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ORIGINAL ARTICLE

Comparison of greater curvature and lesser curvature circular-stapled esophagogastrostomy after esophagectomy in patients with esophageal cancer: a prospective randomized controlled trial

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Abstract

Purpose Using a circular stapler to create an anastomosis for esophagogastrostomy after esophagectomy is well accepted; however, it remains uncertain if the greater curvature (GC) or lesser curvature (LC) of the gastric conduit is better for the anastomosis. We conducted this prospective study to compare the integrity of esophagogastrostomy between the esophagus and the GC or LC side of the gastric conduit.

Methods The subjects of this study were 70 patients who underwent esophagectomy and were randomized to a "GC" group and an "LC" group ($n = 35$ each). The primary and secondary end points were anastomotic leakage (AL) and anastomotic stricture (AS), respectively.

Results The overall AL rate was 22.1%, without a significant difference between the groups. Stump leakage developed in eight of nine patients in the GC group, whereas leakage developed at the esophagogastric anastomosis in five of six patients in the LC group. The rate of stump leakage was significantly higher than that of esophagogastric AL in the GC group. The overall AS rate was 4.4%, with a significant difference between the groups (0% in the GC group vs. 9.1% in the LC group).

Conclusions AL rates were comparable in the two groups, but the sites of leakage were significantly different.

Keywords Esophagogastrostomy · Esophagectomy · Circular stapler · Anastomotic leakage

Introduction

Despite recent advances in surgical devices and techniques, anastomotic leakage (AL) of the esophagogastrostomy after subtotal esophagectomy remains a major concern. Although anastomotic techniques for esophagogastrostomy, such as suturing (hand-sewn or mechanical), stapling (circular or linear), and types of anastomosis (end-to-end, side-to-side, or end-to-side), have been investigated extensively, there is no clear consensus on the best technique. Furthermore, various risk factors and outcomes associated with AL following esophagectomy have been identified [1]. A gastric conduit is most commonly used as an esophageal substitute after subtotal esophagectomy in patients with esophageal cancer and mechanical anastomosis using a circular stapler is generally accepted as a simple and convenient method that requires a short operation time. Generally, when esophagogastrostomy is performed using a circular stapler, an end-to-side anastomosis between the remnant esophagus and greater curvature (GC) of the gastric conduit is created, based on the idea that the blood flow of the GC is better than that of the lesser curvature (LC). However, firing the GC side of the gastric conduit with good blood flow may reduce the blood flow of the LC staple line and stump of the gastric conduit significantly. To date, no randomized controlled trial (RCT) has compared and evaluated the anastomotic

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site of the gastric conduit using a circular stapler for cervical esophagogastrostomy. Thus, it is unclear which side of the gastric conduit, the GC or LC, is better for circular anastomosis. We performed an RCT to identify whether the rates of AL from cervical esophagogastrostomy differed between the GC and LC side of the gastric conduit.

Materials and methods

Eligibility criteria

The eligibility criteria were as follows:

(1) The main lesion of the tumor was located in the thoracic esophagus.
(2) There was clinically confirmed T1–T3, any N, M0, and/or M1 LYM metastases (confined to the supraclavicular lymph nodes) based on the 7th UICC-TNM classification [2] as evaluated by esophagoscopy, esophagogram, computed tomography (CT), surface ultrasound, endoscopic ultrasonography, bronchoscopy, and 18F-fluorodeoxyglucose positron-emission tomography/CT.
(3) The patient was 20–80 years of age.
(4) Eastern Cooperative Oncology Group performance status of 0 or 1 was confirmed.
(5) The patient underwent radical esophagectomy with reconstruction using a gastric conduit passed through the posterior mediastinal, retrosternal, or subcutaneous route.
(6) Cervical anastomosis was performed.
(7) Two- or three-field lymph node dissection was carried out.
(8) There was adequate organ function.
(9) Written informed consent was provided.

Patients with severe comorbidies such as interstitial pneumonia, uncontrolled diabetes mellitus, ischemic heart disease, cardiac failure, liver cirrhosis, and chronic renal failure requiring hemodialysis were excluded from the analysis. This study protocol was approved by the Institutional Committee of Kagoshima University Hospital (approval no. 23–173).

