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FULL PAPER

The application of a vascular closure device for closing a gastrostomy opening used for procedural access

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Objective: To study the feasibility of applying the Perclose ProGlide vascular closure device (PPVCD) *in vitro* for closing a gastrostomy opening for procedural access in the swine stomach in order to prevent peritoneal leakage.

Methods: The study included four experimental groups: one manual suture ($n = 10$), two manual sutures ($n = 10$), one PPVCD suture ($n = 10$), and two PPVCD sutures ($n = 5$). In the two PPVCD sutures group, the “pre-close” technique was used. The leak pressure was measured, and statistical analysis was conducted to compare the leak pressures among the experimental groups.

Results: The gastrostomy openings were successfully closed in all experimental groups. The median (range) values of leak pressure (mmHg) for each experimental group were as follows: one manual suture, 86.0 (75.0–110.0); two manual sutures, 98.5 (44.0–130.0);

one PPVCD suture, 96.5 (56.0–119.0); and two PPVCD sutures, 98.0 (66.0–104.0). The Mann-Whitney U test revealed no statistically significant difference in leak pressure between the manual ($n = 20$) and PPVCD ($n = 15$) suture groups. The Kruskal-Wallis test revealed no statistically significant difference in leak pressure among the four experimental groups. The Bonferroni post hoc test also revealed no statistically significant difference in the pairwise comparisons among the groups.

Conclusion: Application of PPVCD is feasible for the closure of gastrostomy openings in an animal model and is as effective as a manual suture.

Advances in knowledge: In our *in vitro* study, percutaneous closure of gastrostomy opening using PPVCD was possible; animal survival studies and development of specific devices are needed before clinical application.

INTRODUCTION

Surgical gastrostomy was first introduced in 1837, followed by percutaneous endoscopic gastrostomy in 1980 and percutaneous radiologic gastrostomy in 1981.^{1,2} After its introduction, percutaneous gastrostomy (PG) has replaced most surgical gastrostomies. The primary purpose of PG is ensuring long-term access for enteral feeding or gut decompression. In recent years, the number of transluminal procedures through the PG tract, such as stent placement for resolving obstruction of the gastric outlet, distal duodenum, and proximal jejunum^{3,4}; retrograde esophageal stent placement⁵; and transgastric endoscopy in patients undergoing gastric bypass,^{6,7} has been gradually increasing.

After completing the procedure through the PG tract, the PG tube is retained for more than 2 weeks to prevent side-effects, such as leakage of gastric contents through the

PG tract and peritonitis. Once the gastrocutaneous tract has matured, the tube is removed. Major complications such as leakage of gastric contents and peritonitis after gastrostomy occur in about 3% of patients, mostly within the first few days of tube placement before the gastrostomy tract has matured.^{8–10} The PG tract matures approximately 1–2 weeks after tube insertion, but tract maturation can be delayed because of a poor nutritional status, use of steroids, obesity, diabetes, and immunosuppression in patients.¹¹ If PG tract maturation is delayed, the incidence of side-effects may increase during this period.

Therefore, if the PG opening can be closed immediately after the procedure, subsequent complications can be reduced and inconvenience to the patients who have to retain the gastrostomy tube for a long time can be alleviated. The purpose of this study was to determine whether the Perclose ProGlide vascular closure device (PPVCD;

Figure 1. Preparation of the swine stomach. (a) The excised swine stomach was fixed on an acrylic plate, and the stomach openings were sealed using long Kelly forceps with two metal tubes (white arrows) inserted through the esophagus. (b) The tip of one metal tube was positioned near the esophageal orifice (black arrow) for infusing air into the stomach. Another metal tube was used to measure the intragastric pressure, and the tip was placed close to the opposite wall (white arrow) to eliminate the influence of dynamic pressure.

Abbott Vascular, Santa Clara, CA, USA.), a suture-based closure device designed to close arterial puncture sites, could be applied for closing gastrostomy openings.

