CLINICAL STUDY

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