Annals of Gastroenterology (2018) **31,** 506-512

Clinical profile and treatment outcomes in autoimmune pancreatitis: a report from North India

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Abstract

Background Autoimmune pancreatitis (AIP) is a rare disease, and data from countries like India concerning its clinical presentation and long-term outcomes are scarce. We retrospectively evaluated the clinical presentation, imaging features and treatment outcomes of patients with AIP.

Methods We carried out a retrospective analysis of our database to identify patients diagnosed with and treated for AIP at our unit in a tertiary care hospital in North India.

Results Eighteen patients with AIP (mean age: 54.9±11.1 years; 13 male) were evaluated. Of these, 9 (50%) patients had probable type 1 AIP, 2 (11%) patients probable type 2 AIP, and 4 (22%) definite type 1 AIP. Patients with type 2 AIP were significantly younger than patients with type 1 (40.0±2.8 vs. 58.4±9.6 years). In type 1 AIP, other organ involvement was observed in 3/18 (17%) patients, whereas both patients with type 2 AIP had coexisting ulcerative colitis. The diagnosis of AIP was made after resective surgery in 6/18 (33.0%) patients. An accurate diagnosis of AIP could be made in all patients who underwent resection or core biopsy, but cytological examination after endoscopic ultrasound-guided fine-needle aspiration could not provide a definitive diagnosis in any patient. Initial treatment with steroids was given to 12 (67%) patients, with a 100% response, but the disease relapsed in 5/13 (38%) patients over a mean follow-up period of 34.2±21.6 weeks.

Conclusion AIP is not rare in India and the majority of clinical manifestations, imaging features, treatment response and long-term outcomes are similar to those reported in the literature.

Keywords Autoimmune pancreatitis, endosonography, contrast-enhanced computed tomography, tuberculosis, adenocarcinoma

Ann Gastroenterol 2018; 31 (4): 506-512

Introduction

Autoimmune pancreatitis (AIP) is a rare autoimmune inflammatory disease of the pancreas with characteristic clinical, radiological, serological, and histopathological features [1-3]. A dense lymphoplasmacytic infiltrate (predominantly immunoglobulin [Ig] G4-positive plasma cells) with fibrosis and dramatic response to steroids are the salient features of AIP [1-3]. Although initial reports described AIP as a disease affecting only the pancreas, more recent studies have described the association of AIP with other IgG4-related autoimmune diseases [1-4]. Because of the widespread infiltration of the organ systems by IgG4-positive plasma cells, this disease is now classified as an IgG4-related systemic disease.

Over the last few years, there has been a better understanding of the clinical profile as well as the immunopathogenesis of this rare disease. Consequently, it has been classified into type 1 and type 2 AIP; the vast majority of AIP cases seen in clinical practice are type 1. These types have different histological as well as clinical phenotypes. The histological subtype of type 1 AIP is lymphoplasmacytic sclerosing pancreatitis, whereas type 2 AIP is duct-centric chronic pancreatitis [1-4]. Type 1 AIP is a systemic IgG4-positive disease in which the pancreas also becomes affected. It typically presents with obstructive jaundice, diffuse pancreatic enlargement, diabetes and steatorrhea in the active phase, and with calcifications,

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Conflict of Interest: None

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Received 1 February 2018; accepted 24 March 2018; published online 28 April 2018

DOI: https://doi.org/10.20524/aog.2018.0267

parenchymal atrophy and persistent pancreatic insufficiency in the late phase [5]. In contrast, type 2 AIP is a pancreas-specific disorder, in which almost 50% of patients present with acute pancreatitis and almost half have coexisting inflammatory bowel disease (IBD) [2,6].

Despite the increased awareness as well as the number of diagnosed cases of AIP worldwide, the majority of published studies are based on small patient populations and mainly originate from Japan and the USA [1-7]. AIP has rarely been reported from India and the majority of publications are either surgical series, case reports or small case series with no follow-up data [8-14]. In developing countries like India, where pancreatic tuberculosis is also common and can closely mimic both pancreatic cancer and AIP, it is important to study the clinical and imaging features of AIP, as well as the treatment outcomes along with long-term follow up. In this retrospective study, we report the clinical presentation, imaging features and treatment outcomes of patients with AIP seen in our unit over the last eight years.

