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Complications of Gastric Catheters Implanted in Rhesus Macaques (*Macaca mulatta*)

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As part of a study addressing chronic alcohol consumption and simian immunodeficiency virus, 31 rhesus macaques (*Macaca mulatta*) were implanted with gastric catheters used to deliver alcohol or isocaloric sucrose (control). Once implanted, the animals wore jackets and were housed in specialized cages modified with swivels and tethers. During the course of the study, 3 animals developed clinical signs indicating possible instability of the implanted gastric catheter. All 3 animals were found to have a string foreign body wrapped around the distal end of the catheter, with 2 of the catheters perforating the intestinal wall. Gastroscopy was used to screen remaining animals to determine catheter position and the presence of a foreign body attached to the end of the catheter. Results of the screening revealed that of the 28 remaining animals, 9 had malpositioned catheters; string foreign bodies were associated with 3 of the 9 malpositioned catheters. We initially hypothesized that the peristaltic motion of the stomach, combined with the attachment of string, which was probably ingested by subjects after manipulating their jackets, led to eventual catheter displacement. We later concluded that the string may have played a secondary role but was not the primary cause of catheter instability, because several malpositioned catheters had no string attached at the time of diagnosis. Subsequent modifications were instituted, including modifying the surgical technique, altering the type of gastric catheter used, and increasing environmental enrichment for animals with known tendency to manipulate their jackets.

Abbreviations: HIV, human immunodeficiency virus; PEG, percutaneous endoscopic gastrostomy; SIV, simian immunodeficiency virus

Human immunodeficiency virus (HIV) infection and alcohol abuse have been associated concurrently as public health risks in several studies and remain a problem not only in the United States but throughout the world.[5,17,21] To mimic the combined effects of HIV infection and chronic alcohol consumption, a model of simian immunodeficiency virus (SIV) infection in rhesus macaques has been used because of similarities in pathology, depletion of CD4+ T cells, and AIDS-like end-stage disease.[4,20] To control alcohol consumption in this model, alcohol is delivered through gastric catheters surgically implanted through open laparotomy by using a technique similar to what has been described previously in human patients and nonhuman primates.[6,16,23] In our use of this gastric catheterization model, alcohol has been delivered effectively during 5-h sessions to achieve blood alcohol concentrations between 0.23% and 0.28%; catheters in some animals have been maintained for more than 3 y. Silastic gastric catheters of the same design have been used since inception of the study and require open surgical implantation.

The study described herein retrospectively evaluates gastric catheter stability in 31 rhesus macaques (*Macaca mulatta*) assigned to the alcohol–SIV investigation just described. The study first focused on 3 animals and the clinical signs, diagnostics, and treatment of the complications suspected to be related to chronic catheter implantation. The study then followed the remaining animals, which had no clinical signs but which underwent endoscopic examination in an effort to identify subclinical catheter complications and reasons for the catheter-related problems noted in the first 3 animals.

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Materials and Methods

This study was conducted at the Tulane National Primate Research Center (Covington, LA) in collaboration with the Louisiana State University Health Sciences Center (New Orleans, LA). The Tulane National Primate Research Center is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International.

Animals. A total of 31 male, Indian-origin, rhesus macaques (*Macaca mulatta*) were assigned to a SIV infection study that focused on the complications associated with alcohol consumption. Body weight of the animals ranged from 3.85 to 13.25 kg, with a mean weight of 6.02 kg, and the age range was 3.29 to 7.81 y, with a mean age of 4.45 y. All experimental and clinical procedures, including removal and replacement of catheters, were approved by the institutional animal care and use committees of the Tulane National Primate Research Center and Louisiana State University Health Science Center. All animals were antibody- and virus-negative for simian retrovirus and seronegative for simian T-lymphotrophic virus 1 prior to assignment to the study. The animal housing rooms were maintained on a 12:12-h light:dark cycle with relative humidity of 30% to 70% and a temperature of 17.8 to 28.9 °C. All animals were fed a standard commercially formulated nonhuman primate diet (Lab Fiber Plus Monkey DT, no. 5K63, PMI Nutrition International, St Louis, MO) with fruit offered 3 times weekly as part of the enrichment program.

