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REVIEW

The revised Japanese clinical diagnostic criteria for chronic pancreatitis

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Abstract In Japan, we are now using the clinical diagnostic criteria for chronic pancreatitis (CP) that were revised in 2001 to add the findings of magnetic resonance cholangiopancreatography to the criteria compiled by the Japan Pancreas Society (JPS) in 1995. Because the current criteria are set for diagnosing advanced CP, they are unlikely to improve patients' prognoses. In addition, they seem unsuitable for current clinical practice because exocrine pancreatic function tests, which have become obsolete in Japan, are included in the diagnostic factors. For these reasons, the

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Research Committee on Intractable Pancreatic Diseases supported by the Ministry of Health, Labour and Welfare of Japan, the JPS and the Japanese Society of Gastroenterology have revised the criteria. The revised criteria are unique in that they contain an introduction to the concept of early CP. It is a challenge aimed at improvement of the long-term prognosis of CP patients by early diagnosis and therapeutic intervention in this disease. We need to determine and clarify the clinico-pathological outcome of early CP by a prospective long-term follow-up of the patients in this category.

Keywords Chronic pancreatitis · Diagnostic criteria · Early chronic pancreatitis · Endoscopic ultrasonography

Introduction

Since the establishment of the landmark classification of pancreatitis at the Marseille symposium in 1963 [1], many classifications and diagnostic criteria have been proposed for chronic pancreatitis (CP), chiefly from Western countries [2–9]. According to Uomo [10], the ideal classification for CP would be simple, objective, and accurate using non-invasive procedures, and it should include etiology, pathogenesis, structure, function, and clinical status in one overall scheme. In spite of continuous efforts, however, no ideal criteria completely satisfying all of the requirements have been established.

The history of diagnostic criteria for CP in Japan began with "The clinical diagnostic criteria for CP" proposed by the Japanese Society of Pancreatic Disease in 1971 [11]. Those criteria were revised by the Japanese Society of Gastroenterology (JSGE) in 1983, addressing the development of various imaging modalities [12]. The JSGE criteria contributed to gathering detailed data on CP from imaging and exocrine function tests, and analyses of the accumulated data paved the way to the establishment of the criteria proposed by the Japan Pancreas Society (JPS) working committee for the clinical diagnostic criteria for CP in 1995 [7, 13]. In Japan, we are now using the 2001 criteria proposed by the JPS [14], which include a modification of the 1995 JPS criteria by the addition of magnetic resonance cholangiopancreatography (MRCP) findings. This is the fourth revision of the diagnostic criteria for CP in Japan. We provide here an outline, and describe the characteristics, of the revised diagnostic criteria with reference to the process of preparation.

Necessity of revision

Since the current diagnostic criteria adopted the findings highly specific to CP for the definite and probable categories, they have turned out to be criteria for the diagnosis of the advanced CP, making them unlikely to be useful for the improvement of CP patients' prognoses. The criteria have numerous diagnostic items that make them complicated to use and, in addition, they do not refer to the pathogenesis and clinical stages of the disease; thus they have been criticized because they give a diagnosis of definite CP solely by the results of pancreatic exocrine function tests, which are not specific to CP [8, 9]. In addition, the secretin test, which is the centerpiece of the pancreatic exocrine function tests, has become unavailable because of the suspension of domestic production of secretin. Additionally, the fecal chymotrypsin test, which was adopted as the exocrine function test for the diagnosis of probable CP, cannot be used because the chemicals for the test are no longer distributed in Japan. Although partially revised in 2001, the current diagnostic criteria are based largely on the 1995 JPS criteria [7, 13] and therefore require revision as they are becoming unsuitable for present clinical practice.