Patients and methods

We carried out a retrospective analysis of the database to identify patients diagnosed with and treated for AIP between January 2010 and December 2017 at our unit in a tertiary care hospital in North India. The clinical, laboratory and imaging findings of each of these patients were retrieved from the database. The clinical details specifically sought were AIP-related symptoms, extra-pancreatic disease manifestations, laboratory data (especially IgG4 levels), radiographic studies, previous treatments, any maintenance treatment and information about disease relapse.

Diagnostic criteria for AIP

The cases enrolled in the study had to meet the diagnostic criteria for the diagnosis of AIP, as defined by the International Consensus Diagnostic Criteria (ICDC) published in 2011 [15].

Definitive AIP: diagnosis confirmed by histological analysis of pancreatic resection specimen or endoscopic ultrasound (EUS)-guided fine-needle aspiration (FNA) [15].

Probable type 1 AIP: diagnosis based on imaging criteria, clinical and/or radiological response to steroids, high level of serum IgG4 (>119 mg/dL) and other organ involvement.

Probable type 2 AIP: diagnosis based on imaging criteria, clinical and/or radiological response to steroids (if introduced for pancreatic manifestations) and association with IBD.

All the symptomatic patients were initially treated with steroids (prednisolone 40 mg/day) for 4 weeks and in patients with complete remission the dose was tapered off by 5 mg/week. Patients with incomplete remission or intolerance to steroids were treated with two doses of rituximab. Patients with relapse were retreated with prednisolone 40 mg/day and maintenance therapy with azathioprine 2 mg/kg/day.

Relapse after steroid treatment was defined as the development of recurrent symptoms and concurrent supportive imaging findings or liver function test abnormalities consistent with a new or worsening disease process. The occurrence of acute pancreatitis after the diagnosis of AIP was also considered as a disease relapse.

Statistical analysis

The data were expressed as percentages for categorical variables and mean±standard deviation (SD) for quantitative variables. The continuous variables were compared using Student's *t*-test, whereas the categorical variables were compared using the chi-squared test. A P-value <0.05 was considered as significant.

Results

Eighteen patients with AIP (mean age: 54.9±11.1 years; 13 male) were diagnosed and treated in our unit during the study period. Of these 18, 9 (50%) patients were diagnosed as probable type 1 AIP, 2 (11%) as probable type 2 AIP, 4 (22%) as definite type 1 AIP, and one (5.6%) each as IgG4 cholangiopathy, disseminated IgG4-related disease and isolated IgG4 esophageal disease. Overall, type 1 AIP was diagnosed in 72% of the patients and type 2 AIP in 11% (Table 1). At the time of diagnosis, patients with type 2 AIP were significantly younger than patients with type 1 AIP (40.0±2.8 vs. 58.4±9.6 years; P=0.02)

The most common symptom was obstructive jaundice (61.0%; 11/18), followed by abdominal pain (39%; 7/18 patients). All patients with type 2 AIP presented with abdominal pain and had coexisting IBD (ulcerative colitis). The IBD was diagnosed prior to the diagnosis of AIP. Pre-existing diabetes was present in 8/18 (44.4%) patients with AIP. In type 1 AIP, other organ involvement was observed in 3/18 (17%) patients, whereas both the patients with type 2 AIP had coexistent ulcerative colitis.

The diagnosis of AIP was made after resective surgery in 6/18 (33.0%) patients, all of whom had type 1 AIP. The reason for surgery was a complication of chronic pancreatitis in one patient and suspicion of malignancy in 5 patients. The majority of these resective surgeries occurred during the early study period when the awareness of AIP was low.