For the experimental protocol, animals were divided equally into an alcohol infusion and sucrose control infusion group. At 3 mo after initiation of alcohol or sucrose administration, animals

1, 2, and 3 were inoculated intravenously with SIVmac251 at 100 times the dose infective to 50% of cultured cells. Animals 2 and 3 were inoculated with *Streptococcus pneumoniae* by bronchoscopic instillation in the right caudal lung lobe, (10^6 colony-forming units) 4 mo after inoculation with SIV.

All animals were given a 2-wk acclimation period, during which they wore the jackets only, followed by 2 wk of acclimation to the tether–jacket combination, which was connected to the swivel on top of the cage. The protocol allowed replacement of animals that did not tolerate the jackets; however, no animals were replaced in this particular study. After the acclimation period, the gastric catheters were implanted surgically. To protect the gastric catheters, all animals were fitted with a commercially available nonhuman primate jacket (Lomir Biomedical, Malone, NY) that had a tether attached to the back of the jacket and to a swivel located on top of the cage. Standard nonhuman primate cages were modified to allow use of the swivel and tether system by attaching a sheet of stainless steel to the top of the cage to prevent access to the syringe pumps used to administer alcohol or sucrose to the animals.

Surgical procedures. Each animal was surgically implanted with a commercially available 7-French silastic catheter. The distal end of the catheter was closed with a 4-cm slit valve closed end, a secured mesh impregnated silastic disc, and a 9-French 56-cm clear extension (Access Technologies, Skokie, IL). The preanesthetic protocol consisted of 0.2 mg/kg acepromazine maleate (Promace, Fort Dodge Laboratories, Fort Dodge, IA) and 0.01 mg/kg glycopyrrolate (Robinul-V, Fort Dodge Laboratories). Both drugs were administered subcutaneously approximately 30 min prior to induction of anesthesia. Animals then were anesthetized with ketamine hydrochloride (10 mg/kg; Ketaset, Fort Dodge Laboratories) administered intramuscularly. After anesthetic induction, animals were intubated and maintained on a mixture of isoflurane gas (concentration, 1% to 3%) and 100% oxygen.

Physiologic monitoring during surgery consisted of O_2 partial pressure, indirect blood pressure, end-tidal CO_2, and electrocardiogram. The ventral abdominal area was shaved and aseptically prepared with alternating povidone-iodine scrub and alcohol. A 6-cm ventral midline incision was created to exteriorize the stomach. The stomach was isolated with saline-moistened laparotomy pads and stabilized with Babcock tissue forceps. A #11 scalpel blade was used to make an incision into the gastric lumen, the fundal area, just dorsal to the greater curvature. The distal end of the catheter was inserted through the stab incision into the gastric lumen. A pursestring suture was placed in the gastric serosal surface around the catheter to secure the catheter and prevent gastric leakage. The 1.5-cm catheter disc was secured to the serosa by using a simple interrupted pattern with 3-0 nylon suture attached to a 3/8-circle cutting needle (Ethilon, Ethicon, Johnson and Johnson Medical, Berkshire, UK; Figure 1).

