

# Balloon Dilatation of the Pylorus After Gastric Pull-up in a Single Centre

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**Abstract:** *Background:* The mainstay of intended curative treatment for esophagus cancer is surgery. Symptoms of gastric outlet obstruction can occur in some patients postoperatively. Some of these patients require alleviating treatment which may include balloon dilatation of the pylorus. The aim of this study was to investigate the use for balloon dilatation of the pylorus following esophagectomy in patients treated for carcinoma of the esophagus with intent to cure. *Methods:* A retrospective study of 120 patients who underwent esophagectomy with gastric pull-up at Aarhus University Hospital, Denmark, between January 2017 and December 2018 and were followed until December 2020. Primary outcome was number of postoperative balloon dilatations of the pylorus. *Results:* A total of 63 patients (53%) went through at least 1 balloon dilatation of the pylorus, 40 (63%) needed more than 1 dilatation. The median time between esophagectomy and first dilatation was two months. There was a strong association between squamous cell carcinoma and postoperative dilatation compared to adenocarcinoma (OR=4.13). An association was also seen between ex-smokers and postoperative dilatation compared to non-smokers (OR=3.95). *Conclusions:* More than fifty percent of the patients needed postoperative balloon dilatation. The need for dilatations was strongest between the second and the ninth postoperative month. A nationwide multicentre study of gastric pull-up patients is needed in the future to develop clinical tools to assess the need for pyloric dilatation.

**Keywords:** Esophagus, Esophageal Cancer, Gastric Pull-up, Endoscopic Treatment, Dilatation

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## 1. Introduction

Approximately 900 patients are diagnosed with cancer in the esophagus and gastroesophageal junction (GEJ) each year in Denmark [1]. The mainstay of intended curative treatment is surgery [2, 3]. In Denmark approximately 30% of the patients are diagnosed in time to receive curative treatment and the number is increasing. In the majority of cases the treatment is a combination of medical oncological treatment and surgery and a small minority are treated with surgery alone [4].

Although esophageal cancer still has a poor prognosis long-term survival has increased, which highlights the importance of postoperative morbidity after esophagectomy

[5].

In Denmark the majority of patients who undergo surgery for carcinoma of the esophagus, have the distal part of the esophagus and the upper part of the stomach is resected with a gastric pull-up ad modum Ivor Lewis [6, 7]. As part of the resection both branches of the vagal nerve are dissected leading to a complete denervation of the distal innervation area of the vagal nerve including the remaining part of the stomach and the pylorus. These vagal fibers are normally a part of a complex regulation of the motility in pylorus [8]. The vagal stimulation induces contractions and pumping action of the stomach and pylorus [9]. This sequence is disturbed by the esophagectomy, and it can cause post-esophagectomy gastric outlet obstruction. So despite possible curative treatment,

esophagectomy can induce a significant negative impact on quality of life [10, 11].

Half of the patients who undergo esophageal resection with gastric pull-up will have dysmotility of the pylorus, including the feeling of early satiety, postprandial pain, dysphagia or regurgitation, risk of recurrent aspiration pneumonia and dumping syndrome [12-14]. Terms such as gastric outlet obstruction and delayed gastric emptying have been used to describe the dysmotility of the pylorus. Several studies have described the underlying pathophysiology of delayed gastric emptying and the following symptoms but the results have been contradictory [9, 15, 16]. The underlying mechanisms behind delayed gastric emptying may even vary between patients; it can be non-synchronized peristalsis in some patients, and dysfunctional relaxation of the pylorus in others or even a combination of both in some, all caused by the vagotomy [9, 17]. Because of delayed gastric emptying the patient is at risk of malnutrition and impaired health-related quality of life [9].

Several procedures are available to treat the motility symptoms following gastric pull-up. Pyloroplasty, pyloromyotomy, intrapyloric botulinum injection, no intervention or endoscopic balloon dilatation is practiced at different centres with no international consensus regarding the preferred treatment. [18-20].

In this study, we aim to assess the need for pyloric balloon dilatation following esophageal resection with gastric pull up for esophageal- or GEJ cancer in a single centre.