METHODS AND MATERIALS

Preparation

To minimize animal sacrifice in this study, we used porcine stomach purchased from a slaughter house, which was slaughtered for commercial purposes and was 7 months or older of age. The stomachs were cleaned and refrigerated immediately after slaughter, and the experiments were conducted within 12 h. The excised stomach was fixed on an acrylic plate and two metal tubes were inserted into the stomach through the esophagus. The tip of one metal tube was positioned near the esophageal orifice and the hub was connected to a rubber pump to increase the pressure inside the stomach by infusing air. Another metal tube was used to measure the intragastric pressure in connection with the arterial pressure measurement sensor of a patient monitoring device (IntelliVue MP30; PHILIPS, Amsterdam, Netherlands), and the tip was placed close to the opposite wall, away from the esophagus, to eliminate the influence of the dynamic pressure generated by the infused air. After placing the metal tubes, the esophagus and stomach along the line from the gastric angle to the greater curvature were sealed tightly by using long Kelly forceps (Figure 1).

Gastrostomy

The upper gastric body was punctured with an 18 G sheathed needle, and a 0.035-inch guidewire (Radifocus guidewire; Terumo, Tokyo, Japan) was inserted. Gastrostomy openings were sequentially dilated using fascial dilators (Cook Medical, Bloomington, IN) to 18 F, the standard size of an esophageal stent delivery system.

Closing the gastrostomy openings

This study was designed to compare the results of the one manual suture group ($n = 10$), two manual sutures group ($n = 10$), one PPVCD suture group ($n = 10$), and two PPVCD sutures group

($n = 5$). A control group without the closure of the gastrostomy opening was also included ($n = 10$).

When the gastrostomy opening was closed with a manual suture, one or two simple intermittent sutures were made using a 3-0 polypropylene thread and a 26 mm semicylindrical needle (Ethicon, Somerville, NJ). The needle was inserted into the stomach wall perpendicularly at a point 3–5 mm from the border of the gastrostomy opening, and a knot was tightened so that the borders of the openings abutted against each other.

In the case of PPVCD closure, the general procedure used for closing an arterial puncture was followed. For closing an arterial puncture, PPVCD is inserted into the artery along the guidewire until the blood flows back through the marker lumen of the device, and the return of blood indicates the intra arterial location of the foot (a part containing the knotted thread, 3-0 polypropylene) of the PPVCD. In this study, we could observe the gastric fold by injecting contrast media through the marker lumen to check whether the foot was located in the stomach. The lever of the device was lifted to deploy the foot, and the device was gently pulled back to position the foot against the stomach wall, which was confirmed by observing and touching the stomach wall. The needle plunger was depressed to deploy the needles through the stomach wall and into the cuffs on the foot, thereby completing the suture loop (Figure 2). The device was then withdrawn, and a suture loop was formed through the gastric wall. The knot was pushed towards the gastric wall and tied to close the gastrostomy opening.

Five gastrostomy openings were closed with two PPVCDs by the pre-close technique. The gastrostomy opening was dilated to 8 F (the maximum diameter that can be closed using one PPVCD) to allow the wound edge captured by PPVCD. After the first PPVCD was inserted and rotated about 30° counterclockwise, the foot was deployed and the first suture loop was formed, which was held by using a small clamp and was not tied. The second device was inserted with a 30° clockwise rotation, and the second suture loop was held by using a second clamp without tying. The two suture loops remained untied, and the gastrostomy openings were sequentially dilated to 18 F. Thereafter, the knot of the first suture loop was tied first followed by that of the second suture loop to complete the closure of the gastrostomy opening (Figure 3). If the device was rotated over 30°, the probability that the needles might not be deployed accurately into the foot could increase.

In the case of PPVCD, device success was defined as a full-thickness suture with the needle passing through the entire layer of the gastric wall. When a partial-thickness suture was placed, or the needle was not pulled out or failed to catch the suture, it was considered as device failure. The device success rate was calculated in a total of 20 PPVCD attempts.

Measurement of leak pressure

To measure the leak pressure in each group, soapy water was applied to the sutured openings and air was slowly pumped. The pressure at which soap bubbles were formed (Figure 4) was

Figure 2. Perclose ProGlide. (a) Names of components are shown. (b) The lever of the device was lifted and the feet were deployed. (c) The needle plunger was depressed to deploy the needles through polystyrene plate and into the feet. (d) Two needles penetrated the gastric wall and captured the pre-knotted sutures at the feet of the PPVCD. PPVCD, Perclose ProGlide vascular closure device.

