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ABOUT COVER

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ORIGINAL ARTICLE

Clinical Trials Study

Evaluating the efficacy of endoscopic sphincterotomy on biliary-type sphincter of Oddi dysfunction: A retrospective clinical trial

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Abstract

BACKGROUND

Although endoscopic sphincterotomy (EST) has a positive therapeutic effect on biliary-type sphincter of Oddi dysfunction (SOD), some patients still have little relief after EST, which implies that other functional abdominal pain may also be present with biliary-type SOD and interfere with the diagnosis and treatment of it.

AIM

To retrospectively assess EST as a treatment for biliary-type SOD and analyze the importance of functional gastrointestinal disorder (FGID) in guiding endoscopic treatment of SOD.

METHODS

Clinical data of 79 patients with biliary-type SOD (type I and type II) treated with EST at Affiliated Hospital of Guizhou Medical University from January 2014 to January 2019 were retrospectively collected to evaluate the clinical therapeutic effect of EST. The significance of relationship between FGID and biliary-type SOD was analyzed.

RESULTS

Seventy-nine patients with biliary-type SOD received EST, including 29 type 1 patients and 50 type 2 patients. The verbal rating scale-5 (VRS-5) scores before

EST were all 3 or 4 points, and the scores decreased after EST; the difference was statistically significant ($P < 0.05$). After EST, the serum indexes of alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase and total bilirubin in biliary-type SOD were significantly lower than before ($P < 0.05$). After EST, 67 (84.8%) and 8 (10.1%) of the 79 patients with biliary-type SOD had obviously effective (VRS-5 = 0 points) and effective treatment (VRS-5 = 1-2 points), with an overall effectiveness rate of 94.9% (75/79). There was no difference in VRS-5 scores between biliary-type SOD patients with or without FGID before EST ($P > 0.05$). Of 12 biliary-type SOD (with FGID) patients, 11 had abdominal pain after EST; of 67 biliary-type SOD (without FGID) patients, 0 had abdominal pain after EST. The difference was statistically significant ($P < 0.05$). The 11 biliary-type SOD (with FGID) patients with recurrence of symptoms, the recurrence time was about half a year after the EST, and the symptoms were significantly relieved after regular medical treatment. There were 4 cases of post-endoscopic retrograde cholangiopancreatography pancreatitis (5.1%), and no cholangitis, bleeding or perforation occurred. Patients were followed up for 1 year to 5 years after EST, with an average follow-up time of 2.34 years, and there were no long-term adverse events such as sphincter of Oddi restenosis or cholangitis caused by intestinal bile reflux during the follow-up.

CONCLUSION

EST is a safe and effective treatment for SOD. For patients with type I and II SOD combined with FGID, single EST or medical treatment has limited efficacy. It is recommended that EST and medicine be combined to improve the cure rate of such patients.

Key Words: Sphincter of Oddi dysfunction; Endoscopic sphincterotomy; Functional gastrointestinal disorders; Functional dyspepsia; Functional heartburn; Irritable bowel syndrome; Curative effect

Core Tip: This article retrospectively analyzed the effect of endoscopic sphincterotomy on biliary-type sphincter of Oddi dysfunction (SOD), which increased the pain score system and the breakdown of SOD types. At the same time, functional gastrointestinal disorder and SOD are both functional diseases and often co-occur, thus affecting the endoscopic treatment of SOD. For this type of patient, this article gives appropriate guidance and treatment opinions.

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INTRODUCTION

The sphincter of Oddi is a group of fibromuscular structures surrounding the common bile duct, pancreatic duct and common channel, which was first reported by Ruggero Oddi in 1887[1]. Biliary-type sphincter of Oddi dysfunction (SOD) has two pathogenesis mechanisms: functional motor dysfunction and benign stenosis[2]. EST has a good effect on benign organic stenosis, but its efficacy in the treatment of functional biliary-type SOD has been controversial[3]. Some patients still have no improvement in symptoms after EST, which may be related to functional gastrointestinal disorders (FGID)[4]. FGID are the most common gastrointestinal diseases, with an incidence of 10%-20% in the population[5]. Clinically, functional dyspepsia (FD), functional heartburn (FH) and irritable bowel syndrome (IBS) are more common[6]. They are more likely to occur in women and have similar symptoms of functional abnormal

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pain or cross symptoms, and the symptoms recur[7]. It has been reported that 33.3% of patients with biliary-type SOD may also have FD, FH and IBS[8]. FD, FH and IBS have the same pathophysiological mechanisms (such as visceral hypersensitivity), which may also appear in biliary-type SOD[9,10]. EST is an effective treatment for biliary-type SOD without for FGID[4]. FGID interferes with the diagnosis and treatment of biliary-type SOD. There are few reports showing the relationship between biliary-type SOD and FGID.

