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Original Article

Use of a closed suction, perfused drainage system for peripancreatic drainage after pancreaticoduodenectomy

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Abstract: Objective: To use a novel drainage system in pancreaticoduodenectomy. Method: The data of 150 patients who underwent pancreaticoduodenectomy from January 2009 to July 2011 were analyzed, and all the surgeries were performed by a single team. First 93 surgeries were performed a novel drainage tube, the other 57 patients were placed the traditional one. The incidence and grade of postoperative pancreatic fistula (POPF), and the incidence of biliary leakage, delayed gastric emptying, bleeding and death within 30 days after the surgery were monitored. Result: In the first group, there were 22 patients had POPF (23.66%), the proportion of Grade A, B and C was 23.66%, 20.43% and 0%, respectively. In the contrary group, there were 17 patients had POPF (29.82%), the proportion of Grade A, B and C was 12.28%, 12.28% and 5.26%, respectively. Grade B and Grade C POPF rates between the two groups were statistically significance ($P<0.05$). Regarding the incidence of postoperative biliary leakage, delayed gastric emptying, bleeding and death, no significant differences were observed ($P>0.05$). Conclusion: The application of the novel drainage system in pancreaticoduodenectomy was safe, and could reduce the incidence of high grade POPF.

Keywords: Pancreaticoduodenectomy, drainage tube, complications, pancreatic fistula

Introduction

Pancreaticoduodenectomy (PD) is the standard procedure to treat patients with resectable tumors in pancreatic head and the periampullary region. The mortality of this procedure has decreased to 1%-4% thanks to the progress of surgical techniques, but the postoperative complication rates are still as high as 30%-60% [1], the most common including postoperative pancreatic fistula (POPF), delayed gastric emptying (DGE), biliary fistula and infections. Among them POPF plays a central role in the genesis and development of various postoperative complications, and major causes of postoperative death such as massive hemorrhage, severe sepsis are related with POPF. The reported POPF rates are still relatively high, about 5%-35% [2]. To reduce POPF effectively, especially Grade C POPF is a critical issue to decrease postoperative interventions, shorten hospital stays, and reduce death rates [3]. Various methods have been tried, including different techniques of pancreatic-enteric reconstruction (pancreaticogastrostomy, pancreaticogastrostomy with gastric partition, pancreaticojejunostomy, binding pancreaticojejunostomy), pancreatic duct occlusion, using of fibrin sealants, somatostatin and its analogues, but the results were conflicting and require further verification [4].

Postoperative drainage is one of the standard procedures in the prevention and management of POPF [5, 6], and yet its prophylactic value has been challenged in recent years. A randomized prospective trial conducted by Conlon et al. [7] failed to show that intraperitoneal drainage after pancreatic resection reduces the rate of postoperative death or complications, including POPF. Despite that it is a well-designed RCT with a proper sample size, it should not be ignored that so many factors are possibly associated with the clinical outcomes that a single-center's experience may not tell the whole story. This study was so controversial that, in fact, most surgeons still use drains in their clinical practice [8]. Thus it is of great clinical value

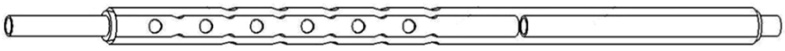

Figure 1. The schematic diagram of the novel two-point fixed, multisite running-through, double-lumen drainage tube.

to design new drainage tubes that could be safer and more effective, but drainage tubes are so common and fundamental that we tend to overlook the possibility that they could be further improved. And in clinics, postoperative drainage is not always satisfying: location shifts or block of side holes could all result in poor drainage. To overcome these shortcomings, we designed a novel two-point fixed, multisite running-through, double-lumen drainage tube that is more fixed and irrigates and drains more efficiently, hoping to possibly reduce the POPF rate or grade. This study is aimed to compare the postoperative complication rates of PDs using the novel drainage tubes or using traditional drainage tubes, especially the POPF.

Patients and methods

Patients and design

From January 2009 to July 2011, 150 consecutive patients with benign or malignant tumors in pancreatic head or periampullary region were registered and enrolled in this study. The recruitment criteria were in accord with the indications of pancreatectomy, so, we did not list detailedly in the text. All the patients were performed PD by a single surgery team. The initial 93 surgeries were performed from January 2009 to August 2010, and a novel two-point fixed, multisite running-through, double-lumen drainage tube was placed; the other 57 surgeries were performed from September 2010 to July 2011, and a traditional drainage tube was placed (To avoid the disturbance by surgeon's experience, we placed the novel tube in the former group).

