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Original Article

Safety of open gastrostomy using the modified bumper gastrostomy catheter compared with conventional gastropexy in cancer patients

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ABSTRACT

Background: Open gastrostomy is a safe, low-cost, available technique for enhancing nutrition in advanced cancer patients with a limited ability to feed from the oral route directly. However, variations in the technique for open gastrostomy result in different outcomes and complications. Gastropexy in open gastrostomy needs to extend the upper midline incision to securely fasten the stomach to the left side of the anterior abdominal wall. The aim of this study was to evaluate the safety of a new technical variation, which is simple, fast, and cost-efficient, via a small midline incision replacing the conventional gastropexy in patients admitted for gastrostomy.

Materials and Methods: This retrospective study was performed in patients who underwent open gastrostomy to evaluate the outcomes between conventional gastropexy and a new technical variation to fasten the stomach using a modified bumper gastrostomy catheter, which consists of a rubber tube covering the Foley catheter. The demographic data, diagnosis, operative time, and complications of both gastrostomy procedures were analyzed by multivariate analysis.

Results: Sixty-nine consecutive open gastrostomies performed in Chulabhorn Hospital between January 2018 and June 2021 were studied. All patients presented with advanced malignancies, including 63.7% categorized as head and neck cancer and 34.7% classified as esophageal cancer. Forty-nine patients underwent conventional gastropexy. Twenty patients underwent the modified bumper gastrostomy technique. The most common complications were catheter occlusion, leakage, and aspiration (8.7%, 7.2%, and 7.2%, respectively). The operative time in the modified bumper gastrostomy group was shorter than that in the conventional gastropexy group (27.95 ± 8.44 vs 35.06 ± 8.94, mean difference = 7.11 minutes, P = 0.003). The primary outcome of catheter dislodgement occurred in 6.12% and 5% of patients in the conventional gastropexy and modified bumper gastrostomy groups, respectively (relative risk = 0.68, 95% confidence interval 0.05–8.56, P = 0.763). The 3-month follow-up data on secondary outcomes, including peristomal irritation, content leakage, catheter occlusion, granulation, lung complication, and surgical site infection, were comparable between the groups. Bleeding requiring exploration because of early inadvertent tube extrusion or removal and buried bumper syndrome were not present in this study.

Conclusion: Using the modified bumper gastrostomy catheter in open gastrostomy provides an alternative method. This method via a small upper midline incision has a reduced operative time and is safe, easy, and available without increasing the risk of tube dislodgement and other local complications. Early inadvertent tube extrusion and removal requiring reoperation were not present in our study. In limited resource situations, the cost-efficient and widely available modified bumper gastrostomy catheters can be used in cancer patients who require open gastrostomy.

Keywords: Open gastrostomy, modified bumper gastrostomy, gastropexy, and safety

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Introduction

Malnutrition can be defined as a state resulting from a lack of nutritional intake caused by starvation, disease, or advanced age.[1] In Chulabhorn Hospital, the major causes of malnutrition include head and neck cancer and esophageal cancer leading to upper gastrointestinal tract obstruction. These conditions can be treated short-term by creating an artificial enteral route with a nasogastric tube. Cancer patients with a limited ability to feed from the oral route directly for a long-term duration of more than 3 weeks will be considered for percutaneous gastrostomy or open gastrostomy. However, at present, percutaneous gastrostomy is preferred over open gastrostomy. In some situations, such as stenosis of the esophagus or upper airway tract, previous abdominal surgery, or absent endoscopic light in the left upper abdominal quadrant, open gastrostomy has become an essential procedure to improve nutrition.[2]

In head and neck cancer, malnutrition is observed in 44%–88% of patients.[3] Similar to esophageal cancer, estimates of sarcopenia prevalence in esophageal cancer patients prior to treatment vary from 16% to 75%.[4] The evaluation and treatment of malnutrition before starting multimodality therapy play a crucial role in decreasing complications and increasing the survival rate of these patients.