Revision process

The Research Committee on Intractable Pancreatic Diseases (RCIPD), supported by the Ministry of Health, Labour and Welfare of Japan, prepared for the revision of the criteria by (1) promoting research on the clinical features of early CP [15] and examining the usefulness of endoscopic ultrasonography (EUS) in the diagnosis of CP [16] in 2002; (2) developing new diagnostic criteria for alcoholic pancreatic injury [17] in 2003; and (3) establishing the diagnostic criteria for early CP and the guidelines for therapy [18] as well as determining the initial findings of alcoholic pancreatic injury [19] in 2007. In a related action, the JPS set up a committee for the preparation of the clinical diagnostic criteria for CP in 2005 to begin the actual work for the revision. In starting the compilation of the "Clinical practical guidelines for CP" by the JSGE in 2006, in the first committee meeting for revision of the criteria, the RCIPD, JPS, and JSGE met on July 28, 2006, and the process of revision actually began. The committee consisted of 13 members: Tooru Shimosegawa (Chairman, Tohoku University), Keisho Kataoka (Kyoto Prefectural University of Medicine), Terumi Kamisawa (Tokyo Metropolitan Komagome Hospital), Hiroyuki Miyakawa (Sapporo-Kosei General Hospital), Hirotaka Ohara (Nagoya City University), Satoru Naruse (Miyoshi Municipal Hospital), Tetsuhide Ito (Kyushu University), Koichi Suda (Juntendo University), Naohiro Sata (Jichi Medical School), Yoshifumi Takeyama (Kinki University School of Medicine), Keiko Shiratori (Tokyo Women's Medical University), Takashi Hatori (Tokyo

Women's Medical University), and Makoto Otsuki (University of Occupational and Environmental Health). In the process of revision, the committee asked for advice from experts on pancreatic diseases, including Kazuichi Okazaki (Kansai Medical University), Kenji Notohara (Kurashiki Central Hospital), Kazuo Inui (Fujita Health University School of Medicine), Atsushi Irisawa (Fukushima Medical University), and Tetsuo Hayakawa (Meijo Hospital). Basically, the revised new criteria have been established according to a consensus of these experts in pancreatic inflammatory diseases—physicians, endoscopists, surgeons, and pathologists.

After the first committee meeting in 2006, four committee meetings and three RCIPD meetings, a public hearing titled "Proposal of the revised clinical diagnostic criteria for CP" was held on May 9, 2009, as an adjunct to the 95th annual meeting of the JSGE in Sapporo, and opinions given at the public hearing were taken into consideration for further corrections to complete the final revision. At nearly the same time, the diagnostic criteria of CP based on EUS findings, the Rosemont classification [20], were published in June 2009. Considering that this classification will continue to be used and to unify the terminology of the revised criteria, we made adjustments in the relative weight of the EUS findings and in the nomenclature as well. We ultimately adopted five features of pancreatic parenchymal factors and two features of pancreatic ductal factors for the EUS findings of early CP. The final version was uploaded to the JPS home page together with a solicitation for public comments from August 19 to September 12, 2009, after having confirmed the final proposal at the RCIPD meeting on July 14, 2009, and through a discussion at the special session of the 40th annual meeting of the JPS, titled "Revised clinical diagnostic criteria for CP—comparison with the current criteria" on July 31. Through these processes, the new diagnostic criteria finally appeared as a result of the joint efforts of the RCIPD, JPS, and JSGE.

Characteristics of the revised criteria

The revised criteria basically incorporate the concept of CP that was defined in the current diagnostic criteria. On the other hand, considering the cause of the disease, which is not included in the current criteria, the revised criteria classify CP into alcoholic and nonalcoholic types, two categories with distinct clinico-pathological characteristics. In addition, to make application of the criteria simple and convenient, they were designed to enable a diagnosis of CP when definite or probable findings in the imaging or histological factors are found. At the same time, the criteria were devised to detect alcoholic pancreatic injury in the early stages by including clinical signs related to heavy drinking. The most prominent feature of the revised criteria is the introduction and definition of the concept of early CP by employing EUS findings, which are reportedly most sensitive to early morphological changes in the pancreas [21–24]. We aimed to incorporate clinical stages in the criteria based on the judgment that diagnostic criteria for advanced CP like the current criteria cannot provide active therapies that can benefit the long-term prognosis of CP patients, in agreement with the view suggested by Forsmark [25]. Assuming the difficulty of histological diagnosis by biopsy specimens of the pancreas even in the future [26], we depend on clinical trials to clarify the real nature of early CP by defining it and by pursuing prospectively the clinical course of patients in this category. Considering the current inability to perform secretin tests and to examine fecal chymotrypsin activity, the revised criteria place great importance on imaging findings for the determination of a diagnosis. Although several recent reports have introduced new pancreatic function testing such as secretagogue-stimulated endoscopic pancreatic function tests [27, 28] and secretin-enhanced MRCP [29] or the ^{13}C-dipeptide breath test [30], the usefulness of these tests has not yet been established for general practice.