This study was approved by the Ethical Committee of Fudan University, and it followed the ethical guidelines of the Declaration of Helsinki. Written informed consent was obtained from each participant.

Construction

A 50 cm long, 1 cm diameter latex tube was taken as the outer sleeve. Bilaterally staggered holes were cut at the place of 15 cm from the right end of the tube, which were 3 mm diameter and 1 cm intervals for a length of about 20 cm. From the right side of the outer sleeve, put in a 0.6 cm diameter silicone suction tube with 2 mm diameter holes cut corresponding to the holes of the outer sleeve. From the left side of the outer sleeve, put in a silicone irrigation tube with no side holes adjacent to the suction tube. Inner tubes and outer tubes were connected by sutures (**Figure 1**).

Surgical procedures

Radical PD was performed for the patients with malignant tumors, and PD was performed for the patients with benign tumors. In all the surgeries, end-to-end Child's pancreaticojejunostomy was carried out by interrupted sutures in one layer, end-to-side hepaticojejunostomy was carried out by interrupted sutures in one layer, and end-to-side gastrojejunostomy was carried out by running sutures in one layer. The diameter of the pancreatic duct was measured, and a plastic stent with the right diameter ranged from 2 mm to 5 mm was chosen accordingly, then put one end of the stent into the pancreatic duct and anchored it by absorbable sutures, and the other end was put into the jejunum with a 10 cm distance from the choledochojejunal anastomosis.

Placement of the drainage tubes

The placement of the traditional drainage tubes: a suction drain was placed beneath the pancreaticojejunal anastomosis (to detect the level of amylase) and pulled out on the right side of the abdomen; a drain was placed over the pancreaticojejunal anastomosis and behind the gastrojejunal anastomosis, and pulled out on the left side of the abdomen; a suction drain was placed behind the hepaticojejunal anastomosis and pulled out on the right side of the abdomen. The placement of the novel drainage tubes: to puncture the abdominal wall 2 cm below the right costal margin, along the lateral boarder of the rectus abdominis, put through the novel drainage tube and put it downward along the gallbladder bed, passed it across the abdominal cavity behind the hepaticojejunal anastomosis, in front of the pancreaticojejunal

