Gastric Cancer (2018) 21:864–870
https://doi.org/10.1007/s10120-018-0814-1

ORIGINAL ARTICLE

Clinical outcomes of intraoperative manual dilatation of pylorus in pylorus-preserving gastrectomy: a retrospective analysis

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Received: 4 November 2017 / Accepted: 15 February 2018 / Published online: 13 March 2018

Abstract

Background Delayed gastric emptying is one of the most disturbing complications of pylorus-preserving gastrectomy (PPG) and it increases hospital stay. We investigated the clinical outcome of intraoperative manual dilatation of the pylorus as a preventive method of pyloric spasm after PPG.

Materials and methods We reviewed gastric cancer patients who underwent PPG between January 2014 and December 2016 at Seoul National University Hospital by a single surgeon. During operation, manual dilatation (MD) was performed after laparoscopic dissection and gastric resection by mini-laparotomy. Pyloric stenosis was diagnosed by the finding of severe narrowing in pylorus on upper gastrointestinal series (UGIS), if patients suffered from postprandial abdominal fullness and discomfort. Patient's characteristics, surgical data and complication data were reviewed and compared between the groups (MD vs non-MD).

Results 232 patients were included in this study. 93 patients underwent manual dilatation (40.1%). The overall complication rate was 12.9% in the MD group and 18.7% in the non-MD group ($p = 0.242$). Mean postoperative stay was 10.0 ± 5.8 in the MD group versus 10.9 ± 8.4 in the non-MD group ($p = 0.304$). Only one case suffered pylorus stenosis in the MD group (1.1%) but there were twelve cases seen in the non-MD group (8.6%), which reflects a significant difference ($p = 0.019$).

Conclusion Simple intraoperative manual dilatation of pylorus may provide prevention from pyloric stenosis caused by pyloric spasms for patients who undergo PPG.

Keywords Manual dilatation · Pylorus-preserving gastrectomy · Pyloric stenosis

Introduction

Although gastric cancer is still a leading cause of cancer death worldwide [1], most early gastric cancer (EGC) patients have a favorable prognosis with low tumor recurrence rate and long survival time after an appropriate surgical treatment [2]. Due to this fact, recently more focus has been laid on quality of life (QOL) in EGC patients as well as minimal invasive and function-preserving surgery. Pylorus-preserving gastrectomy (PPG) is a typical method of function-preserving surgery, which can be applied in EGCs located in middle-third of the stomach [3–5]. PPG has been demonstrated to have a similar oncological safety compared to distal gastrectomy in EGC patients [6, 7]. PPG operation can also overcome some disadvantages of distal gastrectomy such as bile reflux, dumping syndrome, gastritis, gallbladder stone formation, malnutrition and immunologic function suppression and improve the postoperative QOL [8–10].

Chun-Chao Zhu and Tae-Han Kim contributed equally to this work.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s10120-018-0814-1) contains supplementary material, which is available to authorized users.

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PPG operation was designed to preserve the reservoir function of remnant stomach, but postoperative gastric stasis or delayed emptying became the most common and challenging complication of this surgery, occurring in 6.2–23% [3, 11–15]. In terms of maintaining the blood supply and innervation of the pylorus in PPG operation, the pyloric branch of right gastroepiploic vessel and the hepatic branch of vagus nerve should be preserved [16]. While performing this procedure, thermal insult to pyloric area caused by ultrasonic energy device may induce edema of the tissue, which might further cause pyloric dysfunction. Because of the pyloric dysfunction, patients suffer sensation of fullness after food intake or even vomiting in some extreme cases [17]. Delayed gastric emptying caused by pyloric spasm after PPG operation can cause delayed recovery of patients, and sometimes invasive treatment is necessary [18]. Therefore, it is important to find methods helping to reduce the incidence of pylorus spasm.

Gastric balloon dilatation has been reported as an effective remedy to release the pylorus spasm. However, some patients show poor response to balloon dilatation and even to interim stent insertion [19]. These invasive treatments definitely increase hospital stay. To prevent postoperative pyloric stenosis, manual dilatation of pylorus was introduced and performed from July 2015 up to present in our hospital. In this study, we compared surgical outcomes between patients who underwent PPG operation with or without intraoperative manual dilatation.