There are many variations of the open gastrostomy technique. Our institution's technique is the Stamm gastrostomy starting with a 6–8 cm midline incision, followed by placing a gastrostomy tube on the anterior gastric wall. Next, 2–3 purse string silk sutures are used to invaginate the gastric wall. The tube is removed via a stab incision in the left upper quadrant. There are some challenges when performing this technique, including difficulties with suturing gastropexy stitches and hanging the stitch of the gastric wall in the closest abdominal wall behind the gastrostomy tube, particularly in patients with abdominal obesity, a wide abdomen, or left lobe liver enlargement. These challenges may cause longer operative times, larger incisions, or granulation tissue resulting from a slanted gastrostomy tract.

The percutaneous endoscopic gastrostomy technique uses an inner disk to pull the stomach tightly against the abdominal wall and an outer disk to press the gastrostomy tube against the skin to maintain the position of the stomach to the abdominal wall. Thus, we invented a new technique using a balloon catheter and modified bumper gastrostomy catheter to maintain the position of the stomach and abdominal wall instead of using gastropexy stitches.[5]

Many studies have researched various complications of gastrostomy techniques, which are divided into major and minor complications. Major complications consisted of lung complications, peritonitis, bleeding, and buried bumper syndrome, and minor complications were categorized as dislodgement, blockage, leakage,

peristomal irritation, surgical site infection, and granulation.[6-10]

The aim of this study was to evaluate the safety of a new technical variation, which is simple, fast, and cost-efficient, via a small midline incision replacing the conventional gastropexy in patients admitted for gastrostomy.

Material and Methods

This study was a retrospective study review of medical records of patients who underwent open gastrostomy from January 2018 to June 2021 at Chulabhorn Hospital. The inclusion criteria were 15–80 years old, requiring enhanced nutritional status by gastrostomy, and diagnosis of esophageal cancer or head and neck cancer with near total occlusion of the upper gastrointestinal tract. The exclusion criteria were previous gastrostomy, loss to follow-up in the 3-month period, a short life expectancy of less than 3 months, and missing data. After some patients were excluded, there were 69 remaining patients who underwent the gastrostomy procedure. The data collected included baseline characteristics, outcomes, and complication rates during the 3 months after the procedure (Figure 1).

The primary outcome was dislodgement of the catheter, meaning spontaneous displacement of the catheter from the gastrostomy site. Secondary outcomes were peristomal irritation, content leakage, catheter occlusion, granulation, aspiration, surgical site infection, bleeding or peritonitis requiring exploration because of early inadvertent tube extrusion or removal, and buried bumper syndrome.

Surgical technique

For this modified bumper gastrostomy technique (Figure 2), the patient was placed in the supine position under general anesthesia, and then an approximately 4-cm vertical upper midline incision was made (Figure 2B). When the abdominal cavity was accessed, the stomach was grasped with a Babcock clamp. We placed a double purse string absorbable 3-0 suture in the anterior lower body of the stomach wall around the clamp. A small 5–10 mm stab incision was made in the left upper quadrant of the abdomen using a curved arterial clamp to penetrate the abdominal cavity. The modified bumper catheter was previously prepared using a balloon catheter and short rubber tube (Figure 2A). We used a 16–22 F ordinary balloon catheter as an inner bumper, a small hole in the short rubber tube was created, and then the short rubber tube was placed over the balloon catheter as an outer bumper. The modified bumper catheter was passed through the abdominal wall into the stomach, and then the balloon was inflated with 10 ml of sterile water. The purse strings were tied, and the balloon was used to draw the stomach against abdominal wall (Figure 2C and 2D). Without gastropexy fixation, the short rubber tube was securely fastened against the skin to maintain the position