This article integrates the diagnosis and treatment standards of biliary-type SOD, retrospectively analyzes the clinical data of 79 patients with type I and type II SOD treated by EST, scientifically evaluates the clinical diagnosis and treatment and analyzes the relationship of FGID and biliary-type SOD.

MATERIALS AND METHODS

Data collection

The clinical data of 910 patients diagnosed and treated with endoscopic retrograde cholangiopancreatography (ERCP) in the Department of Hepatobiliary Surgery, Affiliated Hospital of Guizhou Medical University from January 2014 to January 2019 were retrospectively collected (all performed by one operator). The inclusion criteria for patients with biliary-type SOD were as follows: (1) Conformed to the diagnostic criteria for biliary abdominal pain (Rome IV[11]); and (2) Had abnormal serum indexes of alanine aminotransferase, aspartate aminotransferase, total bilirubin or alkaline phosphatase > 2 times the normal values documented on 2 or more occasions and/or had a dilated bile duct greater than 8 mm in diameter. The exclusion criteria were as follows: (1) Abdominal ultrasound, computed tomography and magnetic resonance cholangiopancreatography were suspicious for bile duct stones, tumors or other biliary obstruction lesions; or (2) Pain was significantly related to defecation, postural changes and the use of antacid drugs such as proton pump inhibitors, histamine type-2 receptor antagonists, calcium or magnesium salts, *etc*. According to the revised Milwaukee classification[11], patients with biliary-type SOD are divided into type I and type II (excluding type III cases).

According to the above criteria, patients with type I and type II biliary-type SOD were selected, and those with cholelithiasis, benign and malignant tumors of the biliary tract, pancreatobiliary malfunction, pancreatic divisum, intrahepatic bile duct stenosis and biliary ascariasis, *etc*., were excluded. In total, 79 patients with biliary-type SOD were finally included in this study, including 27 males and 52 females (male:female approximately = 1:2) aged 8 to 85 years (average 58.72 ± 14.16 years).

According to the impression of the endoscopist's first visit to the patient, the gastrointestinal endoscopy and other auxiliary examination tools were used for diagnosis and in strict accordance with the diagnostic criteria of FGID of Rome IV, a total of 12 FGID patients were screened out of 79 SOD patients. Among them, combined FD, FH and IBS accounted for 5 cases, 4 cases and 3 cases, respectively. There were 29 cases of type I and 50 cases of type II biliary-type SOD. In type II patients, with elevated liver enzymes and no dilated bile ducts were divided into group Type IIa, and patients with normal liver enzymes but dilated bile ducts were divided into group Type IIb. There were 6 patients in group Type IIa and 44 patients in group Type IIb. The diagnostic criteria for FGID are shown in Figure 1. The general data of biliary-type SOD patients are shown in Table 1.

Preoperative evaluation

According to the effect of abdominal pain symptoms on the quality of life of patients with biliary-type SOD, the Verbal Rating Scale-5 (VRS-5)[12] was used to assess the degree of abdominal pain in the patients, which was coded as 0 - 4 points according to the severity of abdominal pain. The VRS-5 score system is shown in Table 2.

Biliary-type SOD patients with FGID were given medical therapy: patients with FD were given acid suppression and other drug treatments for gastrointestinal motility and digestion; patients with IBS were given antispasmodics, laxatives, intestinal microecological preparations and other drug treatments; and patients with FH were given symptomatic supportive therapy such as acid suppression and gastrointestinal motility treatments. All SOD patients including 12 patients with FGID who had undergone medical treatment in this test with poor symptom improvement and VRS-5 scores of 3 to 4 were given EST.