Outline of the revised diagnostic criteria

In the revised diagnostic criteria, CP is recognized as a pathological state defined by chronic inflammatory changes in the pancreas resulting in the decline of pancreatic exocrine and endocrine function, with severe fibrosis in the advanced stage. The pathological changes show an irregular and patchy distribution in the entire pancreas and are generally considered to progress irreversibly after exceeding a certain threshold. Typical cases of CP are associated with clinical symptoms and signs such as abdominal pain, tenderness and/or pancreatic exocrine and endocrine insufficiency. In the revised criteria, CP is classified into two distinct categories according to etiology, namely, alcoholic and non-alcoholic; the latter includes idiopathic, hereditary, and familial factors [31]. In contrast with the previous classifications by others [8, 9], the revised Japanese criteria do not include autoimmune pancreatitis (AIP) and obstructive pancreatitis in the concept of CP but categorize them as chronic inflammation of the pancreas owing to their apparently reversible characteristics. However, there is a possibility that AIP can be included in CP in the future, because some recent studies of long-term follow-up observation of AIP patients revealed that some of them develop pancreatic atrophy or even pancreatic duct stones [32–34] (Table 1). As the definition and clinical criteria for AIP [35–39] and obstructive pancreatitis [40]

have been proposed and described in detail elsewhere, the current revised criteria for CP do not deal with those.

The criteria comprise six items: ① characteristic imaging findings, ② characteristic histological findings, ③ repeated upper abdominal pain, ④ abnormal pancreatic enzyme levels in the serum or urine, ⑤ abnormal pancreatic exocrine function, and ⑥ continuous heavy drinking of alcohol equivalent to or more than 80 g/day of pure ethanol, which was determined in accordance with the criteria for alcoholic CP by Ammann [6] (Table 2). Definite and probable findings are set for items ① and ②, and the standards are specified for ④ and ⑤. Because the revised criteria place importance on the imaging examinations owing to a lack of useful pancreatic exocrine function tests in Japan, the findings of the respective imaging modalities are defined more strictly than those of the current criteria (Table 3).

According to the revised criteria, definite CP is diagnosed by the presence of definite findings in items ① or ②, or the presence of probable findings in ① or ② together with more than two items among ③, ④, and ⑤. Patients with probable findings in ① or ② are diagnosed as probable CP. Practically speaking, specimens large enough for thorough histological examination are required to make a diagnosis of CP according to item ②, so that it may be limited to specific examples such as surgically resected

Table 1 Definition and classification of chronic pancreatitis

Definition:
Chronic pancreatitis is a chronic clinical disorder, pathologically characterized by the loss of exocrine pancreatic parenchyma, irregular fibrosis, cellular infiltration, and ductal abnormalities, which may also affect the endocrine pancreas in the advanced stage. These pathological lesions show irregular and patchy distributions with variable intensities in the whole pancreas. In general, these lesions do not resolve and show various levels of deterioration. Typically, the first clinical manifestations consist of abdominal pain and tenderness, frequently followed by symptoms of exocrine and endocrine pancreatic insufficiency with disease progression
Chronic pancreatitis is classified according to etiology into alcoholic and non-alcoholic pancreatitis. Autoimmune pancreatitis and obstructive pancreatitis are classified as chronic inflammation of the pancreas but are not included in this criteria because of their reversibility in the clinico-pathological findings by therapy
Classification:
Alcoholic pancreatitis
Non-alcoholic pancreatitis (idiopathic, hereditary, familial, etc.)
Autoimmune pancreatitis (AIP) and obstructive pancreatitis are classified as chronic inflammation of the pancreas separately in these criteria

