

The Role of Pyloromyotomy on Gastric Drainage in Esophagectomy and Gastric Pull-up Procedures: A Randomized Clinical Trial Study

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ABSTRACT

Introduction: Gastric drainage disorder is one of the complications of gastric pull-up and esophagectomy after surgery which might lead to esophageal cancer and benign strictures. The aim of this study was to determine the role of pyloromyotomy on gastric drainage.

Materials and Methods: In this prospective randomized controlled clinical trial study, we studied 51 patients in two matched groups from July 2008 to August 2010 in Imam Reza Hospital, Tabriz, Iran. Twenty-seven patients in group one had no pyloromyotomy and 24 patients in group two had pyloromyotomy after transhiatal esophagectomy and gastric pull-up procedure. The outcomes were measured as the incidence of gastric outlet compromise which was diagnosed 12 months after esophagectomy and gastric pull-up. Regurgitation, fullness, respiratory distress, coughing and, clinical delayed gastric emptying were observed and compared in two groups by radioisotope gastric emptying scanning.

Results: A total number of 51 patients, 19 (37.25%) male and 32 (62.75%) female were studied in this research. The overall incidence of delayed gastric emptying was 19 /51 (37.25%). Pyloromyotomy did not reduce the incidence of delayed gastric emptying. There was no statistically significant difference in the length of hospital stay in study groups (group 1= 11 days versus 12 days in group 2, P=0.41). There was no statistical difference in anastomotic leak or anastomotic stricture (P= 0.72). Mortality was two (one patient, 3.7%, in group 1 and one patient, 4.2%, in group 2). The incidences of regurgitation and increased gastric emptying were not statistically different in two groups.

Conclusion: Pyloromyotomy could not reduce the incidence of delayed gastric emptying after transhiatal esophagectomy, and vagotomy.

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Introduction

The incidence rate of esophageal cancer in North-west of Iran is 100 per 100'000 people. However, the incidence of esophageal adenocarcinoma is still low. Prognosis of the patients who underwent surgery for esophageal cancer is rather poor and the 5-year survival rate does not rise to higher than 3% because there is no screening program for esophageal cancer in

Iran despite its relatively high morbidity and mortality (1, 2).

The main intention of surgery in esophageal carcinoma is to cure. However, this is achieved only in an area with screening programs (2). Managing advanced stages of esophageal carcinoma is palliative and it is mostly in order to improve the quality of life and nutrition (3). In all

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four common forms of esophageal resection, Transhiatal Esophagectomy (THE, Orringer) has been the procedure of choice in our center (4, 5). During esophagectomy and gastric release, complete vagotomy is conducted which produces pylorospasm and decreases gastric receptive relaxation with subsequent gastric outlet obstruction. Some surgeons try to do a drainage procedure together with esophagectomy to improve the gastric emptying. Most of them prefer to use pyloromyotomy or pyloroplasty (6, 7). It is still a matter of question whether pyloromyotomy should be performed together with Transhiatal Esophagectomy (8). The aim of this randomized clinical trial was to study the effect of pyloromyotomy on postoperative gastric emptying in Transhiatal Esophagectomy.

Materials and Methods

In this prospective randomized controlled clinical trial, 60 patients from Imam Reza Hospital affiliated to Tabriz University of Medical Sciences, Iran were studied from July 2008 to August 2010. Fifty-six patients had undergone Transhiatal Esophagectomy for esophageal carcinoma and were divided into two groups. A random sequence was generated through computerized random assignment and concealed allocation. Patients who had diabetes mellitus, severe cardiopulmonary compromises, history of preoperative radiotherapy were excluded from the study. The study was approved by the Ethics Committee of Tabriz University of Medical Sciences, Iran and was registered to Iranian Registry of Clinical Trials (IRCT) under the number 201104153831 N2 (www.irct.ir).

Inclusion criteria included the following: respectable esophageal carcinoma by transhiatal approach. Fifty-six patients were included in this study. Patients who did not participate in radioisotope gastric emptying within two months after surgery were excluded from the study.