Randomization

After confirming the eligibility criteria, patients were randomized by the Department of Epidemiology and Preventive Medicine, Kagoshima University, to either the GC or LC group.

Surgical procedure

Esophagectomy and regional lymphadenectomy was performed via right thoracotomy or thoracoscopic right thoracotomy with the patient in the left lateral decubitus position. For patients with severe pulmonary complications, who were unable to undergo thoracotomy, mediastinoscope-assisted transhiatal esophagectomy was performed in the supine position. Abdominal lymphadenectomy was performed with gastric conduit formation via either open laparotomy or a hand-assisted laparoscopic technique. A 3.5-cm wide GC gastric conduit was fashioned using linear staplers. The right gastric artery was ligated at the second or third branch. The right gastroepiploic artery and branches of the left gastroepiploic arteries were preserved and provided the vascular supply to the gastric conduit through an arcade of peripheral vessels. The gastric conduit was pulled up to the neck through the posterior mediastinal, retrosternal, or subcutaneous route, and an esophagogastrostomy was performed using a PROXIMATE® curved intraluminal stapler with a 25-mm (Ethicon Endo-Surgery, Cincinnati, OH, USA) end-to-side anastomosis. A circular stapler was inserted into the gastrostomy at the tip of the gastric conduit, the anvil head of the stapler was inserted into the remnant esophagus, and anastomosis was created at either the GC (Fig. 1a) or LC (Fig. 1b) side of the gastric conduit wall, away from the edge of the gastric conduit. After firing the stapler, the gastric conduit opening was closed using a linear stapler, 4 cm from the anastomosis, and the stapled line was inverted with sutures to prevent its adhesion to the surrounding tissue. Pyloromyotomy was done to allow gastric drainage, using the finger fracture method. Finally, gastrostomy or duodenostomy was performed for parenteral nutrition.

Postoperative management

Postoperative management was the same for both groups. At the completion of surgery, patients were transferred to the intensive care unit (ICU) for systemic monitoring. They were weaned from mechanical ventilation in the ICU and extubated within 12−16 h. Patients were transferred from the ICU to the ward on postoperative day (POD) 2, and 24-h continuous enteral feeding of an elemental diet was initiated on the morning of POD1. The nasogastric and cervical drainage tubes were removed on POD 5–7. Oral intake was initiated on POD8 without any examinations to detect AL. Patients who recovered well were discharged on about POD14. Thereafter, patients were