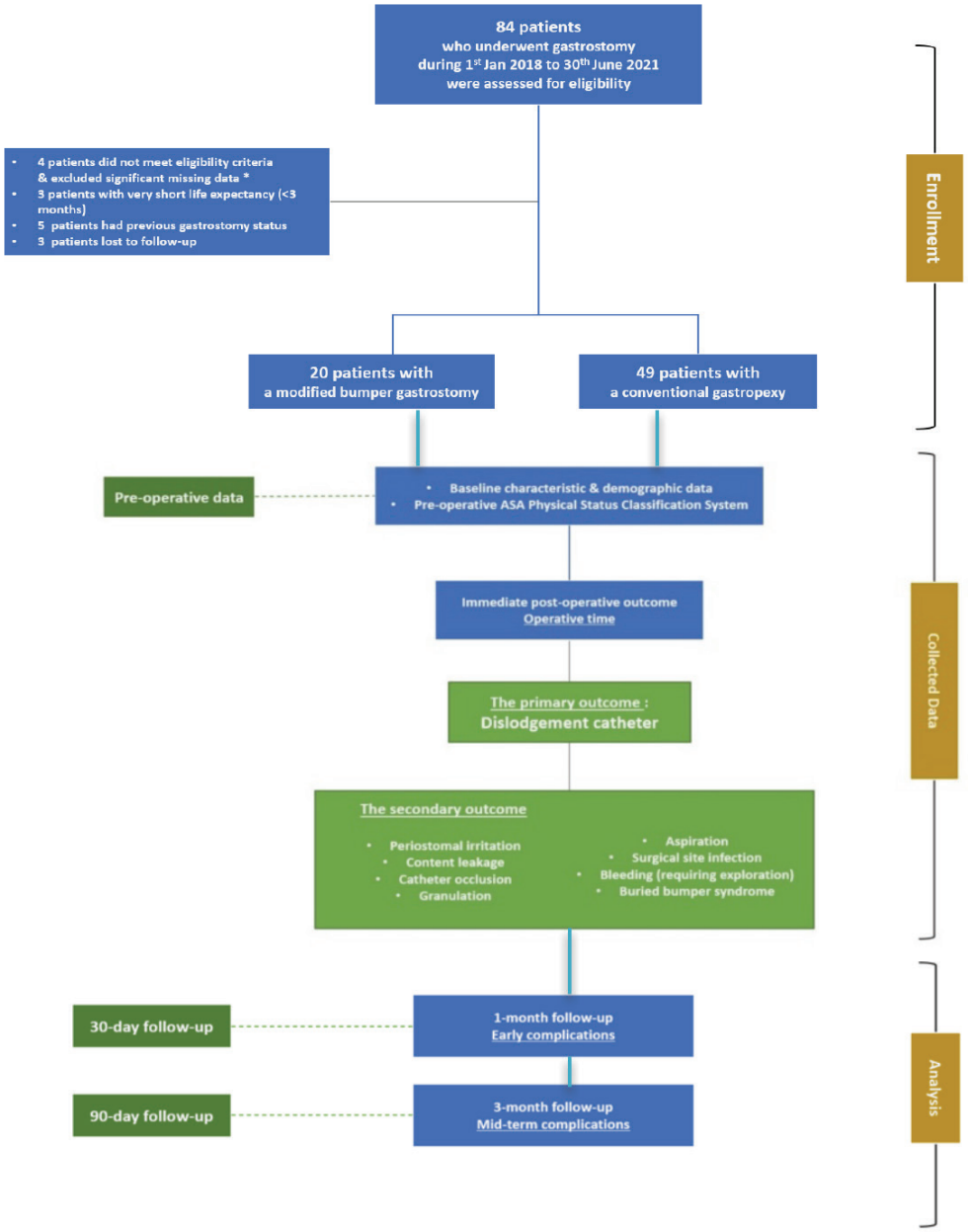

Figure 1 The study flow diagram of the cohort study (STROBE Statement (2008)).

of the stomach and abdominal wall (Figure 2E). The midline incision was closed. Enteral feeding was started in the next morning after surgery, as tolerated, and the patient was safely discharged home. Patients returned after 1 to 2 weeks to evaluate the surgical wound and gastrostomy tube complications and then were routinely followed up every 2 to 3 months.