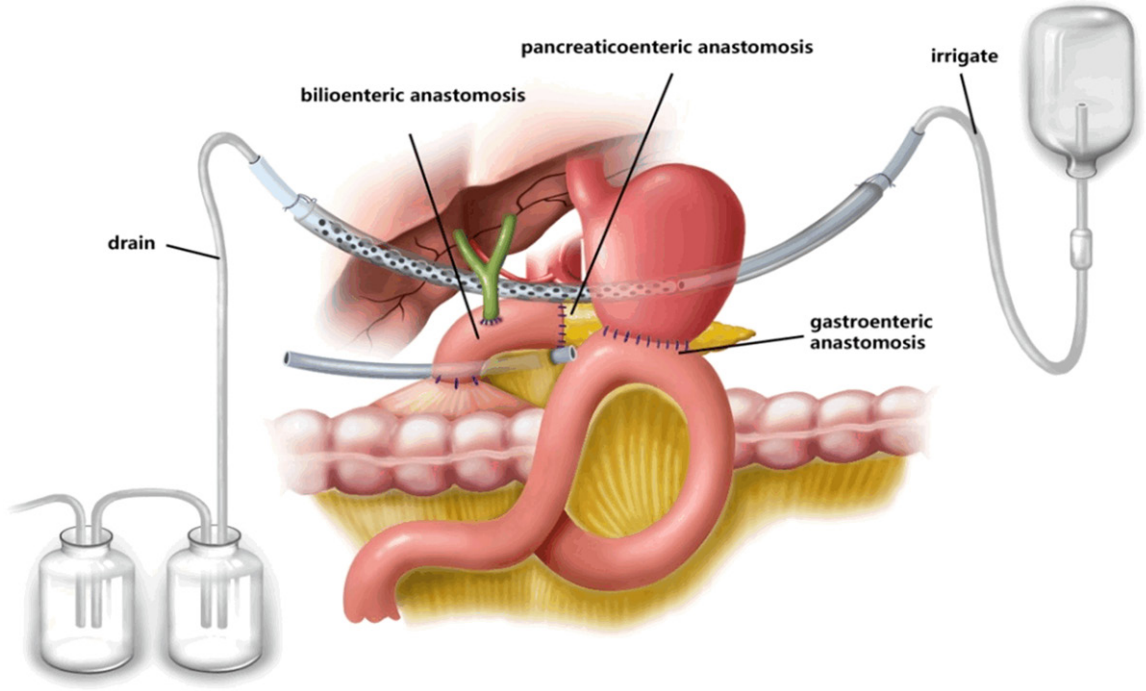

Figure 2. The placement of the novel drainage tube in pancreaticoduodenectomy.

anastomosis and behind the gastrojejunal anastomosis, finally pulled it out 4 cm below the left costal margin along the lateral boarder of the rectus abdominis. Also a suction drain was placed beneath the pancreaticojejunal anastomosis (to detect the level of amylase) and pulled out on the right side of the abdomen (**Figure 2**).

Postoperative management

Patients were managed in the intensive care unit for 24 hours post-surgery, and were transferred to normal wards if the condition was stable. A nasogastric tube was placed to drain the digestive juice, and patients were kept fast. Oral diet was gradually resumed if no complications such as DGE or POPF occurred. Drain fluid volume from the intra-abdominal drains was measured daily, and samples of the drain fluid were tested for the amylase level at postoperative day 3 and day 6. At the seventh day after the surgery, if the outputs were less than 20 ml per day and the fluid amylase level was normal, the drainage tubes were removed. No patients received somatostatin or analogs.

Definitions of postoperative complications

According to the proposal of the International Study Group on Pancreatic Fistula Definition (ISGPF) [9], POPF was defined as output via an operatively placed drain of any measurable volume of drain fluid on or after postoperative day 3, with an amylase content 3 times more than the upper normal serum value. Grade A POPF: No clinical signs or symptoms were observed except for the elevated fluid amylase level. Grade B POPF: Classical clinical manifestations were common, and signs of organ dysfunction could present; usage of antibiotics, nutritional support and sufficient drainage were required. Grade C POPF: The patient's conditions were generally worse, and severe sepsis, organ failures that could lead to death occurred; surgical interventions were needed.

Biliary leakage was defined as the presence of bile-like fluids from drainage tubes near the hepaticojejunal anastomosis, and the outputs exceeding 50 ml per day for more than three days.

DGE was defined to be present when the nasogastric tube was maintained for ten or more days with outputs more than 800 ml per day, or patients vomited after removal of the nasogastric tube and needed re-inserted (excluding intestinal obstruction, anastomotic stenosis, or other mechanical factors).

Table 1. Demographic data and pathologic findings

Category	Traditional drainage tube group (n=57)	Novel drainage tube group (n=93)	P
Age (years)	57.44 ± 14.38	55.55 ± 13.10	NS
Sex (male/female)	32/25	57/36	NS
Jaundice	27 (47.36%)	41 (50.53%)	NS
Pathological type			NS
Malignant tumors	42 (73.68%)	68 (73.12%)	
Ductal adenocarcinoma	24 (42.11%)	42 (45.16%)	
Adenosquamous carcinoma	5 (8.77%)	7 (7.53%)	
Mucinous cystadenocarcinoma	1 (1.75%)	2 (2.15%)	
Neuroendocrine carcinoma	3 (5.26%)	3 (3.23%)	
Non-cystic mucinous carcinoma	1 (1.75%)	2 (2.15%)	
Common bile duct carcinoma	2 (3.51%)	2 (2.15%)	
Duodenal papillary carcinoma	6 (10.53%)	10 (10.75%)	
Benign tumors	15 (26.32%)	25 (26.88%)	
IPMNs	5 (8.77%)	8 (8.60%)	
Inflammatory lesions	1 (1.75%)	2 (2.15%)	
Mucinous cystadenoma	2 (3.51%)	4 (4.30%)	
Serous cystadenoma	2 (3.51%)	2 (2.15%)	
Duodenal papillary adenoma	1 (1.75%)	3 (3.23%)	
Common bile duct papilloma	1 (1.75%)	2 (2.15%)	
Solid pseudopapillary tumor	1 (1.75%)	2 (2.15%)	
Periampullary papilloma	1 (1.75%)	1 (1.08%)	
Duodenal stromal tumor	1 (1.75%)	1 (1.08%)	