Upon reviewing the exclusion criteria during the follow up period, fifty-one patients were analyzed. *Group 1* consisted of 27 patients who had not experienced pyloromyotomy during Transhiatal Esophagectomy. *Group 2* consisted of 24 patients who had undergone pyloromyotomy as a part of Transhiatal Esophagectomy.

Surgery

Transhiatal Esophagectomy, either with or without mediastinal lymph node dissection, was performed on 56 (93.4%) patients of esophageal carcinoma. In three patients with mid third thoracic esophageal tumor, right thoracotomy was required during the operation. The gastric conduit was pulled up and all esophagogastric anastomosis was placed in the patients' neck by

hand-made double layer technique (Vicryl 3-0 Ethicon in the inner layer and silk 3-0 Ethicon in the outer layer). The diameters of cervical anastomosis were 3.5 and 5.5 cm which were attached, in an oblique fashion, to the fundal tip of the stomach. Persisted mediastinal lymph nodes were resected through hiatus together with the resection of tumor and esophagus.

For 27 patients of group 1, pyloromyotomy was not carried out. However, all patients of group 2 went through the procedure. All patients were operated by the same surgical team and managed in Surgical ICU for 1-3 days.

A jejunostomy feeding tube was placed in all patients and enteral feeding was started 3-5 days after the surgery. Nasogastric drainage was maintained 4-5 days postoperatively. Oral feeding commenced on days 6-8 after surgery.

Metoclopramide medication, Erythromycin, and 30-40 (degree) head-up position were recommended after the surgery.

Two months after discharge, all patients were studied with radioisotope (Tc 99m, phytate) gastric emptying scan for detection of delayed gastric emptying.

Radioisotope Gastric Emptying Technique

In fifty one patients of both groups, the radionuclide gastric empty study was performed after at least staying 8 hours in the upright position. The procedure started immediately after a solid meal consisting of an egg sandwich. Images were acquired by using a dual-headed gamma camera (Siemens e-cam) with a low-energy, high-resolution collimator which was interfaced to a computer (Power Macintosh 8100-110) by using a 256×256 matrixes. The egg sandwich contained 1-2 mci of 99m Tc-phytate which had previously been injected into two beaten raw eggs. The eggs were then cooked until they became firm. Afterwards, the patients were given one glass of water. The mean time taken to eat the sandwich was 7 minutes with a range of 5-10 min. The meal had a caloric content of 250 calories (23% protein, 40% fat, 37% carbohydrate).

Upon eating the meal, sequential anterior and posterior images of one-minute duration were collected every 5 minutes for 30 minutes and every 30 minutes during the rest of the study. Each study continued up to 2.5 hours. In the intervals between image acquisitions, the patients were allowed to walk around or to sit down.

The time required of radiotracer to empty was 50% (T1/2) which was defined as normal and delayed gastric drainage. In the patients whose T1/2 was less than 1.5 hour, gastric emptying scanning was reported to be normal and in patients with T1/2 more than 1.5 hour, gastric emptying scanning was reported to have been delayed.

Statistical Analysis

Data were presented as mean± SD & N (%). Variables were analyzed with the independent samples of T-test for continuous variables as well as Chi-square and Fisher Exact Test for nominal or ordinal variables. P-values less than 0.05 were considered as statistically significant. The statistical package for social science (SPSS 16) was used for statistical analysis.

Gastric emptying scan data were also analyzed by using error-bar figure according to the function.

Results

A total of 51 cases were analyzed according to the consort statement of randomized clinical trial flow chart (Figure 1). Mean age was 59.68± 12.98 years for female patients (n=32) and 62.21± 7.84 years for male ones (n=19). The female to male ratio was 1.68 to 1 (53.4% vs. 31.6%).