For conventional gastropexy or Stamm gastrostomy, a 6–8 cm midline incision was made,

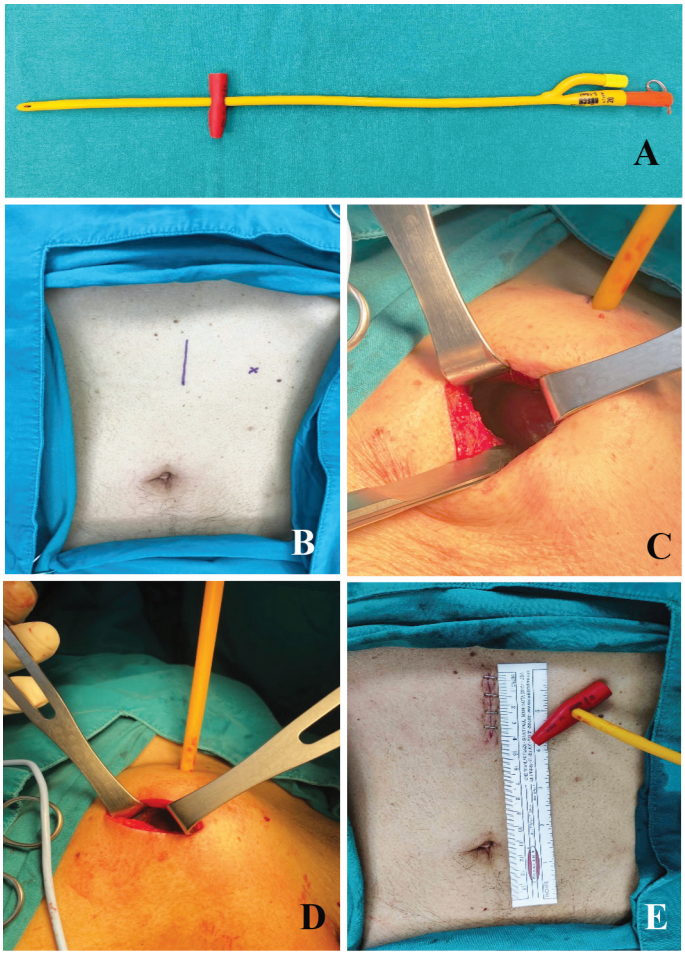

Figure 2 Surgical technique of modified bumper gastrostomy: A) The short rubber tube was placed over the balloon catheter as an inner and outer bumper. B) Marking of a 4-cm vertical upper midline incision and 5-mm stab incision in the left upper quadrant. C) and D) Balloon catheter was used to draw the stomach against the abdominal wall without gastropexy fixation. E) The short rubber tube was securely fastened against the skin to maintain the position of the stomach and abdominal wall, and then the abdominal wall was closed.

and then a gastrostomy balloon catheter was placed on the anterior gastric wall. Next, 2–3 purse string silk sutures were used to invaginate the gastric wall. The tube was removed via a stab incision in the left upper quadrant.

ASA, American Society of Anesthesiology *Important outcome data could not be assessed and >80% missing data in individual patients because of loss to follow-up and other reasons.

Statistical analysis

Comparisons between the gastrostomy techniques regarding baseline characteristics and clinical data, primary disease, operative time, and

perioperative and short-term (3 months) postoperative complications were assessed with a univariate two-sample t-test for continuous data and a chi-squared/Fisher exact test for categorical data, and data were presented as the mean and standard deviation. Data not normally distributed were presented as the median value with the interquartile range, and a multivariate analysis was performed. The relative risk (RR) and 95% confidence interval (CI) were reported. $P < 0.05$ was considered significant. The power was 0.80. All statistical analyses were performed with STATA/SE 16.1 for Windows (Stata Corp LP, TX, USA). The study process and report followed the strengthening of the reporting of observa-tional studies in epidemiology (STROBE) statement for the reporting of cohort studies.[11,12] The authors planned to manage the patients lost to follow-up and missing data by omitting these cases and analyzing the remaining data. However, after data collection, no loss to follow-up cases occurred during the first 3 months.