Figure 3. Two PPVCD sutures with the pre-close technique. (a) After the first PPVCD was inserted and rotated about 30° counterclockwise, the first suture loop was formed, which was not tied and held using a small clamp (arrow). The second device was inserted with a 30° clockwise rotation. (b) The second suture loop was also held using a second clamp without tying. The gastrostomy openings were sequentially dilated to 18 F. (c) The knot of the first suture loop was tied first followed by that of the second suture loop to complete the closure of the gastrostomy opening. PPVCD, Perclose ProGlide vascular closure device.

Figure 4. The measurement of leak pressure via the identification of soap bubbles.

recorded as the leak pressure. Moreover, the first point of leakage was recorded as the suture track or gastrostomy track.

When the leak pressure in the experimental group was higher than that in the control group, it was defined as closure success, and the opposite was defined as closure failure.

Statistical analysis

The median, minimum, and maximum values of leak pressure were measured in each group. The Mann–Whitney *U* test was performed by dividing the stomachs into the manual suture group ($n = 20$) and the PPVCD suture group ($n = 15$). The leak pressures in the four experimental groups were compared using the Kruskal–Wallis test. In addition, the Bonferroni post hoc test was performed to compare the leak pressures between pairs of groups among the four experimental groups. All statistical analyses were performed using IBM SPSS Statistics for Windows/Macintosh, v. 21.0 (IBM Corp., Armonk, NY). Statistical significance was determined at a p -value of 0.05 with a two-tailed test.

RESULTS

Gastrostomy was successfully performed on 45 porcine stomachs in the four experimental groups and one control group. No failure caused by tearing or splitting of the stomach wall occurred during dilation by using the fascial dilator.

In the 20 trials using PPVCD, 17 resulted in full-thickness sutures without malfunction of the instrument, and 3 resulted in partial-thickness sutures (Figure 5); the device success rate was 85%. Partial-thickness sutures were observed in two cases in the one PPVCD suture group and in one case in the two PPVCD sutures group (one suture among two PPVCD sutures).

The leak pressures in the control group ranged from 1 to 9 mmHg with a median pressure of 4.5 mmHg. The leak pressures in each of the experimental groups were approximately 20 times higher than the leak pressure in the control group. Therefore, 100% closure success rate was obtained in the manual suture group (20 successes in 20 trials) and PPVCD suture group (15 successes in 15 trials).

Figure 5. Partial-thickness suture. The knot is buried in the incision.

The median values of leak pressure were 86.0 mmHg in the one manual suture group; 98.5 mmHg in the two manual sutures group; 96.5 mmHg in the one PPVCD suture group; 98.0 mmHg in the two PPVCD sutures group. In three cases of partial-thickness sutures using PPVCD, the leak pressures were 118 mmHg and 114 mmHg in two cases using one PPVCD and 98.0 mmHg in one case using two PPVCDs. These values were equal to or higher than the median values of the PPVCD suture groups. The leak pressures in each experimental group are described in Table 1.

When the Mann–Whitney *U* test was performed by dividing the stomachs into the manual suture group ($n = 20$) and PPVCD suture group ($n = 15$), no statistically significant difference in leak pressure was observed between the two groups ($p = 0.755$) (Table 2). The leak pressures in the four experimental groups did not satisfy the assumption of normal distribution and equi-dispersion in the Shapiro–Wilk and Levene tests. Therefore, the leak pressures were compared among the four experimental groups by using the Kruskal–Wallis test. No statistically significant difference in leak pressure was observed among the four experimental groups ($p = 0.846$). In the Bonferroni post hoc test comparing the leak pressures between pairs of groups among the four experimental groups, differences were not statistically significant.

The following points were noted. (1) In all cases, the suture track along which the suture needle passed was the point where the soap bubbles were first detected. (2) In case of partial-thickness suture with PPVCD, a strong-enough closure similar to that in the full-thickness suture was achieved. (3) Even when one PPVCD was used at the 18 F gastrostomy opening, a sufficiently strong suture could be placed.