All 18 patients underwent contrast-enhanced computed tomography and EUS was used in 13 (72%) patients. Diffuse, sausage-shaped enlargement of the pancreas was noted in 6/18 (33%) patients (Fig. 1) and a mass-like lesion with variable enhancement was observed in the head of the pancreas in 11/18 (61%) patients. All patients who exhibited a mass in the head of the pancreas had obstructive jaundice. No specific imaging features were noted on EUS: patients showed diffuse enlargement of the pancreas with echogenic foci/strands with lobularity and a hyperechoic pancreatic duct

Table 1 Clinical and disease characteristics of patients with autoimmune pancreatitis (AIP)

Sr No	Age/ Sex	Symptoms	Acute Pancreatitis	Diabetes	IgG4	Diffuse enlargement	Focal enlargement/ mass	Multifocal	Dilated MPD	Other site involvement	Distal CBD narrowing	Coexistent IBD	Other disease	IgG4 positive plasma cells in EUS FNA	Diagnosis
1	68/F	Pain Palpable lump Jaundice	No	Yes	Elevated	Yes	No	No	No	No	Yes	No	Branch duct IPMN	Yes (core biopsy)	Probable Type 1 AIP
2	64/F	Jaundice	No	No	Elevated	No	Yes	No	No	No	Yes	No	None	No	Probable Type 1 AIP
3	38/M	Pain	Yes	Yes	Elevated	Yes	No	No	No	No	No	Yes (Ulcerative Colitis)	None	Not done	Probable Type 2 AIP
4	52/M	Jaundice	No	No	Elevated	Yes	Yes	No	No	No	Yes	No	No	No	Probable Type 1 AIP
5	42/M	Pain	Yes	No	Elevated	Yes	No	No	No	No	No	Yes (Ulcerative Colitis)	None	Not done	Probable Type 2 AIP
6	35/M	Pain GOO	No	No	Elevated*	No	Yes	No	Yes	No	No	No	None	Resection (Yes)	Type 1 AIP
7	45/M	Pain GOO	No	Yes	Elevated	Yes	No	No	No	Kidney Bile duct	Yes	No	Annular Pancreas	No	Probable type 1 AIP
8	52/M	Pain Lump	No	Yes	Elevated	No	No	No	No	Liver Mesentery Lymph nodes Lung	No	No	None	Yes (Per cutaneous core Biopsy)	Disseminated IgG4 RD
9	60/M	Dysphagia	No	No	Normal*	No	No	No	No	Esophagus	No	No	No	Yes (Resection)	IgG4 RD of esophagus
10	64/M	Jaundice	No	No	Elevated	No	Yes	No	No	None	Yes	No	None	No	Probable type 1 AIP
11	60/F	Jaundice	No	No	Elevated*	No	Yes	No	No	No	Yes	No	None	Yes (Resection)	Type 1 AIP
12	58/M	Jaundice	No	No	Elevated*	No	Yes	No	No	No	Yes	No	None	Yes (Resection)	Type 1 AIP
13	68/F	Jaundice	No	Yes	Elevated	No	Yes	No	No	No	Yes	No	Hypothyroidism	No	Probable type 1 AIP
14	64/M	Jaundice	No	Yes	Elevated	No	Yes	No	No	No	Yes	No	No	No	Probable type 1 AIP
15	56/M	Jaundice	No	No	Elevated	No	Yes	No	No	Salivary glands	Yes	No	No	No	Probable type 1 AIP
16	62/F	Pain	No	Yes	Elevated	Yes	Yes	Yes	No	No	No	No	No	No	Probable type 1 AIP
17	64/M	Jaundice	No	Yes	Elevated*	No	Yes	No	No	No	Yes	No	No	Yes (Resection)	Type 1 AIP
18	36/M	Jaundice	No	No	Elevated*	No	No	No	No	No	No	No	No	Yes (Resection)	IgG4 cholangiopathy

MPD, Main pancreatic duct; IBD, inflammatory bowel disease; EUS, endoscopic ultrasound; FNA, fine needle aspiration; GOO, gastric outlet obstruction; IPMN, intraductal papillary mucinous neoplasm RD, related disease, *IgG4 levels done post resection/Surgery

wall or a hypoechoic mass lesion (Fig. 2). Three patients also had symmetrical wall thickening of the lower common bile duct (Fig. 3). Contrast-enhanced EUS was used in 2 patients with pancreatic mass lesions and in both patients the lesion was hyperenhancing (Fig. 4). Positron emission tomography-computed tomography was performed in 8 patients with IgG4-related disease (6 type 1 AIP and 2 with only extra-pancreatic involvement); in all these patients the involved areas showed intense fluorodeoxyglucose avidity (Fig. 5).