Bleeding was defined as the presence of hemorrhagic fluids from intra-abdominal drains or nasogastric tube with a progressive decline of hemoglobin, and a transfusion of three units of blood in 24-48 hours or an emergency surgical hemostasis were needed. Wound infection was defined as erythema and induration of a wound with purulent discharge and with a positive bacterial culture.

Pulmonary infection was defined as the presence of pneumonia, or atelectatic changes on radiograph, and was associated with a positive sputum bacterial culture.

Study endpoints

The primary study endpoints were the incidence and grade of POPF. Secondary endpoints were the rates of other postoperative complications, in-hospital death and the duration of postoperative hospital stay.

Data collection and statistical analysis

Demographic and clinical data, details of the surgical process, pathological diagnosis, postoperative course, and complications were collected. All data was imported into the computer and a database was established. The statistical analysis was performed using the SPSS 16.0 statistical software. Continuous data were expressed as mean ± SD. Comparisons of continuous variables were performed using Student's t test, and comparisons of categorical variables were performed using χ^2 test or Fisher's exact test where appropriate. All statistical tests were two sided, and $P<0.05$ was considered statistical significance.

Results

The study included 150 patients with a mean age of 56.27 ± 13.57 years. There were 89 males and 61 females. There were 57 patients in the traditional drainage tube group and 93 patients in the novel drainage tube group, with no significant differences between the two groups in comparison of demographic data and pathologic findings (**Table 1**). The most common pathologic diagnosis was adenocarcinoma in both groups (42.11% in the traditional drainage tube group and 45.16% in the novel

Table 2. Intraoperative data

Category	Traditional drainage tube group (n=57)	Novel drainage tube group (n=93)	P
Surgical type			NS
PD	44 (77.19%)	75 (80.65%)	
PPPD	13 (22.90%)	18 (19.35%)	
Operation time (minutes)	193.12 ± 54.38	199.22 ± 46.40	NS
Amount of bleeding (mL)	133.12 ± 160.78	190.78 ± 193.23	NS
Transfusion (units)	2.13 ± 0.19	1.98 ± 0.22	
Diameter of pancreatic duct at transected neck			NS
(<3 mm)	15 (26.32%)	36 (38.71%)	
(>3 mm)	42 (73.68%)	57 (61.29%)	
Texture of the pancreatic stump			NS
Soft	27 (47.37%)	44 (47.31%)	
Firm	30 (52.63%)	49 (52.69%)	

Table 3. Postoperative and complications

Category	Traditional drainage tube group (n=57)	Novel drainage tube group (n=93)	P
POPF	17 (29.82%)	22 (23.66%)	NS
Grade A	7 (12.28%)	19 (20.43%)	
Grade B	7 (12.28%)	3 (3.23%)	
Grade C	3 (5.26%)	0 (0)	
POPF			0.026
Low grade (A)	7 (12.28%)	19 (20.43)	
High grade (B+C)	10 (17.54%)	3 (3.23%)	
Biliary leakage	1 (1.75%)	2 (2.15%)	NS
DGE	3 (5.26%)	5 (5.38%)	NS
Bleeding	2 (3.5%)	0 (0)	NS
Pulmonary Infection	3 (5.26%)	5 (5.38%)	NS
Wound Infection	2 (3.51%)	2 (2.15%)	NS
Patients with one or more complications	26 (45.61%)	33 (35.48%)	
Drainage tube occlusion	6 (10.53%)	0	<0.001
Reoperation	2	0	NS
In-hospital death	1 (1.75%)	0 (0)	NS
Postoperative hospital stay (days)	22.79 ± 9.5	19.34 ± 5.8	0.006

drainage tube group), followed by the papillary carcinoma of the duodenum and intraductal papillary mucinous neoplasm (IPMN). Overall, there were 110 (73.33%) malignant tumors and 40 (26.67%) benign ones. No significant differences between two groups were observed in comparison of intraoperative data as well (**Table 2**). A total of 119 patients received standard pancreaticoduodenectomy, while 31 patients received pylorus-preserving pancreaticoduodenectomy. The rigidity of the pancreas was considered to be soft by the surgeons in 71 patients, and firm in 79 patients.