DISCUSSION

Feeding access or decompression is the primary goal of PG. But, the PG tract can be a useful access route for percutaneous transluminal GI procedures, especially when peroral procedures are difficult or impossible and the endoscope cannot reach the

Table 1. List of leak pressures in each groups

	Control (<i>n</i> = 10)	Manual suture x 1 (<i>n</i> = 10)	Manual suture x 2 (<i>n</i> = 10)	PPVCD suture x 1 (<i>n</i> = 10)	PPVCD suture x 2 (<i>n</i> = 5)
Leak pressure (mmHg)	1	85	104	99	66
	4	82	79	119	104
	5	75	98	118 ^a	79
	4	79	65	76	98 ^a
	5	92	44	56	98
	9	110	126	72	
	4	91	99	114 ^a	
	5	87	130	82	
	2	96	111	96	
	5	81	66	97	
Median	4.5	86.0	98.5	96.5	98.0
Min–Max	1.0–9.0	75.0–110.0	44.0–130.0	56.0–119.0	66.0–104.0

PPVCD: Perclose ProGlide vascular closure device.

^aPartial-thickness suture

lesion because of surgically altered anatomy or lesion location or general contraindication to endoscopy.^{4–7}

After completing percutaneous transluminal procedures through the PG tract, closing the PG opening is important to prevent complications, improve patient satisfaction, and improve the treatment outcome. Generally, the PG tract matures in about 1–2 weeks after tube insertion, and hence, the PG tube is retained for more than 2 weeks to ensure its safe removal after the gastrocutaneous tract is well formed. However, major complications after PG usually occur before the maturation of the PG tract,^{8–10} and in cases of poor systemic nutrition, steroid use, obesity, diabetes, immunosuppression, old age, and malignancy, the possibility of complication due to delayed tract maturation and longer tube maintenance period may be increased.¹¹ Therefore, if we can close the PG opening immediately after the procedure, it can reduce the complications of PG and inconvenience to patients who otherwise need to retain the gastrostomy tube. However, appropriate equipment for the percutaneous closure of PG openings has not yet been developed.

PPVCD is a device designed to close the arterial puncture site with a suture-based mechanism. The diameter of the device is 6 F and the maximum diameter of the arterial puncture that can be closed using one PPVCD is 8 F. Two PPVCDs can be used to successfully seal the lumen with a diameter of 18–24 F through a

pre-close technique and crossed suture. The price of PPVCD and gastrostomy set (Cook Medical, Bloomington, IN) is \$207 and \$116, respectively, in my country. If the PG opening can be sealed by PPVCD, it potentially reduces post-procedure recovery time, the risk of complications, and it improves patient experience and treatment outcome. The purpose of this study was to investigate the possibility of closing PG openings by using PPVCDs.

In this study, PG openings were successfully closed in all the stomachs. The median leak pressure was 89.0 mmHg (range: 44.0–130.0) in the manual suture group and 97.0 mmHg (range: 56.0–119.0) in the PPVCD suture group. Ryou et al¹² performed an *in vitro* experiment comparing the leak pressure after performing various endoscopic closure methods on the gastrostomy opening. They reported median leak pressures ranging from 32 to 79 mmHg according to each closure method. Our results showed leak pressures similar or superior to those reported by Ryou et al. Merrifield et al¹³ performed survival studies in live pigs after closing gastrostomy openings by using endoscopic clipping, a technique that showed a relatively low leak pressure (40 mmHg) in the study by Ryou et al. They reported that the experimental animals recovered without any side-effects even after endoscopic clipping with low leak pressure if the openings were completely closed. Considering the findings of these studies, simple manual sutures and PPVCD sutures can effectively close gastrostomy openings. In the Mann–Whitney

Table 2. Comparison of leak pressure between the manual and PPVCD suture groups

Leak pressure (mmHg)	Manual suture group (<i>n</i> = 20)	PPVCD suture group (<i>n</i> = 15)	<i>p</i> -value
Median	89.0	97.0	0.755
Min–Max	44.0–130.0	56.0–119.0	

PPVCD: Perclose ProGlide vascular closure device.

p-value obtained using the Mann–Whitney U test

U test comparing the manual suture and PPVCD suture groups, the difference in leak pressure was not statistically significant; hence, PPVCD suture is as effective a closure method as is simple manual suture.

