

Management of patients with sphincter of Oddi dysfunction based on a new classification

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Abstract

AIM: To propose a new classification system for sphincter of Oddi dysfunction (SOD) based on clinical data of patients.

METHODS: The clinical data of 305 SOD patients documented over the past decade at our center were analyzed retrospectively, and typical cases were reported.

RESULTS: The new classification with two more types (double-duct, biliary-pancreatic reflux) were set up on the basis of the Milwaukee criteria. There were 229 cases of biliary-type SOD, including 192 (83.8%) cases cured endoscopically, and 29 (12.7%) cured by open abdominal surgery, and the remaining 8 (3.5%) cases observed with unstable outcomes. Eight (50%) patients with pancreatic-type SOD were cured by endoscopic treatment, and the remaining 8 patients were cured after open abdominal surgery. There were 19

cases of double-duct-type SOD, which consisted of 7 (36.8%) patients who were cured endoscopically and 12 (63.2%) who were cured surgically. A total of 41 cases were diagnosed as biliary-pancreatic-reflux-type SOD. Twenty (48.8%) of them were treated endoscopically, 16 (39.0%) were treated by open abdominal surgery, and 5 (12.2%) were under observation.

CONCLUSION: The newly proposed SOD classification system introduced in this study better explains the clinical symptoms of SOD from the anatomical perspective and can guide clinical treatment of this disease.

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Key words: Sphincter of Oddi dysfunction; Classification; Diagnosis; Treatment

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INTRODUCTION

Sphincter of Oddi dysfunction (SOD) is characterized by a series of clinical pain symptoms caused by abnormalities in sphincter contractility^[1]. The sphincter of Oddi (SO), a fibromuscular sheath encircling the distal common bile duct (CBD), pancreatic duct and common channel, controls the flow of bile and pancreatic secretions into the duodenum and prevents reflux of duodenal contents into the pancreaticobiliary system^[2]. SO dyskinesia caused by injury or/and inflammation can result in a hypo- or

hypertonic sphincter with altered motility, causing an intermittent functional blockage of the sphincter. As it is often difficult to distinguish SO stenosis from dyskinesia, the term “sphincter of Oddi dysfunction” is used to cover both conditions^[3]. For SOD, the Milwaukee classification proposed by Hogan and Geenen has been widely accepted; it classifies SOD into two types: the biliary type and the pancreatic type^[4,6]. Biliary and pancreatic SOD are each sub-classified as type I, II and III on the basis of symptoms, laboratory tests and radiological imaging^[4,5]. This classification explains the clinical manifestations of SOD from the anatomical perspective and reveals the nature of SOD, thus providing a reliable anatomical basis for appropriate clinical treatment. In our long-term clinical practice, however, we have found this classification system somewhat flawed. For instance, the clinical manifestations in some patients with SOD are difficult to be satisfactorily defined using the Milwaukee criteria. Therefore, the existing system is insufficient in guiding the clinical treatment of all SOD patients. In this paper, we introduced a new classification of SOD based on the Milwaukee classification. In the new classification system, SOD is divided into four types according to anatomy, symptoms, endoscopic tests and radiological imaging. These types include not only those already established by the Milwaukee criteria (biliary and pancreatic types), but also two more new types (the double-duct and biliary-pancreatic reflux types) in an attempt to improve the clinical treatment of SOD.