Table 1 General information of biliary-type sphincter of Oddi dysfunction patients

Characteristic	Type I, *n* = 29	Type IIa, *n* = 6	Type IIb, *n* = 44
Sex (male/female)	8/21	4/2	15/29
Age [mean (SD), yr]	59.10 ± 17.36	56.00 ± 19.03	58.84 ± 11.14
With FH (*n*)	1	0	4
With IBS (*n*)	0	0	2
With FD (*n*)	1	1	3
ALT [M (IQR), U/L]	209.90 (121.55-361.39)	170.02 (110.25-203.36)	25.65 (16.75-66.50)
AST [M (IQR), U/L]	194.66 (75.90-345.50)	136.78 (48.81-175.61)	28.00 (22.32-360.06)
TBIL [M (IQR), mg/dL]	4.52 (3.13-8.13)	6.09 (4.24-11.23)	1.69 (1.15-3.12)
ALP [M (IQR), U/L]	199.44 (155.73-311.78)	354.70 (201.68-470.88)	98.20 (78.20-117.40)
Bile duct diameter [M (IQR), cm]	1.20 (1.00-1.50)	0.80 (0.78-0.80)	1.50 (1.10-2.00)

FD: Functional dyspepsia; FH: Functional heartburn; IBS: Irritable bowel syndrome; ALT: Alanine aminotransferase; AST: Aspartate aminotransferase; ALP: Alkaline phosphatase; TBIL: Total bilirubin; SD: SD; M; Median; IQR: Interquartile range.

Table 2 Verbal rating scale-5 scoring system

0 points	No pain
1 point	Mild pain that is tolerable with normal life and sleep
2 points	Moderate pain that can interfere with proper sleep and requires analgesics
3 points	Severe pain and disturbed sleep that require anesthesia and analgesics
4 points	Severe pain causing severe interference with sleep accompanied by other symptoms or passive posture

FGID	FGID is defined as chronic and recurrent functional gastrointestinal symptoms and is diagnosed according to gastrointestinal endoscopy and other auxiliary examination tools to exclude gastrointestinal organic changes. This mainly includes FH, FD and IBS.
FD	FD is manifested as epigastric pain, postprandial fullness,early satiation, and other symptoms, including bloating in the upper abdomen, nausea, vomiting and belching.
FH	FH refers to repeated episodes of post-sternal burning without pathological gastroesophageal reflux or pathologically based abnormalities in the gastric or esophageal motility or structure. The 24-hour esophageal pH monitoring esophageal acid exposure time was normal.
IBS	IBS is defined as a condition of recurrent abdominal pain associated with defecation or a change in bowel habits. The recurrent abdominal pain must have two or more of the following characteristics: (1) related to defecation, (2) associated with a change in stool frequency, or (3) associated with a change in stool form.

Figure 1 Diagnostic criteria for functional gastrointestinal disorder. FGID: Functional gastrointestinal disorder; FD: Functional dyspepsia; FH: Functional heartburn; IBS: Irritable bowel syndrome.

Equipment and consumables

TJF260V electronic duodenoscope (Olympus Corporation), disposable radiography catheter (Olympus Corporation), three-chamber papillary sphincterotomy (Cook company), needle knife (Olympus Corporation), yellow zebra guide wire (Olympus Corporation), balloon dilatation catheter (Cook Endoscopy), stone extraction balloon

(Olympus Corporation), transnasal external bile drainage tube (Olympus Corporation), bile duct and pancreatic duct stent (Cook Endoscopy).

Operative procedure and postoperative treatment

After completing the preoperative examination and obtaining informed consent for ERCP, the diagnosis and treatment of ERCP began, and the preoperative evaluation and intraoperative conditions were given corresponding endoscopic treatment, including endoscopic sphincterotomy (EST), endoscopic retrograde biliary drainage (ERBD), endoscopic retrograde pancreatic drainage and endoscopic nasobiliary drainage (ENBD).

All patients underwent EST. For patients with obvious bile duct dilatation, ERBD was performed. ENBD was performed after the operation to prevent postoperative papillary edema and post-ERCP pancreatitis. If the guide wire repeatedly entered the pancreatic duct during ERCP, then to prevent post-ERCP pancreatitis endoscopic retrograde pancreatic drainage may be performed depending on the situation.