EUS-guided FNA with a 22G needle was performed in 9/18 (50%) patients and in the majority the cytological examination of the smears revealed benign ductal epithelial cells and acinar cells with numerous lymphocytes and occasionally plasma cells. In contrast, the diagnosis of AIP could be established pathologically in 100% (6/6) of the surgically resected patients. Serum IgG4 was elevated in 18/19 patients.

AIP was initially treated with steroids in 12 (67%) patients, with 100% response (Table 2). Only one patient with intractable pruritus required additional common bile duct stenting along with steroids. In contrast, only 1 patient (16.6%) of the 6 who underwent resective surgery required additional therapy with steroids because of relapsing symptoms. The disease relapsed in 5/13 (38%) patients who responded to initial steroids over a mean follow-up period of 34.2±21.6 weeks; none of the patients with type 2 AIP had a relapse. Three or more relapses were observed in only 2/13 (15%) patients, both of whom were put on maintenance therapy with azathioprine. One of these patients relapsed for a fourth time, despite being on azathioprine, and showed an inadequate response to steroids. Therefore, he was subsequently treated successfully with two doses of rituximab.

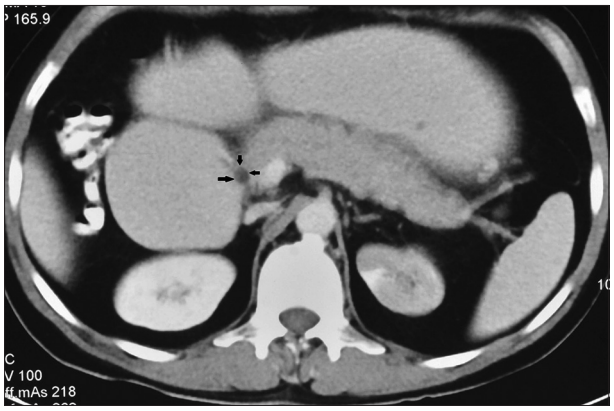

Figure 1 Computed tomography of the abdomen showing a sausage-shaped pancreas with a dilated common bile duct (arrows)

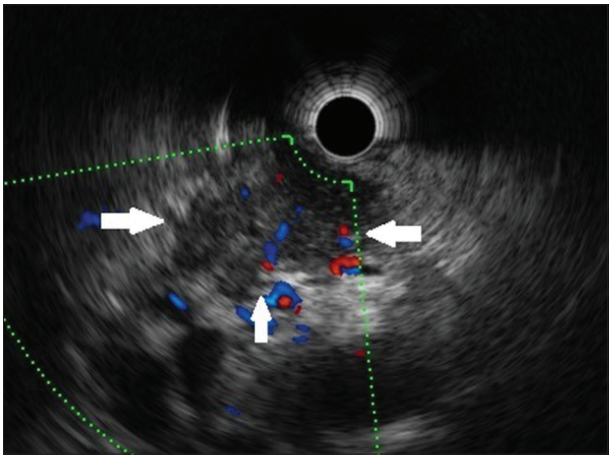

Figure 2 Endoscopic ultrasound showing a hypoechoic mass in the head of the pancreas

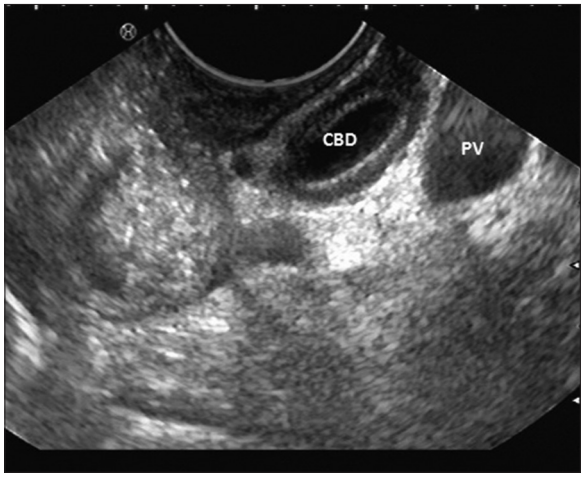

Figure 3 Endoscopic ultrasound showing a thickened common bile duct (CBD) wall in a patient with autoimmune pancreatitis
PV, portal vein