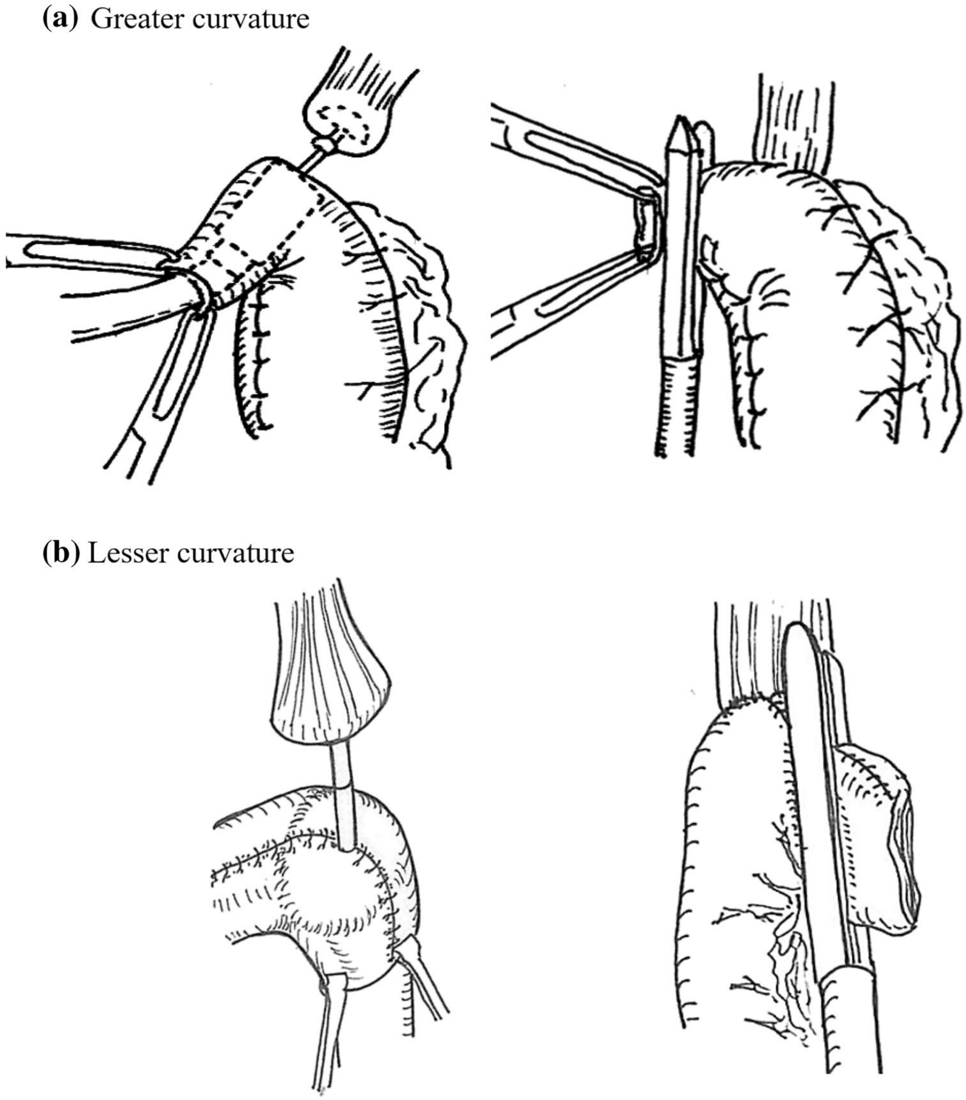

Fig. 1 End-to-side esophago-gastrostomy using a circular stapler. **a** A circular stapler was inserted into the gastrostomy at the tip of the gastric conduit, the anvil head of the stapler was inserted into the remnant esophagus, and anastomosis was created using the greater curvature of the gastric conduit wall. After firing the stapler, the end of the gastric conduit was closed by stapling 4 cm from the anastomosis with a linear stapler. **b** A circular stapler was inserted into the gastrostomy at the tip of the gastric conduit, the anvil head of the stapler was inserted into the remnant esophagus, and anastomosis was created using the lesser curvature of the gastric conduit wall. After firing the stapler, the end of the gastric conduit was closed by stapling 4 cm from the anastomosis with a linear stapler

examined every 3 months during the first year after the operation.

Outcome

The primary end point was AL, and the secondary end point was anastomotic stricture (AS). All postoperative complications were defined as Clavien–Dindo classification Grade I or higher [3]. AL was defined as redness and emphysema around the cervical wound and spillage of saliva through the cervical wound. AL was confirmed using endoscopy, esophagogram, or CT. AL patients were examined to identify the presence of either gastric conduit stump leakage or circular stapler AL. If there was any dysphagia, endoscopy was performed, and benign AS was diagnosed if a flexible endoscope with a 10-mm diameter could not be passed. Perioperative mortality was defined as death within 30 days of surgery.

Statistical analysis

Continuous variables are expressed as medians. The Chi-squared test for categorical data and Wilcoxon test for continuous data were used to compare the proportions between the two groups. A p value < 0.05 was considered significant. All statistical analyses were performed using JMP10 (SAS Institute, Cary, NC, USA).

Results

Patient characteristics

Between January, 2012 and September, 2015, 70 patients were enrolled and randomly assigned to either the GC group ($n = 35$) or the LC group ($n = 35$) according to the site of anastomosis. Figure 2 shows the allocation of patients.