Method

Patients

We reviewed all cases of pylorus preserving gastrectomy (PPG) for middle-third early gastric cancer (cT1N0M0) being treated between January 2014 and December 2016 at Seoul National University Hospital, Seoul, Korea by a single surgeon. The surgeon started manual dilation of the pylorus during PPG in July 2015. The following clinicopathological data were collected and compared between MD and non-MD group: age, sex, body mass index (BMI), surgical approach, American Society of Anesthesiologists (ASA) Score, postoperative TNM stage, number of resected LN. Clinicopathological findings were classified according to the 3rd edition of Japanese classification of gastric carcinoma [20] and the 7th edition of American Joint Committee on Cancer (AJCC) TNM classification [21]. Surgical outcomes including operation time, blood loss, postoperative hospital stay and complications were collected. PPG patients after discharge are asked to visit the hospital following the standard follow-up schedule. In our routine practice, the patients were followed up 2 weeks after discharge. The patients who underwent PPG were educated to visit our center earlier than their scheduled visit when they experience excessive postprandial fullness. Endoscopic findings 1 year postoperatively were collected to analyze the long-term consequence of intraoperative manual dilatation.

Surgical procedures

Patients under general anesthesia were placed in the supine, reverse Trendelenburg position, with leg elevation. A 11-mm trocar for the camera port was inserted through infraumbilical incision using open technique and a pneumoperitoneum was established by CO_2 inflation at a pressure of 12 mmHg. Under laparoscopic visualization, one 12 mm trocar and one 5 mm port was inserted in the right side of the patient's abdomen and two 5 mm trocars were inserted at the left side. After placing the trocar, lifting of the falciform ligament was done with prolene stay sutures.

Partial omentectomy started with division of the omentum 3–4 cm inferior to the gastroepiploic arcade using an energy device. This procedure included the No. 4d (right gastroepiploic artery) and No. 4sb (left gastroepiploic artery) lymph node dissection. The No. 6 (infrapyloric) lymph nodes were meticulously dissected, preserving the infrapyloric vessels, followed by ligation of the right gastroepiploic vessels distal to the branching of infrapyloric vessels. The No. 5 (suprapyloric) lymph nodes were not dissected, and the right gastric artery and vein arcade was ligated approximately 3 cm apart from the pylorus. Subsequently suprapancreatic lymph node dissection was performed followed by ligation of the left gastric artery. During this procedure, No. 7 (left gastric artery), 8a (common hepatic artery), 9 (celiac artery) were dissected and also partial 11p (proximal splenic artery) lymph nodes were retrieved. The lesser omentum along the hepatoduodenal ligament was divided in a manner not to injure the hepatic branch of anterior vagus nerve (Fig. 1). Then, lymph node dissection No. 1 (right cardia) was performed carefully to prevent injury of the hepatic branch of anterior vagus nerve followed by dissection for No. 3 area (lesser curvature). After lymph node dissection, the stomach was extracted through a 5-cm mini-laparotomy at the epigastric area. The tumor location was identified by palpating the endoscopic metal clips, and the distal stomach was resected leaving at least 3-cm antral cuff. After resection of the stomach with an adequate proximal margin, the manual dilatation was performed gently using an intestinal clamp. The clamp was inserted into the distal lumen and gentle dilatation was done stretching the muscular layers of the pylorus for 10–15 s (Fig. 2). After manual dilatation, an extracorporeal handsewn (continuous interlocking single layer) gastro-gastral anastomosis was performed.