To create an exit site for the catheter, a cannula was used to penetrate the lateral abdominal wall musculature just medial to the second to last rib. The hollow cannula then was tunneled through the subcutaneous tissue from the abdominal wall catheter exit site to a location caudal to the scapulae. The catheter was passed through the cannula, which then was removed. Excess catheter length was pulled from the abdomen through the catheter exit site in the skin until the gastric wall abutted the lateral abdominal musculature. The midline abdominal incision was closed in 3 layers by using 2-0 Vicryl attached to a 3/8-circle tapered needle (Ethicon, Johnson and Johnson Medical) in a simple continuous pattern for the abdominal wall and

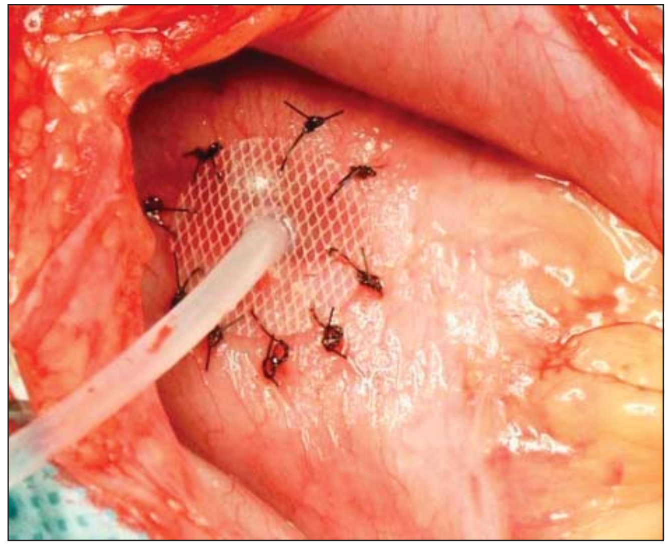

Figure 1. Intraoperative image of gastric catheter secured to gastric serosal surface by using a simple interrupted suture pattern.

3-0 Vicryl attached to a 3/8-circle tapered needle in a simple continuous pattern for the subcutaneous tissue layer. Skin was closed by using an intradermal pattern with 3-0 Vicryl attached to a 3/8-circle cutting needle. All animals received 0.01 mg/kg buprenorphine hydrochloride (Hospira, Lake Forest, IL) intramuscularly twice daily for 3 d for postoperative analgesia. A 2-wk postsurgical recovery period was given prior to alcohol or sucrose administration and other study procedures.

Catheter maintenance and study procedures. A catheter maintenance program was instituted in the immediate postoperative period and was continued for the duration of the study. Catheter maintenance consisted of twice daily flushing with tap water to maintain catheter patency. All animals on the study underwent weekly physical exams, when the catheter exit site was examined, shaved, and cleaned with chlorhexidine diacetate solution (Nolvasan solution, Fort Dodge Laboratories). As part of the protocol, the nonhuman primate jackets, tethers, and swivels were replaced at least once monthly with new or disinfected, undamaged components. In the event that an animal damaged its jacket, the jacket was immediately replaced with a new or disinfected, undamaged jacket.

Either alcohol (ethyl alcohol, 200 proof, AAPER Alcohol and Chemical Company, Shelbyville, KY) or isocaloric sucrose was administered through the implanted gastric catheters to each animal for 5 h daily for 4 consecutive days each week. First, a 30-min rapid priming infusion was administered to achieve target blood alcohol levels of 50 to 60 mM. The animals then were infused to maintain that blood alcohol level for an additional 4.5 h. Syringe pumps were used for alcohol and sucrose infusions (model no. A-99.FJ/FM/FJM, Razel Syringe Pumps, St Albans, VT).

Statistical methods. Case records were examined for history of infections and other abnormalities, including visible exudates, crusting or leaking, and rubbing. To determine whether these problems were significantly associated with endoscopic findings, Fisher exact tests were done. The threshold for significance was set at $P < 0.05$.