If ENBD was performed after EST, the tube shall be removed within 3 d after EST according to the patient's condition. For patients undergoing ERBD or endoscopic papillary balloon dilation, the tubes fell off within 3 mo of treatment after EST in most circumstances. If the tube has not fallen off after 3 mo, it shall be taken out with ERCP for the second time.

Those who had postoperative adverse events were fasted and treated with gastrointestinal decompression, acid suppression, anti-inflammatory agents and other comprehensive treatment or repeated endoscopic and surgical treatment.

Postoperative observation indicators

The improvement in various serum indicators in patients with biliary-type SOD was observed 1 wk after EST. All patients were followed up after EST, with a follow-up interval of 1 year to 5 years. VRS-5 scoring methods were used to evaluate the improvement in symptoms of patients after EST, with 0 being obviously effective, 1 to 2 being effective and 3 to 4 being ineffective.

Biliary-type SOD patients with FGID before EST were followed up to observe if their gastrointestinal symptoms had improved, and those with poor symptom resolution (patients still having VRS-5 score of 3 or 4) continued to be given medical supportive treatment.

Statistical analysis

Statistical analysis software 25.0 was used for data analysis. Measurement data conforming to a normal distribution were expressed as the mean ± SD. Measurement data that did not conform to a normal distribution were expressed as the median (interquartile range), and the Mann-Whitney *U* test was used to analyze these data. Count data are expressed as a percentage (%), and Fisher's exact probability method was used to analyze these data. Grade data were analyzed with the Mann-Whitney *U* test. $P < 0.05$ was considered statistically significant.

RESULTS

Biliary-type SOD diagnosis and treatment

The preoperative VRS-5 scores of 79 patients were all 3 and 4 points; among them, the symptoms of 12 patients with FGID did not receive relief with medication. All patients were given EST. The VRS-5 score of biliary-type SOD before EST was shown in Table 3. ERCP intraoperative situation was shown in Table 4.

Within 1 wk after endoscopic treatment, all patients' symptoms were relieved, and the serum indexes of alanine aminotransferase, aspartate aminotransferase, total bilirubin and alkaline phosphatase were significantly lower than before ($P < 0.05$) (Table 5). Sixty-six patients who used ENBD during the EST were removed within 3 d after the ERCP, and the average extubation time was 2.15 ± 0.44 d. In the 12 patients who underwent ERBD and endoscopic papillary balloon dilation, all the tubes fell off within 3 mo after EST, and the average time for the tubes to fall off by itself was 37.65 ± 11.48 d. Postoperative hyperamylasemia occurred in 2 cases, and pancreatitis occurred in 4 cases (5.1%), all of which were mild and improved with conservative treatment. No postoperative cholangitis, bleeding or perforation adverse events occurred.

Table 3 Verbal rating scale-5 scores before endoscopic sphincterotomy in biliary-type sphincter of Oddi dysfunction patients

Biliary-type SOD	0 points	1 point	2 points	3 points	4 points
Type I, *n*	0	0	0	26	3
Type II, *n*	0	0	0	43	7
Total, *n*	0	0	0	69	10

SOD: Sphincter of Oddi dysfunction patients.

Table 4 Endoscopic retrograde cholangiopancreatography intraoperative situation

Successful intubation rate	*n* = 79
EST	79
With ENBD	66
With EPBD	21
With ERBD	8
With ERPD	4
The average CBD in cm	1.4 (range: 1.0-1.8)
The average EST incision length in cm	0.52 ± 0.16

SOD: Sphincter of Oddi dysfunction; ERBD: Endoscopic retrograde biliary drainage; ERPD: Endoscopic retrograde pancreatic drainage; ENBD: Endoscopic nasobiliary drainage; CBD: Common bile duct diameter; EST: Endoscopic sphincterotomy; EPBD: Endoscopic papillary balloon dilation.