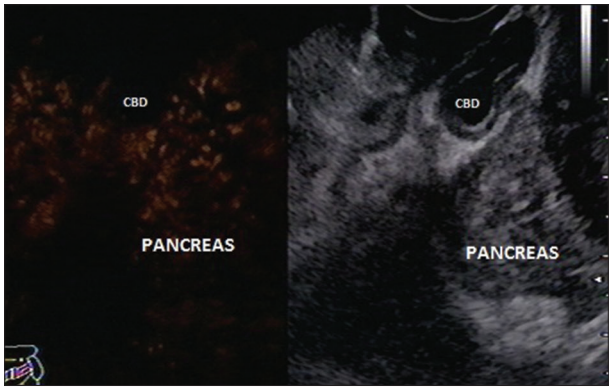

Figure 4 Contrast-enhanced endoscopic ultrasound showing the head of the pancreas (left panel) with a thickened common bile duct (CBD) wall

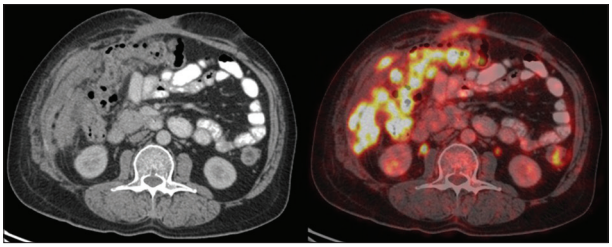

Figure 5 Positron emission tomography showing disseminated immunoglobulin G4 disease with peritoneal thickening, fluorodeoxyglucose avid

Table 2 Treatment and follow up data of patients with autoimmune pancreatitis

Sr No	Age/Sex	Treatment	Relapse	Follow up (months)	Maintenance treatment	Biologicals	Endoscopic stenting
1	68/F	Steroids	None	74	No	None	No
2	64/F	Steroids	None	6	No	No	Yes
3	38/M	Steroids	None	18	No	No	No
4	52/M	Steroids	Once	23	No	No	No
5	42/M	Steroids	None	15	No	No	No
6	35/M	Surgery alone	None	68	No	No	No
7	45/M	Steroids	None	3	No	No	No
8	52/M	Steroids	Four	21	Azathioprine	Rituximab	No
9	60/M	Surgery alone	No, Anastomotic strictest (managed by dilatation)	15	None	No	No
10	64/M	Steroids	Two	37	None	No	No
11	60/F	Surgery alone	None	64	None	No	No
12	58/M	Surgery alone	No	59	None	No	No
13	68/F	Steroids	Three	44	Azathioprine	No	No
14	64/M	Steroids	None	51	None	No	No
15	56/M	Steroids	None	38	None	No	No
16	62/F	Steroids	None	26	None	No	No
17	64/M	Surgery alone	None	33	None	No	No
18	36/M	Surgery plus steroids	Two	21	None	No	No

Discussion

In this study, we reported our unit's experience with the diagnosis, treatment and long-term outcomes of patients with both type 1 and 2 AIP seen over the last 8 years. Ours is a pancreatology unit in one of the busiest and largest tertiary care hospitals in North India. As far as we can tell from the literature, this is the first study from the Indian subcontinent that has looked at the various clinical manifestations, imaging features, management protocols and long-term outcomes of AIP in a fairly large cohort of patients with this rare disease.

In our study, type 1 AIP was more common than type 2, being diagnosed in 72% vs. 11% of patients; this is in accordance with the published literature from other parts of the world [1-3]. Our observation that patients with type 2 AIP were significantly younger at presentation than patients with type 1 is also in accordance with previous reports [1-3]. We also found that type 1 AIP was more commonly seen in elderly males, with the mean age at presentation being 58.4 years. We had only two patients with type 2 AIP and both of them had coexistent IBD (ulcerative colitis), a feature typical of type 2 AIP.

Consistently with previously published studies from Japan and the USA, our patients with type 1 AIP also had jaundice and abdominal pain as common presenting manifestations, while patients with type 2 AIP had acute pancreatitis as their most common clinical manifestation [1-6]. In addition, diabetes was seen in 44% of patients with type 1 AIP, a finding also consistent with those of previously published studies [1-7,16]. In type 1 AIP, the pancreas is affected by an IgG4-related systematic disease often accompanied by extra-pancreatic lesions, such as bile-duct stricture, sclerosing sialadenitis, renal involvement, lymphadenopathy, orbital pseudo-tumor and retroperitoneal fibrosis [1-7]. In our study, 16% (2/13) patients with type 1 AIP had extra-pancreatic lesions, whereas none of the type 2 AIP patients had such lesions. This frequency of extra-pancreatic involvement is less than the previously reported frequency of 25-50% from other centers across the world [1-7].