## 2. Material and Methods

### 2.1. Methodology

A retrospective cohort study population in a single centre setting was collected at the Department of Surgical Gastroenterology at Aarhus University Hospital in Denmark. One hundred and twenty patients underwent esophagectomy with gastric pull-up ad modum Ivor Lewis. The majority underwent a hybrid approach performing laparoscopy and thoracotomy with an intrathoracic anastomosis (Table 1). The standard prophylactic treatment to prevent gastric outlet obstruction following gastric pull-up at our institution is peroperative endoscopic dilatation of the pylorus with a 20 mm balloon for 3 minutes. No further medical or surgical adjuncts were standardly used to facilitate gastric emptying. Surgery was performed in the period between January 2017 and December 2018 and the patients were followed until December 2020.

The level of anastomosis was defined to be above ( $\geq 2$  cm), on or under ( $\leq 2$  cm) the level of azygos.

One unit of alcohol is defined to be 12g of alcohol according to the Danish standard [21].

Comorbidity status of the patients at the baseline was determined with the use of Charlson Comorbidity Index (CCI) [22]. The CCI was subdivided into No (0-1 point), Low (2-3 points) or Severe ( $>3$  points) comorbidity.

If patients postoperatively complained of early satiety,

dysphagia, regurgitation, postprandial pain etc these patients were screened for delayed gastric emptying and evaluated with gastroscopy. No further diagnostic modality was performed to evaluate gastric emptying. If the clinical evaluation related the symptoms to pyloric dysfunction the patients were offered balloon dilatation at the surgeon's preference.

The primary outcome was the use for postoperative balloon dilatation of the pylorus.

### 2.2. Data Source and Ethics

The research was conducted according to the World Medical Association Declaration of Helsinki. Patient data was retrieved from the electronic patient journal from Central Denmark Region (MidtEPJ) and all data was entered into the online database, REDcap [23], and analyzed in anonymous form. The ethical approval to conduct the study was obtained locally.

### 2.3. Study Population

Inclusion criteria of the study population were; patients who underwent esophagectomy with gastric pull-up within the year of 2017 and 2018 at Aarhus University Hospital, only patients with a malignant tumour (adenocarcinoma or squamous cell carcinoma) were included and all patients were treated with intent to cure. Patients with missing data of weight and symptoms at the time of postoperative balloon dilatation and patients with stage IV cancer were excluded (figure 1). Baseline characteristics and demographics are given in table 1.

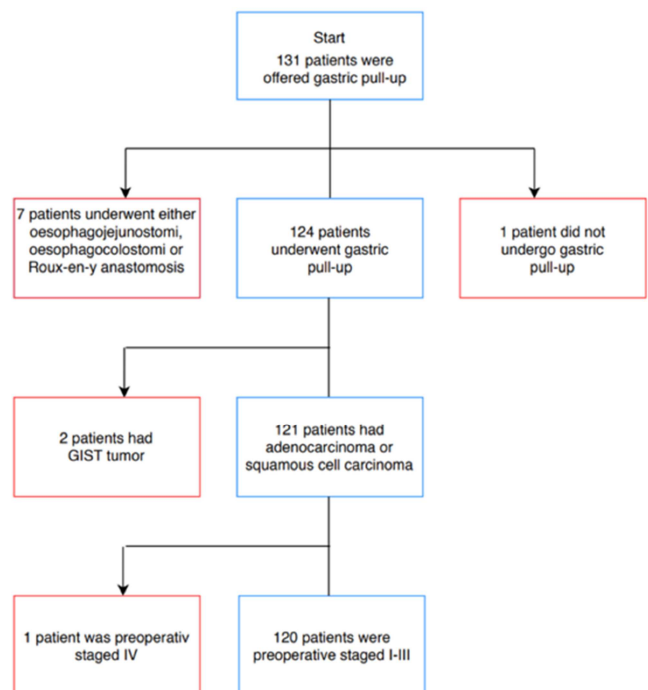


Figure 1. Flowchart of the patients who underwent gastric pull-up.

### 2.4. Outcomes

Data were collected retrospectively from baseline, day of surgery, until December 2020. Every balloon dilatation of the

pylorus performed between baseline and December 2020 were registered. The included patients were divided into two groups based on postoperative balloon dilatation of the pylorus. The group 'dilatation' (D) had undergone one or more postoperative dilatations of the pylorus aiming at 20 mm; the other group 'no dilatation' (ND) did not undergo postoperative dilatation.