MATERIALS AND METHODS

Patient data

A total of 1013 patients underwent endoscopic retrograde cholangiopancreatography (ERCP) from January 1999 to January 2009, and 305 (30%) patients who met the diagnostic criteria of SOD were included in this study. In the 305 SOD patients, there were 198 men and 107 women, aged from 36-79 years (mean age, 47.5 years) (Table 1). All the patients had to meet the following diagnostic criteria for SOD: (1) typical clinical symptoms, with or without abnormal liver function and amylase levels^[4,5]; and (2) baseline sphincter of Oddi manometry (SOM) pressure > 40 mmHg^[7], and/or paradoxical pressure response to cholecystokinin^[8], and/or delayed emptying of contrast medium in the common bile duct as indicated by ERCP^[9], and/or a diameter of common bile duct \geq 10 mm without evidence of stones or tumors^[6]. Preliminary classification was performed based on the development of the disease, examinations and treatment, e.g. ERCP, magnetic resonance cholangiopancreatography (MRCP), endoscopic sphincterotomy (EST) and endoscopic pancreatic duct sphincterotomy (EPS). Some patients were ultimately classified according to the findings of surgical exploration. Intraoperative choledochography, choledochoscopy and pancreatoscopy were performed if necessary.

It may still take a long time to establish the diagnosis for double-duct type and biliary-pancreatic reflux type SOD. For SOD of the double-duct type, both the biliary and pancreatic ducts of the sphincter of Oddi are affected. So, the

Table 1 Clinical features of sphincter of Oddi dysfunction patients

Clinical features	n (%)
Abdominal pain	
Retrosternal pain	235 (77.05)
Epigastric pain	70 (22.95)
Radiating pain	45 (14.75)
Timing of onset	
After high-fat meals	241 (79.02)
After ordinary meals	21 (6.89)
Uncertain	43 (14.10)
Jaundice	
With	21 (6.89)
Without	284 (93.11)
Liver enzyme levels	
Abnormal	58 (19.02)
Normal	247 (80.98)
Serum amylase	
Abnormal	63 (20.66)
Normal	242 (79.34)
Cholangiectasis	
\geq 10 mm	289 (94.75)
< 10 mm	16 (5.25)
Pancreatic duct dilation	76 (24.92)

biliary pain and pancreatic pain may occur simultaneously or alternately. For SOD of the biliary-pancreatic reflux type, the patients may have a congenital abnormality in the convergence of the biliary and pancreatic systems. When the ampullary anti-reflux valve is dysfunctional, small amounts of bile may repeatedly reflux into the pancreatic duct, which often induces pancreatitis. That is why sometimes an over long common duct of the biliary and pancreatic duct is found in auxiliary examination and operation.

Therapeutic methods

The therapeutic methods and results in patients with different types of SOD are shown in Table 2.

Typical cases

Case 1: A 43-year-old man first suffered from pancreatitis in November 2004. Three months later, his pancreatitis recurred, and B-mode ultrasonography suggested cholelithiasis. The patient suffered from recurrent pains in the upper abdomen six months after cholecystectomy performed in March 2005 due to clinically diagnosed biliary pancreatitis. Computed tomography (CT) suggested swelling of the pancreatic head and pancreatic duct distension, accompanied by stones. Moreover, the common bile duct had a diameter of 8 mm. With the duodenum preserved, the patient underwent resection of the swollen head of the pancreas, which was assumed to be compressing the bile duct, resulting in bile duct distension before the surgery. However, three months after surgery, the patient began to experience biliary colic with a frequency of 2-3 times per month. Laboratory tests showed normal blood amylase levels and aggravated liver dysfunction with alkaline phosphatase increasing from 579 to 1858 IU/L and glutamyl transpeptidase from 658 to 2006 IU/L, accompanied by enlargement of the diameter of the common bile duct

Table 2 Detailed classification, treatment and outcomes associated with sphincter of Oddi dysfunction