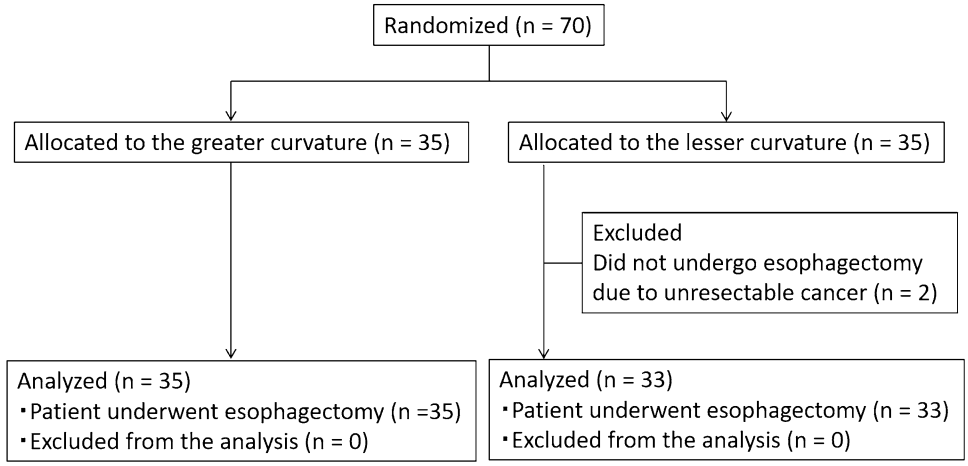

Fig. 2 Consolidated standards of reporting trials flow diagram demonstrating the progress of all participants through the study

Table 1 summarizes the clinicopathological characteristics of the patients at diagnosis. The baseline patient characteristics were well balanced in the two treatment groups. Patients whose cancer was diagnosed as above stage II received neoadjuvant chemotherapy (NAC) with a combination of cisplatin and 5-fluorouracil [4] or a combination of docetaxel, cisplatin, and 5-fluorouracil [5]. Patients presenting with either a large tumor or multiple lymph node metastases underwent neoadjuvant chemoradiotherapy (NACRT) of 36–42 Gy [6, 7]. The clinical target volume of NACRT included the primary tumor, metastatic lymph nodes, and prophylactic areas, in addition to the bilateral supraclavicular, mediastinal, and perigastric lymph nodes. Two LC group patients did not undergo esophagectomy as the intraoperative findings revealed the disease to be unresectable. Table 2 summarizes the surgical procedures in the two groups. No significant differences were observed in the surgical approach, route of reconstruction, total operative time, or intraoperative blood loss between the two groups. Reconstruction was performed via a subcutaneous route

Table 1 Clinicopathological characteristics of the patients at diagnosis

	GC group (*n* = 35)	LC group (*n* = 35)	*p* value
Age, years, median (range)	65 (46–80)	65 (51–75)	0.620
Sex			0.642
Male	33 (94%)	32 (91%)	
Female	2 (6%)	3 (9%)	
Histological type			0.422
Squamous cell carcinoma	33 (94%)	33 (94%)	
Adenocarcinoma	1 (3%)	2 (6%)	
Malignant melanoma	1 (3%)	0 (0%)	
Tumor location			0.893
Upper thoracic	3 (9%)	2 (6%)	
Middle thoracic	20 (57%)	21 (60%)	
Lower thoracic	12 (34%)	12 (3%)	
Stage [a]			
I	9 (26%)	8 (23%)	0.498
II	4 (11%)	4 (11%)	
III	16 (46%)	18 (51%)	
IV	6 (17%)	5 (14%)	
Neoadjuvant therapy			
None	12 (34%)	14 (29%)	0.862
Chemotherapy	8 (23%)	8 (23%)	
Chemoradiotherapy	15 (43%)	13 (37%)	

GC greater curvature, *LC* lesser curvature, stage status

[a] TNM Classification of the International Union Against Cancer (UICC), 7th edition

Table 2 Surgical procedures performed in the greater curvature (GC) and lesser curvature (LC) groups

	GC group ($n=35$)	LC group ($n=33$)	p value
Approach			0.900
Thoracotomy	23 (66%)	21 (64%)	
Thoracoscopic	8 (23%)	7 (21%)	
Mediastinoscopic	4 (11%)	5 (15%)	
Route of reconstruction			
Subcutaneous	19 (54%)	18 (55%)	0.994
Retrosternal	4 (11%)	4(12%)	
Posterior mediastinal	12 (34%)	11(33%)	
Total operative time, median (range), min	582 (373–848)	593 (378–711)	0.907
Blood loss, median (range), ml	320 (95–1960)	325 (65–925)	0.731

GC greater curvature, *LC* lesser curvature

Table 3 Postoperative complications in the greater curvature (GC) and lesser curvature (LC) groups