Results

This retrospective investigation includes 31 animals with gastric catheters observed between the dates of November 2004 to October 2006. During the study period, 3 of the 31 animals

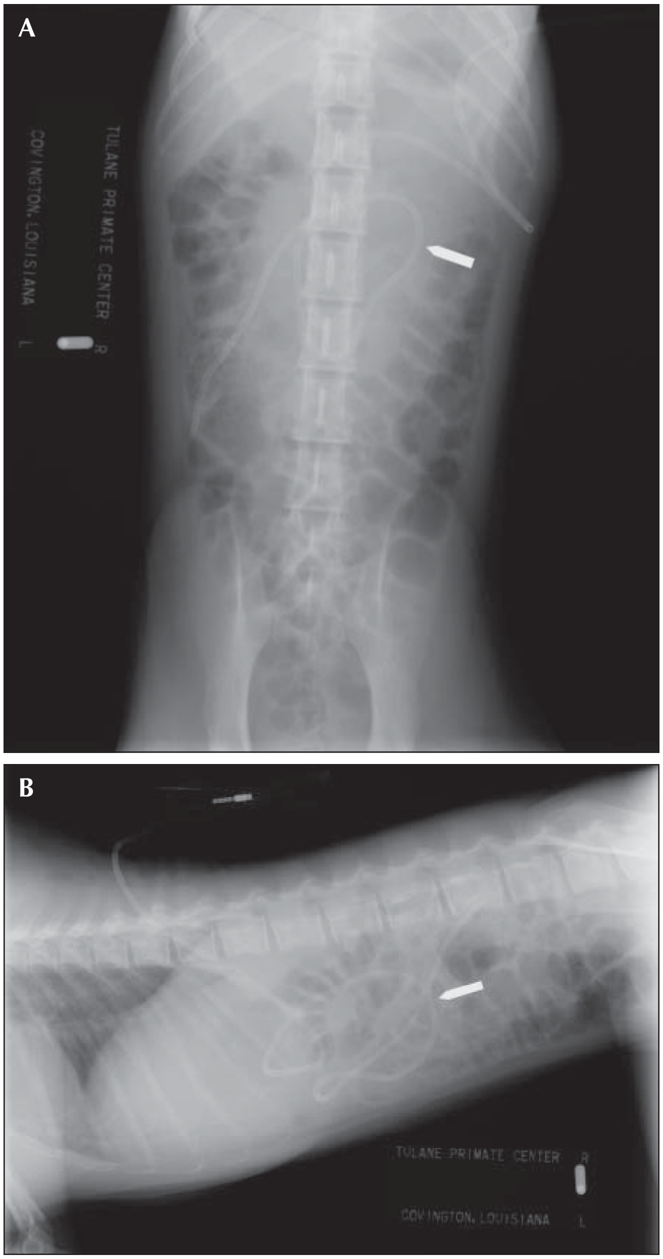

Figure 2. (A) Ventrodorsal and (B) right lateral abdominal radiographs demonstrating a displaced gastric catheter free in the peritoneal cavity.

had catheter-related clinical signs. All 3 animals had been inoculated with SIV prior to initiation of clinical signs; 1 animal was assigned to the sucrose infusion group, and the remaining 2 animals were assigned to the alcohol-infusion group. The primary clinical signs that ultimately were attributed to unstable gastric catheters were vomiting, dehydration, anorexia, and lethargy. Because of the sudden onset of the clinical signs and no evidence of common secondary opportunistic infections, SIV-related disease was deemed an unlikely cause for the presenting clinical signs. Supportive care was administered and consisted of fluid therapy, nutritional support, and thermal support.

Animal 1 presented with signs of vomiting, dehydration, lethargy, and poor appetite. After the animal was stabilized by fluid therapy and thermal support, radiography and a gastroscopic exam were performed. The gastric catheter had been implanted 12 mo prior to the onset of clinical signs. Radiographs revealed that the distal end of the gastric catheter was located in the peritoneal cavity (Figure 2 A, B). Flexible videogastroendoscopy (Olympus America, Center Valley, PA) confirmed that the catheter transversed the lumens of the pylorus and duodenum and that the distal end was free in the peritoneal cavity through a 2-cm rent in the proximal duodenum.