	<i>n</i> (%)
SOD biliary type	229/305 (75.08)
EST preferred	213/229 (93.01)
Improved	202/213 (94.83)
Good	182/202 (90.10)
Moderate	10/202 (4.95)
Poor	10/202 (4.95)
Failed	11/213 (5.16)
Exploratory laparotomy	29/229 (12.66)
Choledochointestinal anastomosis	21/29 (72.41)
Sphincter of Oddi plasty	8/29 (27.59)
Conservative treatment	8/29 (27.59)
Pancreatic type SOD	16/305 (5.25)
EPS preferred	13/16 (81.25)
Improved	10/13 (76.92)
Good	8/10 (80.00)
Moderate	2/10 (20.00)
Failed	3/13 (23.08)
Pancreatojejunal anastomosis	8/16 (50.00)
Double-duct type SOD	19/305 (6.23)
EST preferred	11/19 (57.89)
Improved	7/11 (63.64)
Failed	4/11 (36.36)
Exploratory laparotomy	12/19 (63.16)
Choledocho-, pancreato-intestinal anastomosis	7/12 (58.33)
Pancreatic head resection, choledocho-intestinal anastomosis	1/12 (8.33)
Duodenopancreatectomy	1/12 (8.33)
Biliary sphincterotomy, pancreato-intestinal anastomosis	3/12 (25.00)
Biliary-pancreatic reflux type SOD	41/305 (13.44)
EST preferred	34/41 (82.93)
Improved	20/34 (58.82)
Failed	14/34 (41.18)
Laparotomic BPD	16/41 (39.02)
Conservative treatment	5/41 (12.16)

SOD: Sphincter of Oddi dysfunction; EST: Endoscopic sphincterotomy; EPS: Endoscopic pancreatic duct sphincterotomy; BPD: Biliopancreatic diversion.

from 8 to 14 mm. Endoscopic bile duct sphincterotomy was performed twice in three months but without satisfactory curative effect. Consequently, an open abdominal surgery was performed at our center for frequent biliary colic. The common bile duct was transected, and then a cholangiojejunostomy was performed. During the two-year follow-up, liver function returned to normal levels and no further abdominal pain was reported by the patient.

Case 2: A 41-year-old man was diagnosed as having acute pancreatitis in June 2001 due to pains in the upper abdomen and an increase in blood amylase levels. The patient was discharged one week later. In October 2001, the patient experienced abdominal pain again and was diagnosed as having pancreatitis from a swollen pancreas head according to CT examination. In addition, B-mode ultrasonography detected small stones in the gallbladder. Laparoscopic cholecystectomy was performed in February 2002. Pancreatitis recurred dozens of times during the period from Febru-

ary 2002 to August 2003. Accordingly, emergent EST was then carried out, with subsequent intraoperative findings including a swollen ampulla of Vater, duodenal hyperemia, and mucosal edema. No bile flow was observed within the ampulla of Vater after a 10-mm incision was cut. This suggested that EST had failed, and ERCP could not be performed. In November 2003, EST was performed again when duodenal hyperemia and edema subsided. ERCP was successful, which indicated a narrow and flexuous common duct of the bile and pancreatic ducts. After a 15-mm incision in the ampulla of Vater was executed, bile flow was observed; however, it was still difficult to insert a tube into the bile duct. Even though bile samples were collected occasionally from the hepatic portal area through a tube for amylase measurement, the amylase level was still as high as 7600 U/L, demonstrating that the previous EST had failed to prevent pancreatitis. During a period of one year after the second EST, pancreatitis recurred eight times in this patient, indicating the failure of the second EST. Biliary-pancreatic shunting was then performed based on evidence of biliary-pancreatic reflux. In January 2005, the patient received transection of the common bile duct and choledochointestinal anastomosis. During the operation, the bile duct pressure was measured to be 12 cmH₂O, and the bile amylase level was 690 U/L. In addition, pancreatoscopy revealed an 11-mm stenotic segment of the common duct after two ESTs, and the common duct was tortuous, which may lead to biliary-pancreatic reflux. During the two-year follow-up, pancreatitis did not recur. Moreover, a CT scan performed one year after the last surgery showed obvious shrinkage of the swollen pancreatic head, indicating an effective relief of the edema.

RESULTS

Based on our clinical observations, we added the double-duct type and the biliary-pancreatic reflux type of SOD to the Milwaukee classification, to achieve greater clarity in the SOD clinical symptoms and to guide the clinical treatment of SOD. The therapeutic methods and effects using this new classification are shown in Table 3.