After the surgery, 91 patients (60.67%) had an uncomplicated recovery, and 59 patients (39.33%) had one or more complications, with no significant difference between the two groups. The postoperative complications are listed in **Table 3**. POPF was the most common complication, with a rate of 29.82% in the traditional drainage tube group and 23.66% in the novel drainage tube group (P>0.05). Although the difference was not significant, it is worth noted that the rate of Grade B and Grade C POPF in the novel drainage tube group was significantly less than the traditional drainage

tube group (P<0.05). Although the novel drainage tube group had a larger population, no Grade C POPF was observed. One of the three patients with Grade C POPF finally died due to the subsequent abdominal abscess and multiorgan failure. Reoperation was performed in two patients for abdominal bleeding in the traditional drainage tube group. The incidences of biliary fistula, DGE and pulmonary infection were similar between the two groups. Meanwhile the postoperative hospital stay of the novel drainage tube group (19.34 ± 5.8 days) was significantly shorter than the traditional drainage tube group (22.79 ± 9.5 days).

Discussion

Pancreaticoduodenectomy was the only potential way to cure the patients with pancreatic head carcinomas [10], yet it had been associated with high morbidity and mortality rates for decades [11]. In recent years, due to the improvements in surgical techniques and perioperative care, the mortality rate has been dramatically reduced to less than 5%, but the morbidity rate still remains as high as 30% to 50% [9]. POPF, known as the Achilles' heel of the pancreatic surgery, was one of the most common complications after PD and also one of the major issues that puzzled the pancreatic surgeons most [12]. It was reported that major complications of PD such as intra-abdomen hemorrhage, abdominal abscess, sepsis, and even death were related with POPF [13].

Risk factors of POPF have been identified to three categories: (1) patient factors, such as age, gender, level of preoperative jaundice, and comorbidities; (2) operation factors, such as operative time, blood loss, anastomotic technique, and biliary or pancreatic stenting; (3) disease factors, such as pancreatic texture, pancreatic duct size, pancreatic juice output, and pathologic diagnosis [5, 14, 15]. Since the patient factors and disease factors were relatively objective, extensive studies have been conducted focusing on the operation factors, such as anastomosis type (pancreaticojejunostomy vs. pancreaticogastrostomy), anastomosis techniques (duct-to-mucosa or invagination anastomosis), internal duct stents, etc [5, 6]. However, randomized control trials regard these technical modifications were rare, and a recently systematic review showed that no pancreatic reconstruction technique was applicable to all kinds of pancreatic remnants [16]. Despite that some novel approaches such as binding PJ [14] and PPPD with gastric partition [17] revealed promising results, further validation was still needed.

Although the overall POPF rate and complication rate were not decreased, the novel homemade drainage tube we presented here significantly reduced the rates of Grade B and Grade C POPF compared with traditional drains. Grade C POPF was considered to be life threatening and was most concerned by surgeons, since Grade C POPF per se was defined as the pancreatic fistula that would develop abscesses, peritonitis, sepsis, and hemorrhage with a high mortality rate [18]. In our study, the three Grade C POPFs in the traditional drainage tube group led to two reoperations and one death, in sharp contrast with the novel drainage tube group. Also, the novel drainage tube group presented a shorter postoperative hospital stay. Besides, this new tube could be used in combination with other approaches such as novel anastomosis types or the use of octreotide or fibrin sealants to reach an optimal outcome, therefore we believe that the new drainage tube was potentially clinically beneficial and worth further evaluations. We did not observe any side effects directly associated with this novel drainage tube.