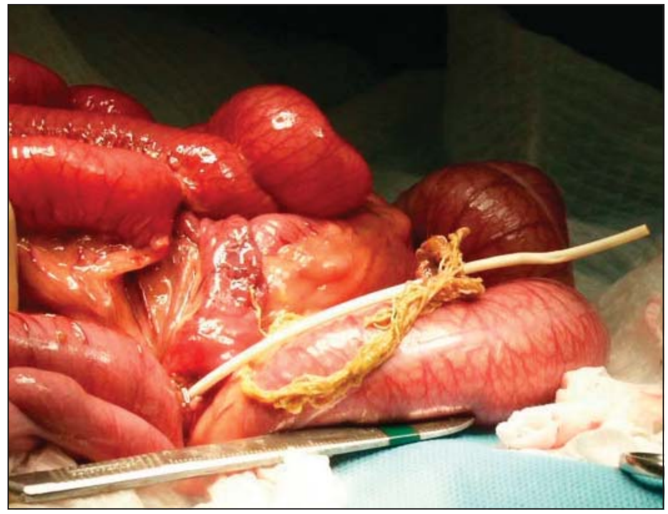

Figure 3. Intraoperative image of the gastric catheter in Figure 2 with string attached to the disk extending through the 2-cm duodenal rent.

A decision was made to perform an exploratory laparotomy to protect the health and well-being of animal 1. The animal's abdomen was aseptically prepared (as described earlier), and a laparotomy was performed to remove the catheter and repair the duodenal defect. The duodenal defect was closed with 3-0 absorbable suture in a simple interrupted pattern, and the repaired segment of duodenum was tested for leaks with saline under moderate pressure by occluding the duodenum proximal and distal to the repaired defect. Intraoperatively, a large amount of string was found attached to the catheter's anchoring disc (Figure 3). The abdominal cavity was lavaged thoroughly with saline prior to closure. Antibiotic therapy was initiated using enrofloxacin intramuscularly once daily (5 mg/kg; Baytril, Bayer Health Care, Shawnee Mission, KS) for 14 d, oral metronidazole once daily (50 mg/kg; Flagyl, Bio-serv, Frenchtown NJ) for 10 d, and cefazolin sodium intramuscularly twice daily (20 mg/kg, Cefazolin, Apotex, Weston, FL) for 14 d, and analgesics were administered in the same regimen as for gastric catheter implantation surgeries. The animal recovered without further complications. Clinical signs associated with the displaced catheter (vomiting, dehydration and anorexia) resolved. Approximately 1 mo after the corrective surgical procedure, a second catheter was implanted in animal 1; sucrose administration resumed 2 wk later without further complication.

Animal 2 developed similar clinical signs as Animal 1 (vomiting, dehydration, and decreased appetite). The animal's catheter had been implanted 16 mo prior to the development of clinical signs. Before demonstrating gastrointestinal signs, animal 2 had a history of chronic respiratory infections that began after SIV inoculation. Radiographic changes consisted of both interstitial and bronchiolar fluid density patterns at different time points, and clinical signs consisting of tachypnea and dyspnea were noted. Multiple superficial catheter tract infections had been noted on physical examinations as well. Bacterial cultures of discharge yielded hemolytic and nonhemolytic coagulase-positive and -negative *Staphyloccocus*. During the course of these chronic clinical conditions, the animal had been treated with appropriate antibiotics according to sensitivity results.

The condition of animal 2 began to deteriorate 16 mo after catheter implantation, and the full range of signs manifested as pronounced weight loss, respiratory distress, and anorexia. Because animal 2 had reached the predetermined humane endpoints, euthanasia was performed with an intravenous overdose of pentobarbital (Beuthanasia-D, Shering Plough Animal Health, Omaha, NE). At necropsy, in addition to the gross findings of pneumonia, the gastric catheter tip was noted to be displaced, and it had descended into the duodenal lumen, causing a 0.5-cm rent in the wall of the proximal duodenum. There was string attached to the disc at the tip of the catheter.