Demographic characteristics of patients are illustrated in Table 1. The tumors were mostly

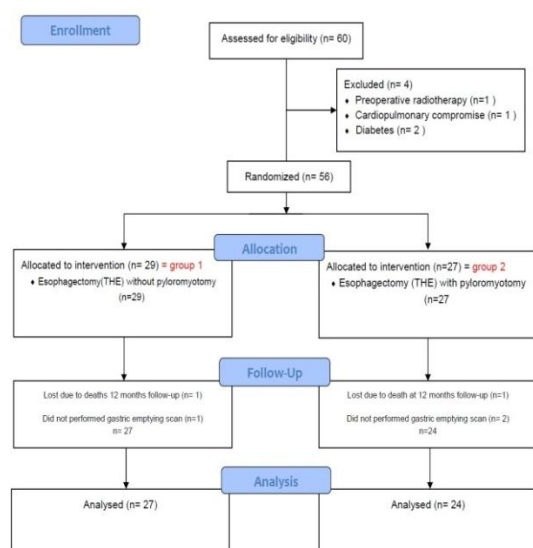


Figure 1. Flow diagram of the study patients

Table 1. Summary of demography and baseline of patients' characteristics

	Group	Transhiatal esophagectomy (THE)	THE with pyloric drainage
Sex	Male	8 (15.6%)	11 (21.5%)
	Female	19 (37.2%)	13 (25.4%)
Mean Age		60.64 ± 3.64	61.17 ± 5.36
Histologic Type	Squamous cell carcinoma	26 (50.9%)	24 (47%)
	Adenocarcinoma	1 (1.9%)	0
Location of Tumor	Upper (0-18 cm)	2 (3.9%)	1 (1.9%)
	Middle (19-29 cm)	15 (29.4%)	14 (27.4%)
	Lower (30-40 cm)	10 (19.6%)	9 (17.6%)
Stage	IA	7 (13.7%)	5 (9.8%)
	IB	3 (5.8%)	3 (5.8%)
	IIA	8 (15.6%)	10 (19.6%)
	IIB	1 (1.9%)	3 (5.8%)
	IIIA	3 (5.8%)	2 (3.9%)
	IIIB	0	3 (5.8%)
	IIIC	2 (3.9%)	1 (1.9%)

located in mid-thoracic portion in 29 patients (56.8%). There was no significant correlation between the age and gender of the patients (p=0.44). Early and late postoperative complications of the surgery in both groups are shown in Table 2. The incidence of regurgitation, reflux and increased gastric emptying in Scintigraphy were not different in both groups (p=0.89).

The overall incidence of gastric pull-up disorder was 12.7% (8/51) and included the patients with symptoms, their sensation of fullness and dilated conduit with air fluid level on chest x-ray. All patients were managed by gastric emptying radioisotope scanning in order to determine their time of gastric emptying.

In group 1, 15(55.55%) patients showed normal gastric emptying and 2 (7.45%) patients had rapid gastric emptying scanning while 10(37%) patients of the same group had delayed gastric emptying radioisotope scanning. In group 2, 13(54.14%) patients had normal gastric emptying and two (8.34%) patients had rapid gastric emptying scanning, while 9(37.5%) patients had delayed gastric emptying radioisotope scanning. However, there was no significant statistical difference in patients with delayed and normal gastric emptying time between the two groups (P=0.97) (Table 3). Pyloric drainage had no influence on gastric emptying time (Figure 2). None of the patients complained of clinical dumping, even the four patients who experienced increased gastric emptying on radioisotope scanning.

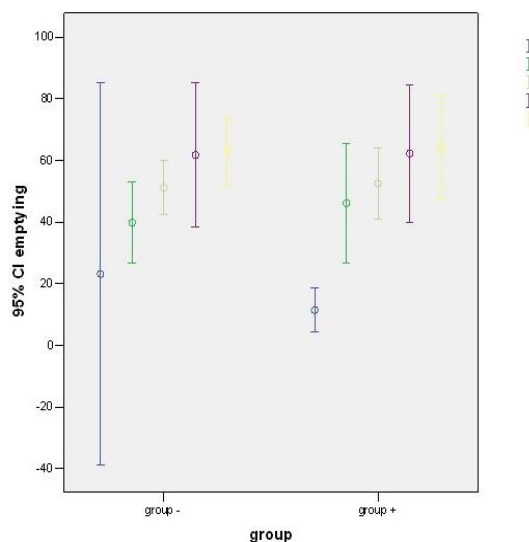
All patients with delayed gastric emptying were medically treated by Metoclopramide, Erythromycin and 40 degree upward positions in their rest time. The patients proved to be satisfied content with this regimen except for one patient who experienced mediastinal recurrence. None of the patients were managed with endoscopic balloon dilation of the pylorus or pyloroplasty.