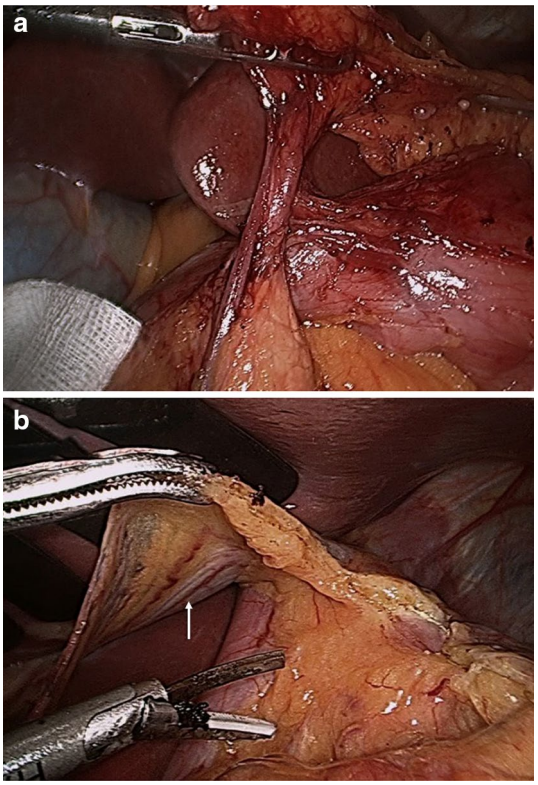

Fig. 1 Operative findings in pylorus-preserving gastrectomy: **a** Preservation of the infrapyloric vein and artery. **b** Preservation of hepatic branch of vagus nerve (arrow)

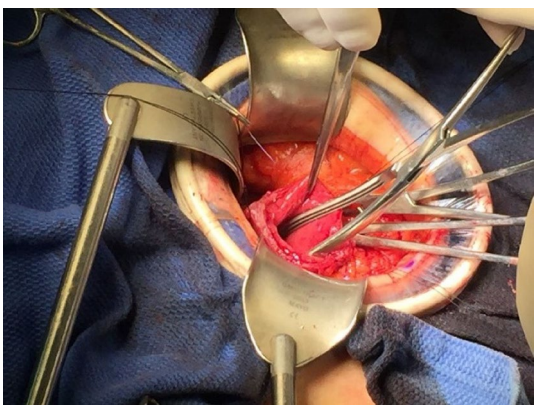

Fig. 2 Operation of manual dilatation: gently dilatate the pylorus using an intestinal clamp

Complication

Complications after PPG were prospectively collected and reported in the weekly based tumor board at Seoul National University Hospital. The complication's severity was classified according to the Clavien–Dindo classification system [22]. Pyloric stenosis was diagnosed by the finding of severe narrowing in pylorus on upper gastrointestinal series (UGIS), if patients suffered from postprandial fullness and discomfort (Supplementary Fig. 1). The patients were initially treated with fluoroscopy-guided balloon dilation. If narrowing persisted, a retrievable stent was placed for 2 weeks.

Statistical analysis

Continuous variables were analyzed using Student's *t* test. Relationships between categorical variables were analyzed using the Chi-square test or Fisher's exact test. Postoperative stay of two groups were compared by the Student's *t* test and Chi-square test. The risk factor for postoperative pyloric stenosis was studied by multivariate analysis. $p < 0.05$ was considered significant. IBM SPSS version 20.0 for Windows was used for all statistical analyses.

Results

Detailed patient information is shown in Table 1. In total, 232 patients were identified matching the inclusion criteria of the study. Intraoperative manual dilatation of pylorus was performed from July 2015 up to present. In 93 cases (41%), PPG with intraoperative manual dilatation of pylorus was performed, 139 cases were carried out without MD maneuver. Baseline analysis of two groups of patients' clinical characteristics was performed. Sex ($p = 0.229$), age ($p = 0.110$), BMI ($p = 0.259$), ASA score ($p = 0.056$) and surgical approach ($p = 0.227$) between MD group and non-MD group shows no significant difference. 8 (8.6%) MD cases and 10 (7.2%) non-MD cases were identified as advanced gastric cancer according to postoperative pathology. TNM staging information also shows no difference between MD and non-MD group ($p = 0.464$). In terms of lymph node dissection, no significant difference has been observed regarding the total number of resected nodes ($p = 0.321$) or infrapyloric nodes ($p = 0.693$).

Table 2 shows the data of operation-related parameters. Postoperative hospital stay appears similar in MD and non-MD group (10.9 ± 8.4 vs 10.0 ± 5.8, $p = 0.347$). The proportion of patients with extreme delayed discharge (postoperative stay ≥ 21 days) was decreased from 12.2 to 5.4% in the MD group, but there is no statistical significance ($p = 0.081$). Operation time (0.693) and blood loss ($p = 0.811$) show no significant difference.