Animal 3 presented with vomiting, dehydration, a distended abdomen, and incomplete anorexia. An endoscopic examination showed that the catheter's attachment disc had migrated into the lumen of the stomach. A large amount of string was present around the disc, descending through the pylorus and into the proximal duodenum. In an attempt to remove the string, 2.4-mm endoscopic biopsy forcep (Olympus Endotherapy Biopsy Forceps, standard cup shape FB-25K-1, Olympus America, Center Valley, PA) was guided down the lumen of the duodenum through the endoscope to grasp portions of the string attached to the catheter disc. Over several attempts, large amounts of string were pulled free from the catheter and removed through the oral cavity. During one of the attempts to remove the string, the string did not come free and the catheter was pulled, along with the string, through the esophagus and removed through the oral cavity. In light of the adhesion of the stomach to the abdominal musculature at the catheter exit site, the risk of contamination of the peritoneal cavity with gastrointestinal contents was determined to be minimal, and no additional procedures were performed. The animal recovered from the procedure without any complications. A second catheter was not implanted.

Because of the findings in animals 1, 2, and 3, the remaining 28 animals assigned to the study were evaluated for catheter instability; evaluation consisted of gastroendoscopic examinations, thorough examination of clinical histories, and investigation into the correlation of catheter-tract abnormalities and catheter instability. The occurrence of catheter-tract infections, erosions over the catheter tract, and exudates from the catheter tract exit site also was investigated. Analysis revealed no statistically significant association between the occurrence of catheter-tract infections and abnormal endoscopy findings.

During the course of the study, the source of the string was determined to be from the jackets used to prevent animal access to the catheters. Animals were observed to be consuming string while picking or chewing on the jackets, and string was found in the fecal material of several animals on the study. Most of the animals that manipulated their jackets did so outside of regular working hours. If a jacket was damaged, it was immediately removed and replaced with a new or disinfected, undamaged jacket.

Of the remaining 28 animals evaluated with endoscopic examinations, 19 had normal or appropriate catheter position with no evidence of the catheter disc present in the gastric lumen (Figure 4). The catheters in these animals had been implanted from 10 to 37 mo (mean, 17.55 mo) before endoscopic examination. Of the 19 animals with normal catheter placement, 1 had string wrapped around the tip of the catheter in the lumen of the stomach; that catheter had been implanted 15 mo before endoscopic examination. Another animal had invagination of the gastric mucosa without protrusion of the catheter disc; the catheter had been implanted 9 mo before endoscopic examination.

Endoscopic evaluation revealed that a total of 9 animals had malpositioned catheters. In 4 of these animals, the catheter disc was completely visible in the gastric lumen; string was attached to the catheter in 2 of these 4 animals (Figure 5). These catheters had been implanted 12 to 13 mo prior to endoscopic examination. In the remaining 5 animals, only a portion of the disc was present in the gastric lumen; string was attached to the catheter disc in 1 of these animals. These catheters had been implanted 10 to 17 mo prior to endoscopic examination.

Figure 4. Endoscopic view of the gastric lumen with normal catheter placement.

Discussion

After finding string attached to the catheter discs during initial evaluations of the 3 clinically affected animals described, we hypothesized that the animals had picked at or chewed on their protective jackets and consumed the string, which resulted in the formation of a string foreign body due to entanglement on the distal end of the gastric catheter. We further hypothesized that the effects of peristaltic motion of the stomach and duodenum on the attached string eventually caused the catheter attachment disc to be pulled into the gastric lumen. However, follow-up evaluations of animals without clinical disease discounted this hypothesis, because the catheter disc was in the gastric lumen and free of string in several animals. Of the 28 animals examined not including the 3 initial clinical presentations, 6 had catheters with the catheter disc completely or partially visible inside the gastric lumen with no string attached. Our current theory is that the gastric wall invaginates around the catheter disc; once the disc is inside the gastric lumen, string accumulates on the catheter disc and further exacerbates the instability of the catheter. Before we found the string attached to the displaced catheters in animals 1, 2, and 3, historical clinical and pathology data gave no indication that string from damaged jackets constituted a risk for the study animals.