Table 2. Postoperative complications in two groups

Characteristics	Group 1 % (n=27) N (%)	Group 11 % (n=24+) N (%)	Total patients (n =51) N (%)	P value
Early complications				
Anastomotic leakage	4(14.8)	5(20.8)	9(17.64)	0.72
Chylothorax	0	0		
Hemopneumothorax	10 (37)	13(54.2)	23(45.1)	0.27
Pneumonia	2(7.4)	1(4.2)	3(5.9)	0.46
Wound infection	1(3.7)	2(8.4)	3(5.9)	
Thromboembolism	0	0		
Tracheal rupture	0	0		
Recurrent nerve injury	0	1(4.2)	1(1.96)	
Empyema& Mediastinitis	0	0		
Late complications				
Fullness sensation	7(25.9)	8(33.3)	15(29.4)	0.76
Anastomotic stricture	1(3.7)	2(8.3)	3(5.9)	
Increased gastric emptying	2 (7.4)	2 (8.3)	6 (11.76)	0.89
Regurgitation	11 (40.7)	14 (58.4)	25 (49)	0.16
Symptomatic reflux	10 (37)	15 (62.5)	25 (49)	0.06

Table 3. Comparison of Gastric Emptying Data (n= 51)

	Normal group	Delayed group	P value
Type of stomach			
Whole stomach, N (%)	32 (100)	19(100)	
Gastric drainage			
Pyloromyotomy (+), N (%)	15 (62.5)	9 (37.5)	0.97
Pyloromyotomy (-), N (%)	17 (63)	10 (37)	
Follow up period			
Within 12 months,N (%)	32(100)	19 (100)	

**Figure 2.** Radioisotope gastric emptying in two groups
Group 1= group (-): Esophagectomy without pyloromyotomy
Group 2= group (+): Esophagectomy with pyloromyotomy

No significant difference was found or associated with the median and the length of hospitalization in either group (11 days in group 1 versus 12 days in group 2) ($p=0.41$).

Nevertheless, respiratory distress due to mediastinal recurrence of the tumor was recorded in one (3.7%) patient of group1 during the 12-

months follow-up period. All patients of esophageal carcinoma in advanced stages were treated concomitantly with radiotherapy and chemotherapy.

On the other hand, one patient in each group (3.7% in group 1 and 4.1% in group 2) passed away due to severe arrhythmia and myocardial infarction and aspiration pneumonia which occurred on days 3 and 5 postoperatively.

Discussion

In this randomized clinical trial study, we emphasized on using pyloromyotomy and gastric pull-up conduit during Transhiatal Esophagectomy as opposed to no pyloric drainage; there was no statistically significant difference on the gastric emptying time. Pyloromyotomy did not quicken the gastric emptying process.

Furthermore, this study demonstrates that gastric-emptying disorders occurred in approximately 37.25% patients of esophageal carcinoma after esophagectomy, bilateral vagotomy and gastric pull-up procedures (19.61% in group 2 and 17.64% in group 1).

The gastric conduit is used as a tube for esophageal reconstruction in malignant esophageal diseases. Truncal vagotomy and gastroparesis in

patients who experience esophagectomy and are two major factors that influence delayed gastric emptying (9).

The patients who underwent esophagectomy, with or without pyloric drainage and gastric pull-up, frequently complained of early satiety, reflux, swallowing difficulty, coughing and vomiting.

Controversy still exists about the need for pyloric drainage procedures (pyloroplasty or pyloromyotomy) after esophagectomy and vagotomy (10, 11).

The incidence of clinically significant gastric outlet obstruction was 6.1% in the literature. Bonavina believed that tubularized gastric conduit and pyloric drainage did not reduce delayed gastric emptying (12). Our estimated rate of incidence is 11.7% in both groups and there was a noticeable difference between the occurrence of radioisotope scanning delayed gastric and clinical gastric disability.