The weight of the patient was registered at every postoperative pyloric balloon dilatation.

### 2.5. Statistical Analysis

To assess the difference in distribution of categorical variables in patient demographics, Pearson's chi-square test was performed. To evaluate the association between histology of the cancer leading to gastric pull up and the need for postoperative balloon dilation a multivariable logistic regression analysis was performed adjusting for gender, age, Body mass index (BMI), smoking status, drinking, performance status (PS), CCI and anastomosis level, providing odds ratio (OR) with 95% confidence intervals. P-values were calculated using chi<sup>2</sup>-test. The statistical

significance was set to  $p < 0.05$ . Chi<sup>2</sup>-test was used for nominal variables after checking for parametric distribution. All statistical tests were performed using the StataCorp. 2013. *Stata Statistical Software: Release 13*. College Station, TX: StataCorp LP, Stata version 13.

## 3. Results

### 3.1. Demographic Data

The median follow-up period for the 120 included patients was 27 months during which 60 patients died (group D 30 patients, group ND 30 patients). At baseline, the groups were comparable with no statistically significant difference regarding gender, comorbidity, performance status et cetera, of patients who had postoperative balloon dilatation and the group who did not (table 1). Twenty-one percent of the SCC patients had >14 (females)/21 (male) units of alcohol per week', compared to 7% of the adenocarcinoma patients ( $p=0.028$ ).

**Table 1.** Demographic data of 120 study subjects n (%).

	No dilatation	Dilatation	Total	P-value
Gender				
Female	11 (19.3)	11 (17.5)	22	NS
Male	46 (80.7)	52 (82.5)	98	
Median age	68 years	69 years		
BMI				
<18	3 (5)	3 (5)	6	NS
18-<25	26 (43.33)	18 (30)	44	
25-<30	23 (38.33)	25 (41.7)	48	
>30	8 (13.33)	14 (23.3)	22	
Alcohol				
<14/21	51 (89.5)	57 (90.5)	108	NS
>14/21	6 (10.5)	6 (9.5)	12	
Smoking				
Non-smokers	14 (24.5)	7 (11.1)	21	NS
Smokers	18 (31.6)	19 (30.2)	37	
Ex-smokers	25 (43.9)	37 (58.7)	62	
PS score				
PS0	51 (89.5)	55 (87.3)	106	NS
PS1	5 (8.8)	6 (9.5)	11	
PS2	1 (1.7)	2 (3.2)	3	
CCI				
No comorbidity	6 (10.5)	4 (6.3)	10	NS
Low comorbidity	31 (54.4)	35 (55.6)	66	
Severe comorbidity	20 (35.1)	24 (38.1)	44	
Histology				
Adenocarcinoma	46 (80.7)	45 (71.4)	91	NS
SCC	11 (19.3)	18 (28.6)	29	
Anastomosis level in relation to azygos				
Under	2 (3.5)	5 (7.9)	7	NS
On	26 (45.6)	30 (47.6)	56	
Over	29 (50.9)	26 (44.5)	55	

\* SCC: Squamous cell carcinoma; BMI: Body mass index; CCI: Charlson comorbidity score PS: Performance score; 14/21: High-risk limits of alcohol a week (14 units for women and 21 for men); NS: Non significant

### 3.2. Dilatation

The median time between the esophagectomy and the first balloon dilatation was 65 days (range 3-728 days). The

median time between the operation and the last balloon dilatation was 260 days (range 3-1354 days) and the median time between the first dilatation and the last dilatation 6.5

months. Of the 120 patients who underwent esophagectomy with gastric pull-up 63 patients (53%) had postoperative balloon dilatation of the pylorus. A total number of 162

dilatations were performed on 63 patients (figure 2). Twenty-three patients (37%) had one postoperative dilatation, however 40 of 63 (63%) had two or more.