Our results indicate that with currently accepted surgical techniques and monitoring, intragastric placement of catheters for long periods of time runs the risk of catheter migration, as evidenced in 3 of 31 animals who presented with signs related to catheter migration and an additional 9 animals in which endoscopic exam revealed unstable catheters. These findings

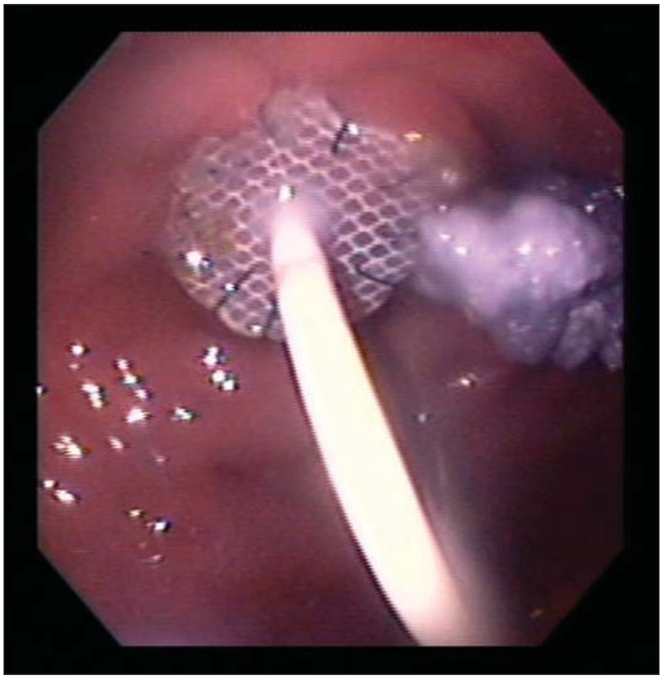

Figure 5. Endoscopic view of a displaced catheter disk in the gastric lumen.

indicate the importance of periodic endoscopic exams and the need for improved surgical procedures and materials for catheter placement and protection.

To address possible causes of catheter instability, we considered several alternative techniques, including use of a different type of catheter and alternative surgical approaches. Possible catheter alternatives included a catheter with 2 discs for attachment—1 inside the gastric lumen attached to the gastric mucosa, and 1 attached to the gastric serosa. This alternative was undesirable because it requires gastrotomy and placement of a disc in the gastric lumen. A second alternative catheter had a larger diameter disc, thus increasing the surface area of attachment and making it more difficult for the catheter disc to pull into the gastric lumen. We considered placing surgical mesh under the catheter disc, reasoning that the large surface area of the mesh would decrease the likelihood of catheter disc migration. Potential complicating sequelae of using mesh include compromise to gastric vasculature and increased adhesions to other abdominal structures.[1,2,7,15,18]

A variety of gastric catheters currently available can be placed either percutaneously or through open surgical approaches. We considered percutaneous endoscopic placement of catheters to decrease the number of major surgical procedures required in this model. Percutaneous endoscopic gastrostomy (PEG) tubes typically are intended for elderly or health-compromised patients that pose anesthetic and surgical risks and who are unable to receive adequate nutrition orally.[8-12,22] Numerous studies have demonstrated a widely variable functional duration of PEG tubes; deaths attributable to underlying disease has complicated determination of the functional life of the tubes.[12,14,22]

