follow-up period, 3 patients in the placebo arm (8.8%), 1 patient in the antibiotics arm (2.9%), and 4 patients in the observation arm (7.4%) died. Only the death in the patient who experienced significant bleeding after the procedure could be directly attributed to the gastrostomy tube procedure (in the observation arm).

Suggested thresholds for major complications and minor complications per SIR guidelines are $< 5\%$ and $< 25\%$, respectively (11). For major complications, including death and bleeding requiring transfusion, suggested thresholds are $< 1\%$ and $< 3\%$, respectively (11). This study is well within these suggested thresholds for overall, major, and minor complication rates.

Table E1. Additional Culture Data for Patients with MRSA

Patients and MRSA Status	Antibiotics
Patient 1, *Staphylococcus aureus*, coagulase positive	Clindamycin (S) Daptomycin (S) Erythromycin (R) Gentamicin (S) Levofloxacin (R) Moxifloxacin (R) Oxacillin (R) Tetracycline (S) Trimethoprim-sulfamethoxazole (S) Vancomycin (S)
Patient 2, *Staphylococcus aureus*, coagulase positive	Clindamycin (S) Daptomycin (S) Erythromycin (R) Levofloxacin (R) Moxifloxacin (R) Oxacillin (R) Tetracycline (S) Trimethoprim-sulfamethoxazole (S) Vancomycin (S)
Patient 3, *Staphylococcus aureus*, coagulase positive	Clindamycin (S) Daptomycin (S) Erythromycin (R) Levofloxacin (R) Moxifloxacin (R) Oxacillin (R) Tetracycline (S) Trimethoprim-sulfamethoxazole (S) Vancomycin (S)

MRSA = methicillin-resistant *Staphylococcus aureus*; R = resistant; S = sensitive.