On pathophysiologic aspect, POPF derived from a failure of healing and/or sealing of a pancreatic-enteric anastomosis, or a parenchymal leak that was not directly related to an anastomosis. The proteases in the pancreatic juice leaked out to start and promote the whole process. When the proteases activated, they started to digest the surrounding tissues and destroy normal anatomic structures, resulted in the anastomosis dehiscence in the end. When the process developed, the pancreatic juice would induce inflammation and autodestruction of the surrounding vessels and organs, resulted in abdominal bleeding, DGE, peripancreatic and retroperitoneal collections, even MOF and death [15]. We believe that the minor leakage of pancreatic juice had an important role in the inception of the POPF. The minor leakage could come from an unsatisfied anastomosis, the cutting impact of the suture, or even the needle passage, and could not be

absolutely avoided [14]. From this point of view, surgically placed intraperitoneal drains could remove the trace amount of pancreatic juice as soon as it was leaked out, and stopped it from aggregating and doing larger damages to the anastomosis. Theoretically, effective drainage would reduce the rate of POPF, and perhaps more important, degrade the POPF.

Currently, several varieties of drainage tubes were used in PD, and could be divided into two main types: active drainage tubes and passive drainage tubes. Active drainage tubes included the negative pressure ball drains, the double-tube negative pressure drains and the cigarette drains, while passive drainage tubes mainly included the latex drains. The negative pressure ball drains were too easily be occluded by blood clots or tissue fragments to maintain for a long time, besides their small volumes became the bottleneck constraint in draining the massive fluids when POPF occurs; the double-tube negative pressure drains were relatively rigid and could be moved easily due to the traction of abdominal wall during closing the abdomen, and were also hard to restore; the passive latex drains usually could not drain fluently and thoroughly in the condition of POPF. The novel drainage tube we presented here could remedy these weaknesses: Firstly, it was placed lower at the level of pancreaticojejunal and hepaticojejunal anastomoses and behind the gastrojejunal anastomosis, that's meaning it could drain fluids from all the three sites, and when pouring into the irrigation solutions, they could flow through the whole tube from one end to the other fluently, and in a sense flush the side holes constantly, so the tube was not easily be occluded and drained efficiently; Secondly, the drainage tube got into the abdominal cavity through the right puncture and passed across the abdominal cavity behind the hepaticojejunal anastomosis, in front of the pancreaticojejunal anastomosis and behind the gastrojejunal anastomosis, and finally got out through the left puncture, thus the tube was fixed at two point and clung to the posterior abdominal wall, so it didn't shift easily; Thirdly, the drainage tube was easy to get exchanged and extracted. It is notable that none of the new tubes were occluded in our study, but six of the traditional tubes.

During the making, placing and managing of this novel drainage tube, there were a few notes: First, the diameters of the side holes of both the inner tube and the outer sleeve should not be too large, for otherwise the holes might be occluded by the sucked omentum or other tissues; Second, the hepaticojejunal anastomosis should be encircled well by the ligamentum teres hepatis to avoid direct contact with the drainage tube; Third, the radian of the drainage tube should be large enough to make exchange or extraction more easily; Fourth, it was better to irrigate from the left side and suck from the right side and keep this pathway clear, meanwhile to avoid warp or flexure; Fifth, the dripping speed should not be too fast, and maintained an irrigation solution of 1000 ml to 1500 ml per day was proper, but a quick rinse should be given twice daily to avoid the incrustation inside the tube; Sixth, when exchanging or extracting the tube, aseptic principles should be strictly followed to avoid intra-abdominal contamination.

Drainage tubes used in the abdominal surgeries have not changed for decades. To our knowledge, this was the first study proposed a novel drainage tube that was designed to overcome the shortcomings of the traditional tubes. Although a total of 150 patients were included in the study, and the clinical and pathological data were all comparable between the two groups, it should be noticed that our study was an observational study without randomization, implying unknown confounding factors might affect the results. The two groups received surgeries one after another, and the surgeons' skills would improve over time. More researches and clinical trials were needed to reach a definitive conclusion.

In summary, our study showed that although the application of the novel drainage tube in PD did not decrease the overall incidence of POPF, but it decreased the incidence of high grade POPF, and thus reduced the rate of severe postoperative morbidities.

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Disclosure of conflict of interest

None.

Abbreviations

POPF, postoperative pancreatic fistula; PD, pancreaticoduodenectomy; PPPD, pylorus preserving pancreaticoduodenectomy; DGE, delayed gastric emptying; RCT, random control trial; SD, standard difference; IPMN, intraductal papillary mucinous neoplasm; MOF, multiple organ failure.

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