Table 5 Comparison of serum index results before and after endoscopic sphincterotomy in biliary-type sphincter of Oddi dysfunction patients

Serum index[1]	Biliary-type SOD		*P* value
	Pre-EST	Post-EST	
ALT [M (IQR), U/L]	70.00 (24.10-190.03)	29.22 (18.00-58.00)	< 0.001
AST [M (IQR), U/L]	61.51 (26.08-157.79)	30.59 (22.00-64.00)	< 0.001
TBIL [M (IQR), mg/dL]	2.98 (1.49-5.02)	2.00 (1.14-3.03)	0.004
ALP [M (IQR), U/L]	129.00 (91.50-220.91)	7.60 (3.70-12.30)	< 0.001

[1]The serum index was 1 wk before and after endoscopic sphincterotomy.
SOD: Sphincter of Oddi dysfunction; EST: Endoscopic sphincterotomy; ALT: Alanine aminotransferase (Reference range: 5-40 U/L); AST: Aspartate aminotransferase (Reference range: 8-40 U/L); ALP: Alkaline phosphatase (Reference range: 40-110 U/L); TBIL: Total bilirubin (Reference range: 1.71-17.1 U/L).

Postoperative follow-up results

The patients were followed up for 1 year to 5 years, with a median follow-up time of 2.34 years. No patients were lost to follow-up. The VRS score of SOD patients decreased significantly after EST ($P < 0.05$) (Tables 6-7). The 8 SOD patients with ENBD and 21 SOD patients with endoscopic papillary balloon dilation during the ERCP were either spontaneously detached or removed under ERCP within 4 mo. No postoperative adverse events such as restenosis of the sphincter of Oddi or cholangitis due to intestinal biliary reflux occurred. None of the patents underwent EST or other surgery again.

The therapeutic effect of EST on SOD is shown in Tables 8-9. There was no statistically significant difference in the overall effectiveness between the type I and type II ($P = 0.291$) and Type IIa and Type IIb ($P = 0.317$).

Of the 12 patients with biliary-type SOD combined with FGID before EST, 11 patients had abdominal pain again with digestive symptoms approximately 6 mo after EST (Table 10), including 4 cases with FH, 2 cases with IBS and 5 cases with FD. Only 1

Table 6 Comparison of verbal rating scale-5 before and after endoscopic sphincterotomy in sphincter of Oddi dysfunction patients

Biliary-type SOD	Period	0 points	1 point	2 points	3 points	4 points	*P* value
Type I (*n*)	Pre-EST	0	0	0	26	3	< 0.001
	Post-EST	24	5	0	0	0	
Type II (*n*)	Pre-EST	0	0	0	43	7	< 0.001
	Post-EST	43	1	2	4	0	

SOD: Sphincter of Oddi dysfunction; EST: Endoscopic sphincterotomy.

Table 7 Comparison of verbal rating scale-5 before and after endoscopic sphincterotomy in Type IIa/b sphincter of Oddi dysfunction patients

Biliary-type SOD	Period	0 points	1 point	2 points	3 points	4 points	*P* value
Type IIa (*n*)	Pre-EST	0	0	0	6	0	< 0.001
	Post-EST	6	0	0	0	0	
Type IIb (*n*)	Pre-EST	0	0	0	37	7	< 0.001
	Post-EST	37	1	2	4	0	

SOD: Sphincter of Oddi dysfunction; EST: Endoscopic sphincterotomy.

Table 8 Curative effect of biliary-type sphincter of Oddi dysfunction patients

Biliary-type SOD	Obviously effective	Effective		Ineffective		Total, *n*	Overall effectiveness, %
	0 points	1 point	2 points	3 points	4 points		
Type I, *n*	24	5	0	0	0	29	100.0
Type II, *n*	43	1	2	4	0	50	92.0

Overall effectiveness (%) = (Obviously effective + Effective)/Total × 100%. SOD: Sphincter of Oddi dysfunction.

Table 9 Curative effect of Type IIa/b sphincter of Oddi dysfunction patients

Biliary-type SOD	Obviously effective	Effective		Ineffective		Total, *n*	Overall effectiveness, %
	0 points	1 point	2 points	3 points	4 points		
Type IIa, *n*	6	0	0	0	0	6	100
Type IIb, *n*	37	1	2	4	0	44	90.9

Overall effectiveness (%) = (Obviously effective + Effective)/Total × 100%. SOD: Sphincter of Oddi dysfunction.

case with FH did not show any discomfort after surgery. Re-examination of liver enzyme indicators and common bile duct structure showed no abnormalities in these 11 patients with abdominal pain again. Patients with FD were treated with gastrointestinal motility and digestive drugs such as acid suppression. Patients with IBS were treated with antispasmodic, laxative and intestinal microecological preparations. Patients with FH were treated with acid suppression and gastrointestinal motility. After taking the medicine for about 1 wk, the patients' symptoms were obviously controlled again, no abdominal pain occurred, and the VRS-5 score was 0.