Biliary type SOD

Among the 305 patients, 229 (75.1%) definitively demonstrated biliary-type SOD, and 6 of them were not eligible for EST due to a diverticulum near the ampulla of Vater; these patients were treated by open abdominal surgery. Of the 213 patients who underwent EST, 202 (94.8%) were successfully treated, but 10 (4.9%) of these patients had unsatisfactory therapeutic effects after EST, with biliary colic and bile duct distension. EST failed in 11 (5.2%) patients. Hence, a total of 21 patients had unsatisfactory therapeutic effects or EST failure. In addition to the 16 patients for whom open abdominal surgery was initially prescribed, only 29 patients actually underwent surgery (choledochointestinal anastomosis in 21 patients and sphincteroplasty in 8 patients) and had good therapeutic effects. The other 8 patients underwent conservative treatment, but showed no stable therapeutic effects.

Table 3 Clinical classification and features of sphincter of Oddi dysfunction

Features	Bile duct type (type I)	Pancreatic duct type (type II)	Double-duct type (type III)	Biliary-pancreatic reflux type (type IV)
Abdominal pain	Retrosternal pain	Epigastric pain	I + II	Same as type II
Radiating pain	The central point of the back	The left back or indefinite site	I + II	Same as type II
Timing of onset	After high-fat meals	After ordinary meals	I + II	At night or in the morning
Jaundice	±	-	±	-
Liver enzyme levels	±	-	+	±
Serum amylase levels	-	+	±	+
Bile duct distension	≥ 10 mm	< 10 mm	≥ 10 mm	≥ 10 mm
Pancreatic duct distension	-	++	+	+
Anterograde cholangiography				
Voiding time	> 10 min	Normal	> 10 min	Unexpected pancreatic duct visualization

Pancreatic type SOD

There were 16 (5.3%) cases of the pancreatic type of SOD, and 3 of them had multiple stones that were difficult to remove thoroughly because they were located deep in the pancreatic duct. Therefore, EPS was not indicated for these 3 patients. The other 13 cases were first treated by EPS, but the treatment failed in 3 cases (a success rate of 76.9%). Hence, a total of 6 cases were managed with pancreatico-jejunostomy subsequently. The therapeutic effect was satisfactory in these cases. The other 10 patients treated by EPS (5 patients with pancreatic duct stent placement) were followed up for more than two years. Satisfactory therapeutic effects were exhibited in 8 (73%) patients, and the other 2 patients were then treated by subsequent open abdominal surgery. These cases suggest that open abdominal surgery may be helpful for treating SOD regardless of whether pancreatic duct stones are involved.

Double-duct type SOD

There were 19 (6.2%) cases of double-duct type SOD, in which both the bile duct and the pancreatic duct of the sphincter of Oddi were affected. Among them, 11 patients were treated by EST, and 7 (63.6%) were cured. The remaining 8 cases were treated surgically. A total of 12 cases were treated by open abdominal surgery. Seven patients underwent choledocho-intestinal anastomosis plus pancreato-intestinal anastomosis, and one was treated with a resection of the pancreatic head with the duodenum preserved, followed by choledocho-intestinal anastomosis. Duodenopancreatectomy was performed on one patient. The other three received biliary sphincterotomies by EST and pancreato-intestinal anastomosis to treat distension of the pancreatic duct. Follow-up results revealed good curative effects in these cases.

Biliary-pancreatic reflux type SOD

Forty-one cases (13.4%) of SOD met the profile of the biliary-pancreatic reflux type, and EST was performed in 34, with a success rate of 58.8% (20/34). Surgical treatment was preferentially carried out for 2 cases, and then, a total 16 cases underwent laparotomic biliopancreatic diversion (BPD). During a follow-up period of 0.5-7 years, 14 patients showed satisfactory therapeutic effects, and in the other 2 cases, sclerotic changes were observed throughout

the pancreas. After surgery, abdominal pain occurred occasionally and was significantly mitigated in these 2 cases. Five cases without receiving any treatment are under observation, and their symptoms still often occurred.