Palmes and colleagues' study indicated that not only pyloric drainage does not improve gastric emptying, but it may also favor to bile reflux and esophagitis. Mucosal damage from acid and bile exposure in the esophageal remnant affects nearly 50% of these patients (10, 12).

Gastric-emptying disorders often occur as a transient problem after esophagectomy with gastric conduit. Previous studies have presented conflicting data concerning the benefit of pyloric drainage on gastric-emptying disorders in patients with esophagectomy. Fok and colleague's compared the gastric-emptying time in the early and long-term follow-up period after esophagectomy and gastric conduit pull-up. Radio-labeled liquid meal study indicated only a significantly improved gastric-emptying in the pyloroplasty group during the early postoperative period (13).

Pyloromyotomy and pyloroplasty are associated with less yet serious complications. Pyloromyotomy or pyloroplasty site leakage is the most threatening complication. Other complications of pyloroplasty are pyloric stricture, lengthening gastric conduit (14).

Some other surgeons claimed that routine pyloric drainage with gastric conduit reconstruction can prevent postoperative gastric outlet obstruction related to vagotomy of the stomach and pulmonary aspiration secondary to pulmonary aspirations.

According to the results of Kim, pyloric drainage is considerably more affective on the gastric-emptying time, decreases swallowing difficulty and pulmonary complications and only a few patients might develop gastric-emptying problems.

Kim and Lantoni reported that the patients usually needed postoperative endoscopic balloon

dilation to treat the gastric outlet obstruction (7, 15). All our patients were treated medically and adapted with the new conduit with time; except for one patient who developed a tumor after 12 months and was not treated by medical procedures.

Urshel and colleagues' meta-analysis clarified that pyloric drainage during esophagectomy and gastric reconstruction might reduce the occurrence of early postoperative gastric outlet obstruction. This meta-analysis also revealed that the presence or absence of pyloric drainage has little impact on most relevant outcomes among patients. However, the validity of this meta-analysis was restricted due to the small number of patients, different conduit sizes, routes of reconstruction and study endpoints of the compared controlled randomized trials (8).

In a randomized controlled trials (RCT) study of Godazandeh and colleague on transposed gastric-emptying rate after esophagectomy and cervical esophagogastric anastomosis, there was no statistical difference in gastric-emptying rate and postoperative complications between pyloric drainage and no-pyloric drainage groups. They concluded that gastric drainage procedures were not required in esophageal resection and gastric transposition procedures (16).

Lantoni and colleagues showed that pyloromyotomy did not reduce the incidence of delayed gastric-emptying (6). In another study, pyloroplasty and pyloromyotomy could be effective and safe drainage procedures, but they might increase biliary reflux esophagitis (11)

Medical treatment with prokinetic agents such as Metoclopramide, Bethanecol, Cisapride and Domperidone has proven to be a success in improving delayed gastric-emptying issues. Erythromycin promotes gastric motility by acting on the motilin receptors in the pylorus, antrum and duodenum. It has been applied in order to relieve symptomatic delayed gastric-emptying medical cases (17, 18). In this study, 18 patients with delayed gastric-emptying were treated with medical procedures.

We found that pyloromyotomy could not reduce the incidence of delayed gastric emptying after transhiatal esophagectomy. Urshel et al. also did not find any significant benefits regarding the decline of delayed gastric outlet obstruction following pyloromyotomy. However, they found decreased occurrence of early gastric delayed emptying (8). In a recent systematic review, it has been shown that pyloric drainage procedures after esophagectomy could not reduce anastomotic leaks and pulmonary complications but reduced gastric stasis rates significantly (19). We also found that regurgitation and increased gastric

emptying are not statistically different in study groups.

Limitations of the present study

This study needs to be performed in larger groups of patients. Tubularized stomach conduit was used in our study. Thus, we could not compare the ultimate results with no tubularized stomach conduit. The mean survival rate of the patients could not be precisely determined in this study.

Conclusion

In this randomized clinical trial, using tubularized stomach and pyloromyotomy as a substitute in Transhiatal Esophagectomy did not have significant effects on gastric-emptying in the course of surgical treatment of esophageal cancer.

Conflict of Interest

The authors declare that they do not have any conflicts of interest.

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