Table 2 Clinical diagnostic criteria for chronic pancreatitis

Diagnostic items for chronic pancreatitis
① Characteristic imaging findings
② Characteristic histological findings
③ Repeated upper abdominal pain
④ Abnormal pancreatic enzyme levels in the serum or urine
⑤ Abnormal pancreatic exocrine function
⑥ Continuous heavy drinking of alcohol equivalent to ≧80 g/day of pure ethanol
Definite chronic pancreatitis: either a or b
a. Definite findings of ① or ②
b. Probable findings of ① or ②, plus more than two items among ③, ④, and ⑤
Probable chronic pancreatitis
Probable findings of ① or ②
Early chronic pancreatitis[a]
More than two items among ③–⑥ plus image findings of early chronic pancreatitis
Patients with more than two items among ③–⑥ but without ① and ② are diagnosed as "possible chronic pancreatitis" after ruling out other pancreatic diseases. Imaging examinations, such as endoscopic ultrasonography (EUS) are recommended for the patients with "possible chronic pancreatitis" within 3 months after the diagnosis
Patients with imaging findings of early chronic pancreatitis plus either ③ or ④ in whom other pancreatic diseases are ruled out could have early chronic pancreatitis; therefore, careful follow-up is required for the patients
[a] The real nature of early chronic pancreatitis will be clarified by a long-term prospective follow-up of the patients in this category

Table 3 Findings defined in the diagnostic criteria

① Characteristic imaging findings

Definite findings: any one of the following:

a. Stones in pancreatic ducts

b. Multiple or numerous calcifications distributed in the entire pancreas

c. Irregular dilatation of the MPD and irregular dilatation of pancreatic duct branches of variable intensity with scattered distribution throughout the entire pancreas on the ERCP

d. Irregular dilatation of the MPD and branches proximal to complete or incomplete obstruction of the MPD (with pancreatic stones or protein plugs) on the ERCP

Probable findings: any one of the following:

a. Irregular dilatation of the MPD and irregular dilatation of pancreatic duct branches of variable intensity with scattered distribution throughout the entire pancreas on the MRCP

b. Irregular dilatation of pancreatic duct branches of variable intensity with scattered distribution throughout the entire pancreas, irregular dilatation of the MPD alone, or protein plugs on the ERCP

c. Irregular dilatation of the MPD throughout the entire pancreas plus pancreatic deformity with irregular contour on the CT

d. Intrapancreatic coarse hyperreflectivities suggestive of stones or protein plugs, or irregular dilatation of pancreatic ducts plus pancreatic deformity with irregular contour on the US (EUS)

② Characteristic histological findings

Definite findings: loss of exocrine parenchyma with irregular fibrosis. The fibrosis is distributed chiefly in the interlobular spaces showing nodular pattern of lobules called "cirrohosis"

Probable findings: loss of exocrine parenchyma with interlobular fibrosis or inter- and intralobular fibrosis

④ Abnormal pancreatic enzyme levels in the serum and urine: either a or b

a. Elevation or decline of serum pancreatic enzymes above or below the normal limits, observed sequentially at multiple points

b. Elevation of urine pancreatic enzymes above the normal limits, observed sequentially at multiple points

⑤ Abnormal results of pancreatic exocrine function test

Abnormal results in the *N*-benzoyl-L-tyrosyl-*p*-aminobenzoic acid test, observed at least two times several months apart

MPD Main pancreatic duct, *ERCP* endoscopic retrograde cholangiopancreatography, *CT* computed tomography, *(E)US* (endoscopic) ultrasonography