DISCUSSION

Although the Milwaukee classification system has been widely accepted for the classification of patients with suspected SOD, it has some potential problems. For example, the description of typical biliary or pancreatic pain may be interpreted differently by different doctors, which may lead to inappropriate referrals for SOM. In addition, according to the Milwaukee criteria, a CBD diameter of at least 12 mm is required for the diagnosis of SOD. Most patients being investigated for SOD have had their gallbladder removed, and in the past, it was believed to be normal for a post-cholecystectomy CBD to be dilated by 2-3 mm^[10]. Moreover, there is a question of whether patients with both biliary and pancreatic pain should be classified into the biliary type or the pancreatic type. Freeman *et al*^[11] stated that for this group, all patients should undergo biliary sphincterotomy, and 40% should have pancreatic sphincterotomies. How to interpret these clinical data? The Milwaukee classification has some limitations. In our study, there were 60 cases that could not be accurately interpreted by the Milwaukee classification criteria. Our long-term observation of the clinical cases suggests that our new classification based on anatomy, symptoms, endoscopic tests and radiological imaging is superior to the Milwaukee criteria in guiding the treatment of SOD. According to the Milwaukee criteria, the two types of SOD (biliary and pancreatic) can be further classified into three subtypes each, making classification complex. The newly proposed classification of SOD and the clinical characteristics associated with each type are listed in Table 3.

The new classification system presented in this paper is simpler than the initial one, but continues to closely follow the Milwaukee classification criteria. For example, biliary-type SOD patients only have biliary pain, and pancreatic-type SOD patients only have pancreatic pain. The two types are no longer divided into subtypes. MRCP usually shows the distension of bile ducts for biliary SOD and dilation solely of the pancreatic duct for pancreatic-

type SOD. With respect to treatment, EST can often yield better results for patients suffering from biliary SOD, and EPS should be a good choice of treatment for patients with pancreatic SOD.

We have paid more attention to the clinical characteristics and significance of the other two types of SOD, i.e. the double-duct and biliary-pancreatic reflux types.

In double duct type of SOD, both the biliary and pancreatic ducts of the sphincter of Oddi are affected. Clinical cases of SOD meeting these criteria have previously been reported but have not been definitively classified^[12]. The characteristics of this SOD type include symptoms typical of both biliary- and pancreatic-type SOD that appear simultaneously or alternately, with mobile positions of abdominal pain and radiating pain. Meanwhile, laboratory tests indicate elevated levels of liver-related enzymes and amylase in the blood. These findings usually result in the diagnosis of chronic biliary pancreatitis, manifested as mild abnormal liver function due to edema of the pancreatic head. Imaging exams usually show distension of both the bile and pancreatic ducts and stones in the pancreatic duct. Notably, frequently recurrent pancreatitis and evident distension of the pancreatic duct could mislead surgeons to focus on pancreatitis, thus underestimating the severity of mild bile duct distension, causing the neglect of possible SOD diagnoses, and resulting in unsuccessful treatment. Therefore, it is necessary to outline the double-duct type of SOD so that patients with these symptoms can be effectively treated. Case 1 is a typical SOD of the double-duct type, with mild bile duct distension due to sphincter of Oddi stenosis, and not due to compression by the head of the pancreas. This was proved by the finding that the obstruction in the extremity of the bile duct was not relieved even when the head of the pancreas was resected in the first operation. In patients with the double-duct type SOD, the sphincter of common duct is short, but the inferior stenotic segment of the bile duct is relatively long. Hence, patients with this form of SOD can be treated by surgery rather than EPS.