	GC group ($n=35$)	LC group ($n=33$)	p value
Overall	18 (51%)	13 (39%)	0.319
AL	9 (26%)	6 (18%)	0.453
AS	0 (0%)	3 (9%)	0.034
Recurrent laryngeal nerve palsy	3 (9%)	5 (15%)	0.398
Pneumonia	4 (11%)	1 (3%)	0.170
Pyothorax	1 (3%)	2 (3%)	0.966
Chylothorax	1 (3%)	0 (0%)	0.247
Surgical site infection	13 (37%)	9 (27%)	0.384
Hospital mortality	1 (3%)	0 (0%)	0.247

GC greater curvature, *LC* lesser curvature, *AL* anastomotic leakage, *AS* anastomotic stricture

in > 50% of patients in both groups because this route is normally considered after NACRT. Table 3 shows the postoperative complications in the two groups. The overall AL rate was 22.1% (15/68), with no significant difference between the two groups: 25.7% (9/35) in the GC group vs. 18.2% (6/33) in the LC group. In the GC group, eight of the nine patients (88.9%) had leakage at the stump of the gastric conduit, whereas in the LC group, five of the six patients (83.3%) had leakage at the esophagogastric circular stapler anastomosis. Furthermore, in the GC group, the rate of gastric conduit stump leakage was significantly higher than that of esophagogastric AL, whereas in the LC group, the rate of esophagogastric circular stapler AL was significantly higher than that of gastric conduit stump leakage. Although there was no significant difference in combinations associated with AL between the reconstruction routes and the LC or GC groups, AL rates tended to be higher with the subcutaneous route in the GC group and with the posterior mediastinal route in the LC group. There was no AL with the retrosternal route in the GC group. We compared the time to healing and postoperative hospital stay between the GC and LC groups in patients with AL, but found no significant difference between the groups (Table 4). The

Table 4 Anastomotic leakage sites in the greater curvature (GC) and lesser curvature (LC) groups

	AL		
	GC group ($n=9$)	LC group ($n=6$)	P value
AL site			0.004
Anastomosis	1 (11%)	5 (83%)	
Stump of gastric conduit	8 (89%)	1 (17%)	
Route of reconstruction			0.087
Subcutaneous	6 (67%)	1(17%)	
Retrosternal	0 (0)	1(17%)	
Posterior mediastinal	3 (33%)	4(67%)	
Duration of anastomotic leakage, median days (range)	38 (9–352)	17.5 (9–78)	0.679
Postoperative hospital stay, median days (range)	52 (18–361)	40 (31–92)	1.000

AL anastomotic leakage, *GC* greater curvature, *LC* lesser curvature overall AS rate was 4.4% (3/68), with a significant difference between the groups: 0% in the GC group vs. 9.1% (3/33) in the LC group. There were no significant differences in the incidences of recurrent laryngeal nerve palsy, pneumonia, pyothorax, chylothorax, and surgical site infection between the groups. The presence or absence of neoadjuvant therapy, type of neoadjuvant therapy, surgical approach, and route of reconstruction were not found to contribute to AL in any of the patients (Table 5).

Discussion

This RCT compared the anastomotic site of the gastric conduit between the GC and LC in cervical esophagogastrostomy after subtotal esophagectomy. To our knowledge, this is the first prospective study to compare whether the anastomotic site of the gastric conduit affects esophagogastrostomy. The overall AL rate was 22.1% less than the 26.1% observed in the CROSS trial [8] and there was no significant difference in the incidence of AL between the two groups. However, the rate of gastric conduit stump leakage was significantly higher than that of esophagogastric circular stapler AL in the GC group, whereas the rate of esophagogastric circular stapler AL was significantly higher than that of gastric conduit stump leakage in the LC group. None of the 35 GC group patients had AS, but 9 had AL, which may explain why the increased leakage of the gastric conduit stump in the GC group was not accompanied by stricture formation of the circular stapler anastomosis, as is often the reported after AL. The gastric conduit is twisted for half a turn when esophagogastrostomy is performed at the LC side, whereas tension-free esophagogastrostomy is performed at the GC side anastomosis. The wound healing processes of AL can also cause AS; however, AL of the gastric conduit stump is far from the circular stapler anastomotic site. Hence, AL of the gastric conduit stump is unlikely to cause AS.