Sample size calculation

The comparative study of the safety and effectiveness of gastrostomy between the new technique using a modified bumper gastros-tomy catheter and conventional gastropexy was performed using a non-inferiority test. The hypothesis was that gastrostomy using the modified bumper gastrostomy catheter to replace conventional gastropexy does not increase complications, including dislodge-ment and inadvertent peritonitis or the need for re-exploration. The sample size was calculated as a non-inferiority trial with a 16% non-inferiority margin (δ).[13,14]

After excluding patients with incomplete outcome data because of loss to follow-up and other reasons, the retrospective data from medical records on the gastrostomy procedure at Chulabhorn Hospital between January 2018 and June 2021 included 69 gastrostomy procedures for analyses. From the non-inferiority two-sample comparison of means with a 1:2.5 ratio between the two groups under a type I error (α) of 0.05 and type II error (β) of 0.2, 69 gastrostomy procedures were required for analysis. Finally, gastrostomy procedures included 49 conventional gastropexy procedures and 20 modified bumper gastrostomy catheter procedures.

Results

Surgery was performed in 69 patients diagnosed with head and neck cancer (63.7%) and esophageal cancer (34.7%). Forty-nine patients underwent open gastros-tomy using the conventional gastropexy technique, and the other 20 patients received modified bumper gastrostomy. The mean age was significantly higher in the conventional gastropexy group (61.42 ± 10.72) than in the modified bumper gastrostomy group (54.95 ± 8.92) ($P = 0.02$). Other factors were similar, including gender, body mass index, American

Society of Anesthesiology class-ification, primary cancer, and gastrostomy tube number (Table 1).

The outcomes and complication rates for both techniques are shown in Table 2. The operative time for the modified bumper gastrostomy was significantly shorter than that for the conventional gastropexy (27.95 ± 8.44 vs 35.06 ± 8.94, P = 0.0033). Major complications (peritonitis, bleeding, and buried bumper syndrome) were not found in these populations, except for lung complications in 7.25% of cases, but there were no statistical differences between the groups. After adjusting for the operative time and mean age, the primary outcome of catheter dislodgement was observed in 6.12% and 5% of patients in the conventional gastropexy and modified bumper gastrostomy groups, respectively (RR by multivariate analysis = 0.68, 95% CI 0.05–8.56, P = 0.773).

Table 1 Baseline characteristics and demographic data between the modified bumper gastrostomy catheter and conventional gastropexy groups

	Conventional Gastropexy (n = 49)	Modified Bumper Gastrostomy (n = 20)	Total	*p*-value
Age (mean ± SD)	61.42 ± 10.72	54.95 ± 8.92	59.55 ± 10.59	0.0200*
Female/Male	12/37	5/15	69	0.9644
BMI (mean ± SD)	19.18 ± 3.83	20.04 ± 3.51	19.43 ± 3.74	0.3934
ASA Physical Status Classification System				0.685
ASA1 (%)	1 (2.04)	0	1 (1.45)	0.520
ASA2 (%)	32 (65.31)	15 (75)	47 (68.12)	0.433
ASA3 (%)	14 (28.57)	5 (25)	19 (27.54)	0.763
ASA4 (%)	2 (4.08)	0	2 (2.90)	0.359
Head and neck cancer (%)	32 (65.31)	12 (60)	44 (63.77)	0.677
Esophagus cancer (%)	15 (30.61)	7 (35)	22 (31.88)	0.981
Cancers (%)	2 (4.08)	1 (5)	3 (4.35)	0.865
Tube number				0.348
16 F (%)	1 (2.04)	0	1 (1.45)	0.520
18 F (%)	6 (12.24)	1 (5)	7 (10.14)	0.366
20 F (%)	38 (77.55)	19 (95)	57 (82.61)	0.083
22 F (%)	4 (8.16)	0	4 (5.80)	0.188

SD=standard deviation; BMI=body mass index; ASA=American Society of Anesthesiology;
*p-value < 0.05 indicates statistical significance.