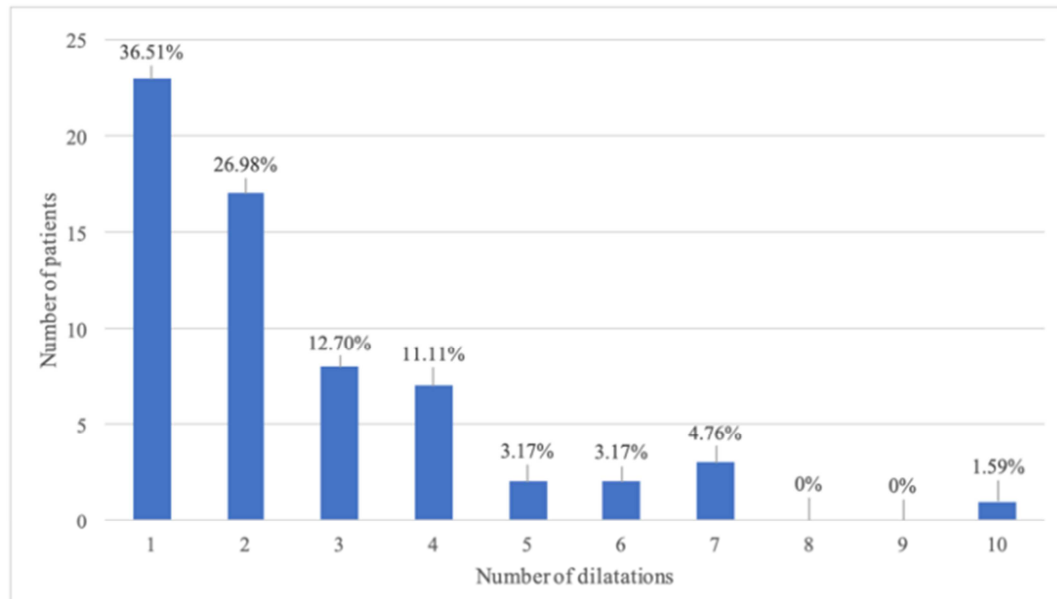


Figure 2. Overview of postoperative balloon dilatations.  $n=63$ , dilatations in total=162.

### 3.3. Sub-groups Need of Dilatation

In the multivariable logistic regression analysis (table 2), the OR for postoperative dilatation of the pylorus was significantly elevated for SCC (OR=4.13, CI 1.19-14.33,  $p=0.025$ ) compared to adenocarcinoma. The crude OR for this association was 1.67. Ex-smokers had a significantly increased risk of dilatation compared to the non-smokers with

an OR of 3.95 (CI 1.24-12.56,  $p=0.020$ ). The OR for males compared to females was 1.74 (CI 0.53-5.74,  $p=0.365$ ). Patients with BMI of 30 or more were more likely to have a balloon dilation compared to patients with BMI of 18 or less, OR of 2.84 (CI 0.29-27.99,  $p=0.371$ ). PS score of 2 gave an OR 2.18 (CI 0.10-47.71,  $p=0.620$ ) for postoperative pyloric dilatation compared to a PS score of 0.

Table 2. Odds ratio for dilatation among the study subjects adjusted for histology, gender, BMI, CCI, smoking, PS score, alcohol and anastomosis level. Multivariable logistic regression analysis.

	Odds Ratio	P-value	95% conf. interval
Gender			
Female	1		
Male	1.74	NS	0.49-4.96
Age			
<50	1		
50-59	1.69		0.08-33.96
60-69	0.91	NS	0.02-34.30
70-79	1.23		0.03-50.52
$\geq 80$	1.24		0.02-65.44
BMI			
<18	1		
18-<25	1.22	NS	0.15-9.94
25-<30	1.95		0.22-17.09
$\geq 30$	2.84		0.29-27.99
Alcohol			
<14/21	1		
$\geq 14/21$	0.55	NS	0.13-2.28
Smoking			
Non-smokers	1		
Smokers	2.34	NS	0.68-8.36
Ex-smokers	3.95	0.02*	1.24-12.56
PS score			
PS0	1		
PS1	1.05	NS	0.25-4.49
PS2	2.18		0.10-47.71
CCI			

	Odds Ratio	P-value	95% conf. interval
No comorbidity	1		
Low comorbidity	1.49		0.12-18.44
Severe comorbidity	1.43	NS	0.10-21.13
Histology			
Adenocarcinoma	1		
SCC	4.13	0.025*	1.19-14.33
Anastomosis level in relation to azygos			
Under	1		
On	0.45	NS	0.06-3.07
Over	0.24		0.03-1.72