There is no in-hospital mortality, and no significant difference on total complication of grade II or above between MD and non-MD group (Table 3). Among 12 pyloric stenosis patients, 1 (8%) patient showed stenosis symptom after discharge. The patient visited our center for epigastric discomfort and postprandial fullness. The

Table 1 Patient characteristics

Characteristics	Non-MD group, $n = 139$ (%)	MD group, $n = 93$ (%)	p value
Age	57.4 ± 11.5	59.9 ± 11.7	0.110
Sex			0.229
Male	73 (52.5)	41 (44.1)	
Female	66 (47.5)	52 (55.9)	
BMI	23.4 ± 3.6	22.9 ± 3.0	0.259
ASA			0.056
Score 1	66 (47.5)	36 (38.7)	
Score 2	73 (52.5)	54 (58.1)	
Score 3	0 (0.0)	3 (3.2)	
Surgical approach			0.227
Laparoscopy	96 (69.1)	71 (76.3)	
Robot	40 (28.8)	22 (23.7)	
Open	3 (2.1)	0 (0.0)	
Tumor depth			0.366
pT1a	87 (62.6)	56 (60.2)	
pT1b	42 (30.2)	29 (31.2)	
pT2	7 (5.0)	8 (8.6)	
pT3	3 (2.2)	0 (0.0)	
Lymph node metastasis			0.445
Yes	127 (91.4)	88 (94.6)	
No	12 (8.6)	5 (5.4)	
TNM (7th AJCC)			0.464
p Stage I	133 (95.6)	90 (96.8)	
p Stage II	3 (2.2)	3 (3.2)	
p Stage III	3 (2.2)	0 (0.0)	
Resected lymph nodes	39.3 ± 16.4	37.3 ± 13.1	0.321
Resected infrapyloric lymph nodes	6.1 ± 3.9	6.3 ± 3.6	0.693

Table 2 Operative data

Variables	Non-MD group ($n = 139$)	MD group ($n = 93$)	p value
Operation time (min)	226 ± 40.4	229 ± 37.6	0.693
Blood loss (ml)	29 ± 31	33 ± 40	0.811
Postoperative stay (d), [median]	10.9 ± 8.4, [7]	10.0 ± 5.8, [8]	0.347
Postoperative stay of ≥ 21 days	17 (12.2%)	5 (5.4%)	0.081

Table 3 Postoperative complication

Complications	Non-MD group ($n = 139$) (%)	MD group ($n = 93$) (%)	p value
Overall complication	26 (18.7)	12 (12.9)	0.242
Grade II or above	25 (18.0)	11 (11.8)	0.204
Functional gastroparesis	0 (0)	2 (2.2)	0.160
Pyloric stenosis	12 (8.6)	1 (1.1)	**0.019**
Intra-abdominal infection	7 (5.0)	5 (5.4)	1.000
Leakage	2 (1.4)	2 (2.2)	1.000
Others	11 (8.0)	6 (6.5)	0.800

Statistical significant value is shown in bold

proportion of pylorus stenosis, however, is significant lower in MD group compared to non-MD group (1.1 vs 8.6%, $p = 0.019$). With an exception of pyloric stenosis, no statistical significance has been found in other complications. In multivariate analysis, manual dilatation appeared independent factor predicting pyloric stenosis ($p = 0.048$, Table 4).

According to the endoscopic findings, 1 year after PPG operation, there were no significant difference regarding bile reflux between the groups (Table 5).

Table 4 Risk factors of postoperative pyloric stenosis by multivariate analysis

Variables	Odds ratio	95% CI	*p* value
Age (vs. ≥ 65 years)	2.203	0.604–8.040	0.946
BMI (vs. ≥ 25 kg/m^2)	0.698	0.182–2.681	0.600
Method (laparoscopic)			0.045*
vs. robotic	0.894	0.216–3.699	0.877
vs. open	22.857	1.507–346.719	0.024*
LN dissection (vs. D1 +)	0.301	0.010–8.742	0.485
Leakage	7.116	0.458–110.457	0.161
Fluid collection	2.847	0.281–28.830	0.376
Intraoperative dilatation	0.116	0.014–0.984	0.048*

*Statistical significance

Table 5 Endoscopic follow up one year postoperatively

Endoscopic finding	Non-MD group (n = 131) (%)	MD group (n = 84) (%)	*p* value
Reflux esophagitis	9 (6.9)	1 (1.2)	0.093
Reflux gastritis	12 (9.2)	10 (11.9)	0.708
Erosive gastritis	2 (1.5)	3 (3.6)	0.381
Hemorrhagic gastritis	3 (2.3)	0 (0.0)	0.283

Discussion

PPG operation has a 50 years' history since as it was introduced as function preserving gastrectomy by Maki and his colleagues in 1967 for gastric ulcer patients [23]. Preservation of pylorus function is the essential feature of the PPG operation. The initial application was limited to the benign disease of stomach such as ulcer. As powerful evidences proved its oncological safety when performing lymphadenectomy, PPG operation has been widely applied in the treatment of middle-third EGCs and became an option for the lesions with appropriate depth and location in the Japanese gastric cancer treatment guideline [7, 24, 25].