Table 5 Neoadjuvant therapy and operative data in patients with vs. those without anastomotic leakage

	No leakage ($n=53$)	Leakage ($n=15$)	p value
Neoadjuvant therapy			0.200
None	19 (36%)	7 (47%)	
Chemotherapy	14 (26%)	1 (7%)	
Chemoradiotherapy	20 (38%)	7 (47%)	
Approach			0.631
Thoracotomy	34 (64%)	10 (67%)	
Thoracoscopic	11 (21%)	4 (27%)	
Mediastinoscopic	8 (15%)	1 (7%)	
Route of reconstruction			0.456
Subcutaneous	30 (57%)	7 (47%)	
Retrosternal	7 (13%)	1 (7%)	
Posterior mediastinal	16 (30%)	7 (47%)	

AL anastomotic leakage

Although the commonly generated narrow gastric conduit provides a long substitute, it also destroys the intramural vascular network, resulting in impaired blood circulation at the tip of the gastric conduit [9, 10]. The blood supply to the cranial 20% of the GC gastric conduit is through a microscopic network of capillaries and arterioles [11]. When a narrow gastric conduit is fashioned and fired using a circular stapler on the GC side, gastric conduit stump leakage occurs despite visualization of a good vascular supply of the conduit; thus, we consider that width is an important factor to reduce gastric conduit stump leakage. End-to-end esophagogastrostomy or surgical techniques, such as supercharge/superdrainage of the anastomosis of arteries and veins of the gastric conduit, would improve the local blood flow to a narrow gastric conduit [12, 13]. In a previous RCT, the rate of AL was decreased to 22% for end-to-end esophagogastrostomy and hand-sewn anastomosis vs. 41% for end-to-side esophagogastrostomy with hand-sewn anastomosis [14], in which stump leakage after end-to-side anastomosis was inferred to be the reason. End-to-end anastomosis with the triangulating stapling method might be better than end-to-side anastomosis with the circular stapling method in terms of the blood supply [15]. However, while firing at the LC side, the vascular supply to the gastric conduit via the GC should be preserved. In this situation, the rate of stump leakage in the LC group was significantly lower than that in the GC group. In the LC group, two staple lines cross between the linear and circular stapler and these intersections of double-stapled anastomoses represent a structural weak spot [16]. The gastric conduit was twisted for half a turn when esophagogastrostomy was performed at the LC side. The anastomosis was subjected to tension, which may have reduced blood supply, causing anastomosis failure. Therefore, it may be necessary to choose either the anterior or posterior wall of the gastric conduit to reduce ALs while firing at the LC side.

Using indocyanine green (ICG) fluorescence to evaluate the network of capillary vessels in the blood flow of the gastric conduit has been described in many articles [17]; however, the heterogeneity in reported variables limits the generalizability of findings. Moreover, although ICG fluorescence is useful for evaluating arterial blood flow before anastomosis, evaluating the venous drainage and blood flow after anastomosis is difficult. In clinical practice, AL is observed frequently, despite visualization of a good vascular supply of the gastric conduit before anastomosis.

The type of neoadjuvant therapy did not contribute significantly to AL in any of the patients (Table 5); however, the AL rate in the NACRT group was much higher than that in the NAC group. Prophylactic radiation, including both the oral stump of the esophagus and gastric fundus, may have an impact on the high rate of AL. A single-center cohort study reported that dose levels to the gastric fundus were associated with an increased risk of AL after esophagectomy and cervical anastomosis [18].

This RCT has several limitations. First, it was a single-center and small-scale study that may not be sufficiently powered to establish the influence of the anastomotic site of the gastric conduit on the rate of AL; thus, a larger study is necessary to fully explore this question. Second, the type of neoadjuvant therapy, surgical approach, and route of reconstruction were different for each patient, although the baseline patient characteristics were well balanced between the two groups.

In conclusion, AL rates and postoperative complications were comparable among patients undergoing esophagogastrostomy using a circular stapler at the GC or LC side. However, factors other than those related to the technique and patients' characteristics may play a major role because the leakage sites were significantly different in the two groups.

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Compliance with ethical standards

Conflict of interest We have no conflicts of interest associated with this article to declare.

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