Partial-thickness sutures were observed in 3 out of 20 trials using PPVCD. The stomach wall is thick and when the unfolded foot was brought into tight contact with the stomach wall by traction, the outer layers of the incision surface of the PG opening could be separated from each other and the needles of the PPVCD might puncture the inner layer of the gastric wall and result in a partial-thickness suture. The device success rate of 85% could be attributed to the anatomical and fundamental characteristics in this situation, as PPVCD was designed for closing small punctures and thinner wall in blood vessels.

In all three cases with partial-thickness sutures, the leak pressure was equal to or higher than the median leak pressure in each PPVCD group (Table 1). Ryou et al¹² reported that a full-thickness suture does not guarantee a higher leak pressure than does a partial-thickness suture. This could be because the suture track, which was created as the suture needle passed over the opening, became the primary air leakage point, and the full-thickness suture created a through-thickness suture track and made air leakage easier. The suture track was also the primary leakage path in all our trials. It can be postulated that the leak pressure in the case of a partial-thickness suture was not lower than the median value of the PPVCD group because the PG opening could be effectively closed using a partial-thickness suture alone, and the outer layer of the stomach wall without a needle path could cover the suture tract. Delius et al¹⁴ reported that transgastric access via an extended submucosal tunnel showed the highest leak pressure when closed using endoscopic clipping. However, additional animal experiments are necessary before clinical application to assess the effect of partial-thickness sutures on the closure of PG openings in the living body.

Because PPVCD has been designed for closing a 5- to 8-F-diameter arterial puncture, multiple PPVCDs and pre-close techniques are used for suturing larger-diameter openings. This study also predicted that using two PPVCDs would be more effective than using one PPVCD for closing gastrostomy openings with an 18 F diameter. However, no statistically significant difference in

leak pressure was observed among the four experimental groups in the Kruskal–Wallis test and between the one and two PPVCD sutures groups in the Bonferroni post hoc test. We believe it is possible to adequately seal an 18 F gastrostomy opening with one PPVCD. However, *in vivo* comparative survival studies need to be performed to confirm that suturing with one PPVCD is sufficient to close the 18-F-diameter PG opening.

Gastropexy is usually performed during percutaneous gastrostomy. It fixes the anterior gastric wall to the anterior abdominal wall, prevent gastric leakage, and promote maturation of gastrocutaneous tract.⁹ Hence, it may help percutaneous closure of PG opening using PPVCD by fixing the gastric wall, promoting healing process, and decreasing complications.

Despite these promising results, the following limitations exist in this study. First, manual suturing of gastric puncture is not an option in clinical practice and direct comparison with the typical endoscopic closure method such as clipping, T tags, stitching in natural orifice transluminal endoscopic surgery (NOTES) was not performed in this study. Second, the results of this study are based on the leak pressure in the *in vitro* environment. In a living body, different results may be obtained depending on factors that affect the stomach environment, such as blood flow, fasting, gastric juice, and peristalsis. Third, in this study, PPVCD was directly used on the excised stomach to easily locate the foot and needle. However, in a percutaneous trial in the living body, directly detecting the location of the foot and path of the needle will be difficult. Therefore, further animal survival studies are needed to evaluate the clinical outcomes after the percutaneous closure of PG openings by using PPVCD. And then, with development of dedicated closure devices, this can be applied to other GI tract closure and the basic operating mechanism can be adopted in the closure after NOTES.

CONCLUSION

PPVCD, a suture-based vascular closure device, is applicable and useful *in vitro* for closing PG openings made on swine stomachs. To confirm the clinical applicability of this technique to the percutaneous closure of PG openings, animal survival studies need to be conducted and optimal percutaneous closure devices specific to the GI tract should be developed in the future.

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