The anatomical basis for biliary-pancreatic reflux type of SOD is probably as follows: Patients may have a congenital abnormality in the convergence of the biliary and pancreatic systems, i.e. an overlong duct (> 11 mm). Inflammation and stenosis mainly occur in the sphincter of the common duct, whereas the sphincters of the superior bile duct and the pancreatic duct remain relatively normal or only mildly affected. If fibrosis of the ampullary septum causes dysfunction in the anti-reflux valve, reflux between the bile and pancreatic ducts is likely to occur. Repeated reflux of small amounts of bile into the pancreatic duct will usually induce pancreatitis, including recurrent chronic biliary pancreatitis and even severe acute pancreatitis. Although the clinical manifestations of this SOD are quite similar to those of the pancreatic duct type, there are a few differences: (1) As the reciprocal reflux between the fluids in the bile and pancreatic ducts is structurally barrier-free, the pancreatic duct orifice has no evident stenosis or obstruction, and so distension of the pancreatic duct does not occur; (2) Because there was only mild biliary-pancreatic reflux in most cases, the pancreatic duct and

gland alveoli in the head of the pancreas near the biliary-pancreatic convergence were usually affected, inducing swelling of the pancreatic head, as indicated by imaging examination. Therefore, these cases are sometimes diagnosed as pancreatitis with a pancreatic head mass. Some authors have reported tumor-like features of chronic pancreatitis, and some of these cases may suffer from biliary-pancreatic reflux^[13,14]; (3) In this type of SOD, EST failed to incise the stenotic segment of the sphincter of Oddi due to the slender and tortuous common duct. EST was successful in only 56% of cases with this type of SOD at our center. However, the achievement ratio of incision on the normal ampulla of Vater was nearly 100%^[15,16]. Moreover, some patients can only be treated by open abdominal surgery due to failure to incise the stenotic common duct after several attempts by EST; and (4) The amylase levels in bile sampled from the biliary tract during ERCP in biliary-pancreatic-reflux-type SOD patients were about 2-10 times higher than normal.

Although distension does not always occur in the pancreatic duct and is usually slight in the biliary duct in the early stages of biliary-pancreatic reflux SOD, the symptoms of pancreatitis may be more serious than those in the simple pancreatic-type SOD. Because the common duct of the bile and pancreatic ducts is simply a potential duct due to the tension of the sphincter of Oddi, an image of an over long common duct was obtained from ERCP or MRCP in only a few cases. Case 2 mentioned above illustrates that the therapeutic effects of BPD were satisfactory for the biliary-pancreatic-reflux-type SOD patients who failed in EST. This demonstrates the significance of using the biliary-pancreatic reflux type classification for SOD.

In summary, the new classification of SOD proposed in this study demonstrates significant advantages for guiding the diagnosis and treatment of SOD patients in China, as compared with the conventional Milwaukee criteria. Nonetheless, further investigations on the applicability of this quaternary classification system to patients in other regions are needed.

COMMENTS

Background

Sphincter of Oddi dysfunction (SOD) is a pathological syndrome that is usually classified into the biliary type or the pancreatic type according to the Milwaukee criteria. However, this classification has some drawbacks in clinical practice, some of which result in flawed classification and failure to properly guide diagnosis and treatment.

Research frontiers

The conventional SOD classification system is insufficient in guiding the clinical treatment of all SOD patients. The authors conducted a retrospective analysis of 305 patients with SOD according to the clinical records in the past 10 years, and proposed a modified classification system based on the Milwaukee classification, which includes all SOD symptoms.

Innovations and breakthroughs

The authors proposed a new classification system for SOD according to anatomy, symptoms, endoscope tests and radiological imaging, i.e. SOD is divided into four types instead of two types: the biliary-type, the pancreatic-type, the double-duct type and the biliary-pancreatic reflux type. The new classification demonstrates significant advantages for guiding the diagnosis and treatment of SOD patients in China, as compared with the conventional Milwaukee criteria.

Applications

The new classification system has significant advantages for guiding the diagnosis and treatment of SOD patients, thus improving the clinical treatment of SOD.

Peer review

In order to solve some problems of the Milwaukee classification of SOD, the authors have proposed a new interesting classification. Compared with the Milwaukee classification, the new classification system presented in this paper is simpler than the Milwaukee classification, better explains clinical symptoms of the disease from the anatomical perspective, and should have some application values in guiding the diagnosis and treatment of SOD.

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