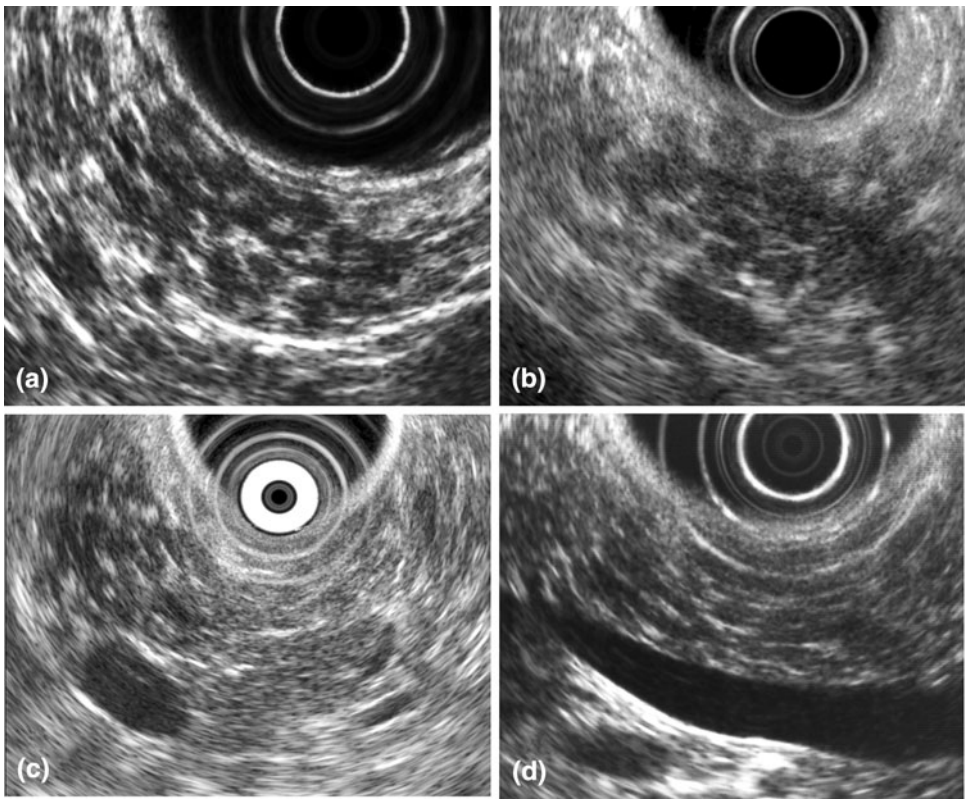

Fig. 1 Endoscopic ultrasonography (EUS) findings of early chronic pancreatitis (CP) defined by the Rosemont classification [20]. **a** Lobularity with honeycombing, **b** lobularity without honeycombing, **c** hyperechoic foci without shadowing, **d** stranding

specimens or autopsy specimens. Patients with more than two items among ③, ④, ⑤, and ⑥ who show EUS [21, 22] or endoscopic retrograde cholangiopancreatography (ERCP) [2, 41] findings of early CP as well are diagnosed as early CP. The involvement of clinical factors and drinking habits in the criteria was based on the view by Kahl et al. [42] that EUS abnormalities must be interpreted only against the background of clinical history in the diagnosis of early CP. On the other hand, patients who show more than two items among ③, ④, ⑤, and ⑥, but lack imaging findings of early CP are diagnosed as possible CP (Table 2). For the EUS findings of early CP, the following seven features (five parenchymal and two ductal features) are adopted: (1) lobularity with honeycombing, (2) lobularity without honeycombing, (3) hyperechoic foci without shadowing, (4) stranding, (5) cysts, (6) dilated side branches, and (7) hyperechoic main pancreatic duct (MPD) margin [20]. More than two among the seven features including any of (1)–(4), which are most likely to reflect fibrous changes in pancreatic parenchyma (Fig. 1a–d), are judged to be sufficient for the EUS findings of early CP [43–47]. For the ERCP findings of early CP, irregular dilatation of more than three side branches is defined in accordance with the "mild changes" defined in the Cambridge classification of 1983 [2, 41] (Table 4).