The animals enrolled in our study were clinically normal at the time of surgical implantation, required only small amounts of ethanol to be administered through the gastric catheter, and were able to consume their normal diet orally. This diet might have caused the distal end of PEG tubes to obstruct with food material, an uncommon event (in our experience) with the closed slit valve end of the silastic catheters.[12,14,19] The placement of PEG tubes has been documented to cause mortality, and complications have included puncture of a nongastric hollow viscus, occlusion of the catheter, balloon deflation, catheter breakage, leakage through the stoma or into the abdomen, aspiration pneumonia, catheter migration.[9,11,12,14,19,24,27] In addition, several PEG tube complications have required open surgical exposure for correction or replacement of the original gastrostomy tube, thus negating the benefit of percutaneous placement.[9,14,19,24,27]

We also considered limitations of the anatomical location of the gastrostomy tube exit site of PEG tubes. The implantation protocol required that the distal portion of the catheter be tunneled through subcutaneous tissue and exit just caudal to the scapulae, where the tether was attached to the jacket. The typical exit location for a PEG tube is the lateral abdomen, a location that might permit manipulation by a nonhuman primate wearing a jacket.[10,19,24,27] To maintain consistency throughout the study period, silastic catheters of the same design have been used since inception.

Alternative surgical approaches that we considered included changing the catheter location site and gastropexy procedures. The current catheter attachment site on the fundal region of the stomach is easily accessed and is the least vascularized area of the stomach, but it is also the site of tonic and phasic motor activity.[3,13,25,26] An area near the cardia was considered but not pursued because of factors such as vascularity and the potential to induce neuromuscular damage, which might lead to gastric reflux. We considered leaving additional catheter length in the peritoneal cavity, instead of removing the excess and approximating the gastric serosa to the peritoneal surface of the abdominal musculature. This technique had been performed during the early development of the model, and no clinical problems due to catheter instability had been reported with this technique. However, because only a few animals in earlier studies had undergone endoscopic examination, catheter displacement may have occurred but was not documented. Because consultation with surgeons indicated that the currently used method of approximating the stomach to the peritoneal surface was preferable to leaving excess catheter length in the abdominal cavity, we did not change this technique. In addition to the current technique of securing the catheter disc to the serosal aspect of the stomach in subsequent catheter implant surgeries, we investigated a procedure in which the gastric serosa is secured to the abdominal wall. In addition, the catheter now is sutured to the abdominal muscle fascia on exit from the abdomen.[6,27]

Because animals with gastric catheters occasionally developed acute or chronic bacterial infections associated with the catheter exit site, we questioned whether these manifestations were associated with catheter instability. Statistical analysis demonstrated no significant correlation between catheter-tract infections and catheter instability.

The effect of the length of time since catheter implantation on catheter stability was examined. There appeared to be no correlation between the duration of catheter implantation and catheter instability. At the time of gastroendoscopic exam, the 9 animals with unstable gastric catheters had a mean catheter duration of 13.6 mo. The 19 animals that had normal catheter position had a mean catheter duration of 14.9 mo.

After evaluating the current surgical procedure for securing the gastric catheter, we have made the following adjustments: 1) a catheter with a larger diameter attachment disc (3 cm rather than 1.5 cm) is used, 2) the catheter disc is secured to the peritoneal surface of the lateral abdominal wall after securing it to the gastric serosa, and 3) the catheter is secured to the abdominal musculature on exit from the abdominal wall.

In addition to the current monitoring protocol for animals with gastric catheters, which includes weekly examinations and maintenance of the area surrounding the catheter exit site, follow up evaluations for all animals with implanted gastric catheters now consists of periodic endoscopic evaluation of catheter placement. All animals that were diagnosed as having the catheter disc partially or completely inside the gastric lumen were identified in the animal records database and are closely monitored and observed for signs associated with catheter instability. In addition, the animals that manipulate their jackets are given supplemental enrichment devices. Although the definitive cause of the catheter instability in this study was not determined, establishing an enhanced monitoring program, newly implemented surgical techniques, catheter disc modification, additional clinical diagnostics (endoscopy), and provision of supplementary environmental enrichment are expected to aid in reducing catheter instability and associated clinical signs in this model.

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