\* SCC: Squamous cell carcinoma; BMI: Body mass index; CCI: Charlson comorbidity score PS: Performance score; 14/21: High-risk limits of alcohol a week (14 units for women and 21 for men); NS: Non significant

Twenty-three of 29 SCC patients (79%) had their anastomosis above the level of azygos compared to 34 out of 91 adenocarcinoma patients (37%). The OR for postoperative dilatation was 0.24 (CI 0.03-1.72,  $p=0.155$ ) for the patients with the anastomosis above the level of azygos, as compared to 0.45 (CI 0.06-3.07,  $p=0.411$ ) for anastomosis on the level of azygos.

pTNM stage was investigated for each patient. The majority of the patients (66 out of 120) had T3, 34 in group ND and 32

in group D and it did not show any significant differences in regard to postoperative dilatations ( $p=0.645$ ). Most patients had N0-disease (63 out of 120), 27 in group ND and 36 in group D ( $p=0.485$ ). When looking at the resection margin, only 5 patients had R1, 2 in group ND and 3 in group D ( $p=0.732$ ).

We found no significant relation between the number of dilatations and loss of weight ( $p=0.685$ ), for further details see table 3.

**Table 3.** Number of dilatations during the follow-up time compared with the weight loss between baseline and the first pyloric dilatation n (%).

Number of dilatations	$\leq 0$ kg	0-5 kg	5-10 kg	10-15 kg	$\geq 15$ kg
1	2 (40)	6 (40)	10 (38.5)	2 (33.3)	3 (27.3)
2-3	2 (40)	5 (33.3)	9 (34.6)	3 (50)	6 (54.5)
4-5	0 (0)	4 (26.7)	3 (11.5)	0 (0)	2 (18.2)
>5	1 (20)	0 (0)	4 (15.4)	1 (16.7)	0 (0)
Total	5	15	26	6	11

## 4. Discussion

In the present study, 53% of the patients complained of symptoms interpreted as delayed gastric emptying and were treated with postoperative pyloric dilatation, 40 patients (63%) had more than one dilatation. Fifty-six (93%) of the 63 patients lost weight (range >0-30 kg) between baseline and first balloon dilatation. The dilatations were in average performed between the second and the ninth postoperative month.

Lee et al. demonstrated delayed gastric emptying in 46% of the patients after esophagectomy [24]. Post-esophagectomy gastric outlet obstruction is caused by vagotomy and the following denervation of the stomach and the pylorus [17]. Beside the denervation, other factors may affect the symptoms of delayed gastric emptying such as the level of anastomosis, anastomosis stricture, torsion of the conduit, decreased stomach volume, onset of per oral diet intake after surgery, BMI, smoking, the histology type of esophageal cancer, etc. [9, 15]. However, controversy still exists on how to minimise post-esophagectomy gastric outlet obstruction. Presently there are at least five modalities to treat (or not treat) and prevent symptoms of delayed gastric emptying: pyloroplasty, pyloromyotomy, intrapyloric botulinum injection, pyloric balloon dilatation or no intervention.

A recent systematic review evaluated different

intraoperative pyloric management strategies, except from balloon dilatation. The review compared 25 publications including 3172 patients, and it did not find any significant difference of delayed gastric emptying when comparing the various modalities [25]. Several studies indicate that endoscopic pyloric balloon dilatation can be effective and safe in managing delayed gastric emptying postoperatively [15, 26, 27]. In contrast to balloon dilatation, pyloroplasty/pyloromyotomy is not without major complications (0,6%) and mortality (0,3%) [28, 29]. Pyloroplasty has been associated with the occurrence of late pyloric stricture [30]. Intrapyloric botulinum injection includes a simpler technique and less pyloric damage than pyloroplasty. The procedure can also decrease the operative time, but patients experience more delayed gastric emptying symptoms compared to pyloroplasty or pyloromyotomy [15].

In this study, standard prophylactic pyloric balloon dilatation was performed in all patients at the time of esophagectomy, however controversy still exists whether to omit the prophylactic pyloric intervention at the time of esophagectomy or not. Antonoff et al. indicates that omission of pyloric intervention including pyloric dilation will result in more complications like frequent aspiration events and increased need of pyloric dilation postoperatively [29]. However, Li et al. showed that omitting the operative drainage procedure will not increase delayed gastric emptying

frequency [26]. A more recent study of Zhang et al. agrees with Li et al. [27]. The study shows that omitting the operative drainage procedure does not increase the incidence of delayed gastric emptying significantly.