Despite the significant advantages of preservation of pylorus, the complication of gastric stasis is also well known. Pyloric spasm and antrum edema may be the most common reasons for gastric stasis or transient delayed gastric emptying. In case of pyloric stenosis, balloon dilation and/or retrievable stent insertion into the pylorus have been introduced for the treatment of patients with gastric stasis after PPG [19]. Although the outcomes are acceptable, it is time consuming, expensive and the risk for stent migration is problematic. Recently, botulinum toxin injection for the treatment of pyloric spasm has been introduced to treat pylori stenosis following PPG [26]. The outcome of this study appears convincing. However, it requires an endoscopic intervention for injection and multiple sessions of endoscopic injections were required in some cases.

As PPG sometimes leads to a feeling of epigastric fullness after meals, along with delayed gastric emptying due to pyloric stenosis, many surgeons have summarized some important tips to protect pylorus function to reduce the number of this complication. Nunobe reported that preservation of vagus nerve and infrapyloric blood flow induces less stasis in laparoscopic pylorus-preserving gastrectomy [16]. This procedure has been routinely performed by most surgeons. Kiyokawa published another report concluding that preservation of infrapyloric vein would further reduce the incidence of gastric stasis [27]. To our knowledge, this present study reports the lowest prevalence of delayed gastric emptying following PPG. The additional manual pyloric dilatation maneuver along with the effort of preserving infrapyloric vessels, preservation of hepatic branch of vagus nerve shows improved outcome after PPG.

Indeed, we performed PPG operation strictly preserving the hepatic branch of vagus nerve and blood flow of pylorus including infrapyloric vessels. Our retrospective study results demonstrated that gastric stasis was observed in the early postoperative period in 8.6% (12/139) of patients who underwent PPG without manual dilatation, which is similar to the results of previous studies in which significant or continuous gastric stasis symptoms were reported in 6.2–23% of patients who had undergone PPG [3, 11, 12, 16, 28]. Comparatively, we had only one case of gastric stasis after PPG with manual dilatation in total of 93 patients (1.1%), which reflects a dramatical decrease. Manual dilatation also appeared as an independent risk factor for pyloric stenosis in the multivariable analysis. Surgical method was also a risk factor of pyloric stenosis according to the statistics, but the number of open cases was only 3, and 2 of them suffered pyloric stenosis, which may cause some bias of the results. According to the postoperative morbidity, the results of our study suggests that intraoperative manual dilatation was a safe procedure if performed carefully to avoid tearing of the duodenal wall.

The dramatic decrease of pyloric stenosis in MD group demonstrated the short-term effect of manual dilatation, which may be the consequence of stretching the pyloric sphincter. Our long-term endoscopic review showed a lower incidence of reflux esophagitis and a higher incidence of reflux gastritis in the manual dilatation group. However, since this difference did not match the statistical significance, it is difficult to conclude that manual dilatation has negative influence on the muscular structure of pylorus in the long term.

Our study has several limitations. The analysis is based on only limited number of cases and the intervention is not tested in a randomized trial. A prospective observational

or even randomized interventional study could determine the role of this surgical maneuver for the patient outcome.

Conclusion

Intraoperative manual dilatation of pylorus is a simple, safe and effective procedure during PPG operation. It can be a valuable maneuver for preventing delayed gastric emptying caused by pyloric spasm.

Compliance with ethical standards

Ethics statement This retrospective study was conducted ethically in accordance with the Ethical Principles for Medical Research Involving Human Subjects, as outlined in The Declaration of Helsinki after approval of the institutional review board of Seoul National University Hospital (No. 1706-176-864). Informed consent was waved by the institutional review board based on its decision that the risk of this study to the patient is minimal.

Conflict of interest The authors declare that they have no conflict of interest.

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