The classic features reported in previous studies, such as elevated serum IgG4, sausage-shaped diffuse enlargement of the pancreas and variably enhancing focal masses, were also seen in our patients with AIP. No specific features of AIP were noted on EUS, with patients having diffuse enlargement of the pancreas with echogenic foci/strands, lobularity and a hyperechoic pancreatic duct wall or hypoechoic mass lesion, while contrast-enhanced EUS revealed a hyperenhancing mass, in accordance with previously published studies [17-19].

One of the greatest challenges to the correct diagnosis of AIP is the need for histology (core tissue biopsy or resected specimen) to make a definitive diagnosis [1-7]. We also

found that an accurate diagnosis of AIP could be made in all patients who underwent resection or core biopsy, whereas cytological examination after EUS-guided FNA could not provide a definitive diagnosis in any patient. This is in accordance with the published guidelines and studies that have demonstrated the limited diagnostic role of FNA cytology, which thus does not feature in the ICDC [1-7]. With increased awareness of AIP and increasing use of the ICDC, the percentage of AIP diagnoses after pancreatic resective surgery has decreased in our unit, in accordance with previously published studies [1-7].

The universally positive response to steroid treatment in our study is consistent with previous reports [1-7]. The relapse rate after stoppage of steroids (38% of patients) and the observation that patients with type 2 AIP had stable disease with no relapse on follow up are in accordance with the published experience in the literature, where there are reports of a 20-60% relapse rate in type 1 AIP and less than 10% in type 2 AIP [1]. Maintenance therapy with azathioprine has been used in AIP to prevent relapses, but experience is limited to a few patients and the results were variable. We used azathioprine in two patients, one of whom relapsed nevertheless and needed rituximab for remission. In severe cases with frequent relapses, rituximab has been shown to be safe and effective [20].

In developing countries like India, isolated pancreatic tuberculosis is also occasionally encountered and needs to be accurately differentiated from both pancreatic cancer and AIP [21,22]. We had previously reported that none of the imaging features of pancreatic tuberculosis are distinctive; however, EUS-guided FNA can correctly differentiate pancreatic tuberculosis from pancreatic cancer [21,22]. None of the features of AIP are distinctive on imaging and the immune processes involved in IgG4-related systemic diseases and tuberculosis appear to have some similarities, with both having elevated IgG4 levels. Therefore, accurate differentiation of these two diseases, which differ in terms of both natural history and treatment, is of paramount importance, as the repercussions of wrong treatment could be disastrous [23].

The small sample size, the single-center design and the retrospective analysis are some of the important limitations of our study. However, AIP is a very rare disease and this study is the first from India that has evaluated the long-term outcomes of AIP in a fairly large study cohort.

In conclusion, AIP is being increasingly diagnosed in countries other than Japan and the USA, as a result of increased awareness and better diagnostic criteria. Treatment with steroids is universally effective, with the majority of patients remaining asymptomatic after successful treatment. The clinical manifestations, imaging features, treatment response and the long-term outcomes of patients with AIP from north India are consistent with previously published reports from other parts of the world, but the frequency of extra-pancreatic involvement of an IgG4-related disease is lower. For further research, large multicenter studies from India are needed to confirm our results and also to evaluate the effectiveness of maintenance therapy with immunomodulatory drugs.

Summary Box

What is already known:

- Autoimmune pancreatitis (AIP) is a rare autoimmune inflammatory disease of the pancreas
- The majority of published studies are based on small patient populations and come mainly from Japan and the USA
- Data from other parts of the world concerning the clinical features of AIP and the response to treatment are scarce

What the new findings are:

- AIP is being increasingly diagnosed in India
- The clinical manifestations, imaging features, treatment response and long-term outcomes of patients with AIP from north India are consistent with previously published reports from other parts of the world
- Treatment with steroids is universally effective, with the majority of patients remaining asymptomatic after successful treatment

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