The 3-month follow-up data on secondary outcomes, including peristomal irritation, content leakage, catheter occlusion, granulation, aspiration, and surgical site infection, were comparable between groups (Tables 2 and 3).

Table 2 Outcomes and complication rates between the modified bumper gastrostomy catheter and conventional gastropexy groups

	Conventional Gastropexy (n = 49)	Modified Bumper Gastrostomy (n = 20)	Total	RR	95%CI	*p*-value
Operative time (mean ± SD)	35.06 ± 8.94	27.95 ± 8.44	33 ± 9.32		30.75–35.24	0.0033*
Peristomal irritation (%)	3 (6.12)	0	3 (4.35)	N/A	N/A	0.258
Leakage (%)	3 (6.12)	2 (10)	5 (7.25)	1.42	0.45–4.45	0.573
Dislodgement (%)	3 (6.12)	1 (5)	4 (5.8)	0.85	0.15–4.86	0.856
Occlusion (%)	5 (10.20)	1 (5)	6 (8.7)	0.55	0.08–3.43	0.486
Granulation (%)	4 (8.16)	0	4 (5.8)	N/A	N/A	0.188
Peritonitis (%)	0	0	0	N/A	N/A	N/A
Bleeding (%)	0	0	0	N/A	N/A	N/A
Buried bumper (%)	0	0	0	N/A	N/A	N/A
Lung complication (%)	3 (6.12)	2 (10)	5 (7.25)	1.42	0.45–4.45	0.573
Surgical site infection (%)	1 (2.04)	0	1 (1.45)	N/A	N/A	0.520

SD=standard deviation; RR=relative risk; CI=confidence interval; N/A=not applicable
**p*-value < 0.05 indicates statistical significance.

Table 3 Gastrostomy catheter dislodgement rate between modified bumper gastrostomy catheter and conventional gastropexy groups

	RR*	Dislodgement of catheter (%)	Missing data	*p*-value	95%CI
Technique for securely fastening the stomach-abdominal wall	0.68	5.8	none	0.763	0.05–8.56
• Modified bumper gastrostomy catheter		5			
• Conventional gastropexy		6.12			

CI=confidence interval; *RR=relative risk by multivariate analysis
**p*-value < 0.05 indicates statistical significance.

Discussion

This retrospective study demonstrated that the new technique using a modified bumper gastrostomy catheter was comparable to conventional gastropexy in terms of the primary outcome of catheter dislodgement. However, in this study, dislodgement of the catheter occurred after patients were discharged from the hospital, usually more than 2 weeks after admission to the outpatient department.

Regarding the secondary outcomes in the modified bumper gastrostomy group, buried bumper syndrome was not observed in this study, despite using the bumper for the percutaneous endoscopic gastrostomy technique. Bleeding and peritonitis from inadvertent tube extrusion were also not observed, although this technique did not require gastropexy stitches. Moreover, peristomal irritation and granulation were not found in the modified bumper gastrostomy group. It is assumed that the gastrostomy tract in the modified bumper gastrostomy procedure was more perpendicular than that using conventional gastropexy, and a smaller incision was used. The operative time is shorter in modified bumper gastrostomy because suturing the gastropexy is not required.

There were some limitations to this study, including its retrospective design, small sample size, and short follow-up period of only 3 months. Thus, some minor complications, such as granulation formation and buried bumper syndrome, would not occur in these populations. A prospective randomized controlled study should be performed to confirm these results.

In conclusion, the results showed that the modified bumper gastrostomy was non-inferior compared with open gastrostomy. This technique using a balloon catheter and short rubber tube to maintain the position of the stomach and abdominal wall instead of gastropexy stitches may provide an alternative method in open gastrostomy. Moreover, this technique had a reduced operative time and was safe, easy, and available via a small upper midline incision without increasing the risk of catheter dislodgement and other local complications. In limited resources settings, the low-cost and available modified bumper gastrostomy is safe and can be performed in cancer patients who require open gastrostomy.

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