In our study fifty-three percent had postoperative dilatation. Other studies have shown similar results. Collard et al. showed that early fullness and dysphagia occurred in up to 50% of the patients [31]. A more recent study, Lee et al. showed that solid foods, immediately after esophagectomy, were delayed in about 50%, but improved over time [24]. On the other hand, Maus et al. and Lanuti et al. demonstrated the need for postoperative treatment to be in the range from 10- 20% [28, 32]. It may be due to the fact that Lanuti et al. only included patients with both clinical and radiographic symptoms of delayed gastric emptying. Furthermore, of the 63 patients in our study who had postoperative pyloric intervention, 40 patients (63%) needed further dilatations. In contrast to our findings Zhang et al. points out that only 10-35% require a second or a third procedure. However, a study of Maus et al. showed that the use of a 20-mm balloon gave a total redilatation rate of 52.9% which is similar to the redilatation rate in the present study [28]. These different redilatation rates may be due to differences in the indication for balloon dilatation.

We found the median time between esophagectomy and first pyloric balloon dilatation to be 63 days (range 3-728 days) and compared to this, Maus et al. had a median time of 19.5 days (range 6-181 days). No prophylactic pyloric balloon dilatation was performed at the time of esophagectomy in the study of Maus et al. This suggests that balloon dilatation at the time of surgery can postpone the need of postoperative dilatation, but it does not significantly affect the redilatation rate of 52.9% compared to 60%. Because of a high rate of redilatation using the 20-mm balloon recent studies have compared this treatment with 30-mm balloon dilatation and found that the need for redilatation decreased from 50% to 20%, respectively [28, 33].

We found a significant correlation between squamous cell carcinoma and postoperative balloon dilatation. Several studies have investigated the histology type of cancer at baseline; however, no study has demonstrated significant correlation. Squamous cell carcinoma occurs most often in the upper and middle third of the esophagus [34]. The typical localization of the SCC in the esophagus may explain why the majority of SCC patients of this study had an anastomosis above the level of azygos.

Maybe a more orally located anastomosis could explain the increased number of patients with the discomfort interpreted as gastric outlet obstruction and treated with dilatation in the SSC-group of patients.

We acknowledge that this study is subject to several limitations. The difficulty to objectivize symptoms and the fact that we are not able to distinguish properly between gastric retention and dysphagia. The recorded symptoms in the patient journals can be the surgeon's subjective interpretation or a misinterpretation of the patients' symptoms. A validated questionnaire in a prospective setting regarding

retention and dysphagia following esophagectomy would have helped to reduce this observer bias. Additionally, we acknowledge the difficulty to objectivize the indication for balloon dilatation. There is no clear threshold for when to offer balloon dilatation in our centre.

This study is strengthened by the fact that all consecutive patients in this single centre who underwent gastric pull up within the period of January 2017 and December 2018 were included. The department performed all the balloon dilatations as well, except from two dilatations.

With this study we hope to revive the debate on whether to treat or not treat the pylorus prophylactically preoperatively during gastric pull-up for malignant tumours of the esophagus and highlight the clinical challenges driving the differences in postoperative interventions in published studies. The present study underlines the need for reliable and clinical relevant objective measurements documenting the presence of gastric outlet obstruction.

Due to the findings of this study and the fact there is no national consensus on the intraoperative treatment of pylorus, we are presently preparing a similar nationwide multicentre study with participation of all of the four centralized hospitals treating gastric and esophageal cancer in Denmark.

## 5. Conclusion

In conclusion, fifty-three percent of the patients treated with peroperative balloon dilatation of the pylorus following esophagectomy with gastric pull up needed further postoperative balloon dilatation. More than sixty percent of these patients received more than one dilatation. Dilatations were predominantly between the second and the ninth postoperative month and diminished over time. This study in comparison to previous studies highlights the difficulty in clinical decision making and need for clinical grading tools when deciding for further postoperative intervention in patients suffering from gastric outlet obstruction following an esophagectomy.

## Declaration of Conflicting Interests

The authors declare that there is no conflict of interests.

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