The revised diagnostic criteria recognize definite, probable, and early CP as confirmative CP but do not classify possible CP as true CP. Considering the problem of potential serious complications of ERCP, EUS is recommended ahead of ERCP for examining patients suspected of early CP, and then ERCP should be tried in symptomatic patients in whom pathological changes of the pancreas are strongly suspected. The diagnostic flow for CP based on the revised criteria is shown schematically in Fig. 2.

Table 4 Imaging findings of early chronic pancreatitis

Either a or b:

a. More than two features among the following seven features of EUS findings including at least one of (1)–(4)
   (1) Lobularity with honeycombing
   (2) Lobularity without honeycombing
   (3) Hyperechoic foci without shadowing
   (4) Stranding
   (5) Cysts
   (6) Dilated side branches
   (7) Hyperechoic MPD margin

b. Irregular dilatation of more than three duct branches on ERCP findings

Conclusion

The clinical diagnostic criteria for CP in Japan have been thoroughly revised after an 8-year interval. The revised criteria include new items such as involvement of the pathogenesis, introduction of the concept of early CP and incorporation of clinical symptoms, signs, and drinking habits among the diagnostic factors. In addition, taking into account the current situation where useful exocrine function tests are unavailable, the criteria heavily emphasize imaging examinations. The aim of the revision is to improve patients' prognoses by diagnosing CP at its early and possibly reversible stage. It is necessary to perform a

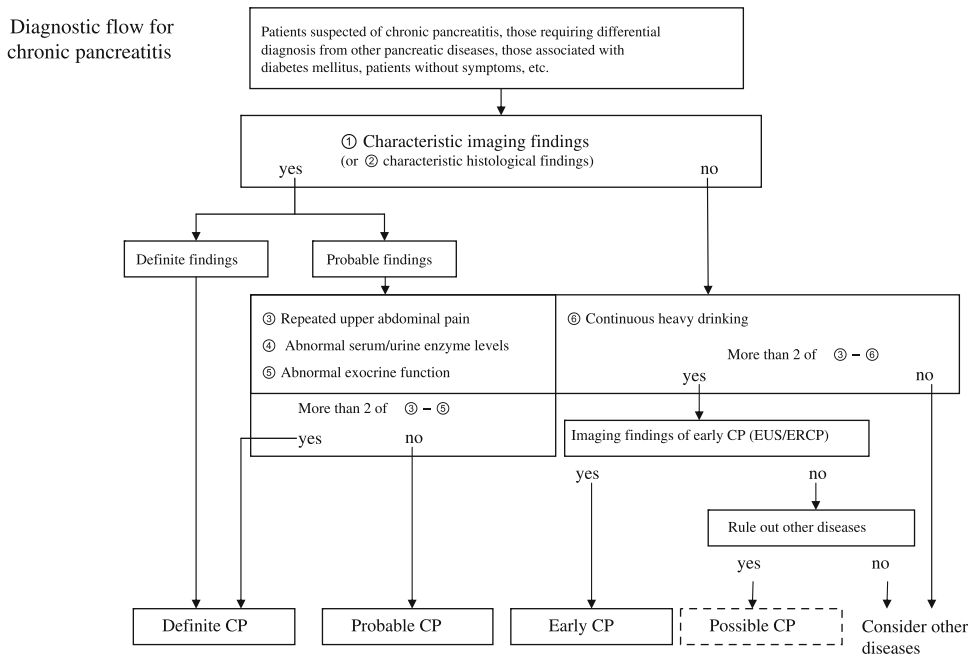

Fig. 2 Schematic flow diagram for the diagnosis of CP. *ERCP* Endoscopic retrograde cholangiopancreatography

prospective verification study to determine whether the revised new criteria can actually play a role in meeting that goal.

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