Table 10 Comparison of verbal rating scale-5 scores of biliary-type sphincter of Oddi dysfunction patients (with/without functional gastrointestinal disorders) before and after endoscopic sphincterotomy

Period	Case	0 points, *n*	1 point, *n*	2 points, *n*	3 points, *n*	4 points, *n*	*P* value
Pre-EST	With FGID	0	0	0	10	2	0.271
	Without FGID	0	0	0	59	8	
Post-EST	With FGID	1	0	0	7	4	< 0.001
	Without FGID	66	1	0	0	0	

FGID: Functional gastrointestinal disorders; EST: Endoscopic sphincterotomy.

DISCUSSION

Evaluation of diagnosis and treatment of biliary-type SOD

The Rome III guidelines divide the biliary-type SOD into three types and determine the patient's treatment according to Milwaukee classification criteria and sphincter of Oddi manometry (SOM) results[13-14]. The modified Milwaukee classification system recommends the use of a non-invasive method instead of ERCP to measure the diameter of the common bile duct and suggests that the biliary contrast agent emptying time should no longer be used as the basis for diagnosis, making it more suitable for clinical practice[15]. Cotton[16] found that the clinical remission rate of patients with type III with EST was only 23%. In addition, patients with type III showed a high degree of somatization disorders, depression, obsessive-compulsive behavior and anxiety, which can cause dysfunction of the papillary sphincter[17]. Thus, endoscopy is not recommended for patients with type III, and the Rome IV guidelines remove biliary-type III SOD and categorize it as a functional digestive disease. There is evidence of organic biliary obstruction in patients with type I SOD, which is not a functional disease. Therefore, the Rome IV guidelines exclude previous patients with type I. Although the Rome IV guidelines only preserve the diagnosis of biliary-type II SOD, type I and type II include benign organic stenosis of the biliary sphincter, and all meet the diagnostic criteria for biliary abdominal pain, with abnormal liver enzymes and changes in the structure of the bile duct. Therefore, discussing EST has important value for the efficacy of treatment of the two types of biliary type SOD. This study included biliary-type SOD patients with type I and type II but did not include those with type III.

Biliary-type SOD is due to abnormal contraction of the biliary sphincter, resulting in obstruction of bile outflow through the bile duct and pancreatic duct junction, which leads to a series of clinical syndromes such as biliary abdominal pain[18]. EST can relieve the abnormal resistance of the sphincter of Oddi so that the clinical symptoms of patients are relieved, and the purpose of effective treatment is achieved[19], which is an important measure for biliary-type SOD[20]. A prospective study of EST in patients with biliary-type SOD found that symptoms disappeared in 96% of patients [5]. In this study, among 79 patients with biliary-type SOD, preoperative VRS-5 scores of 0, 1, 2, 3 and 4 points each accounted for 0 cases, 0 cases, 0 cases, 69 cases and 10 cases, respectively; postoperative VRS-5 scores of 0, 1, 2, 3 and 4 points each accounted for 67 cases, 6 cases, 2 cases, 4 cases and 0 cases, respectively. The VRS-5 score decreased significantly compared with the preoperative score ($P < 0.05$). Of 79 cases, 67 cases (84.8%) and 8 cases (10.1%) were obviously effective and effective, respectively. The overall effectiveness rate was high.

For type I disease, Sugawa *et al*[21] treated 8 patients with EST; all patients had not undergone SOM and were followed up for an average of 26 mo. All their symptoms were relieved. In this study, 29 patients with type I disease were treated with EST, and 24 cases (82.8%) were obviously effective, 5 cases (17.2%) were effective, and the overall effective rate was 100.0% (29/29). The literature also shows that EST can relieve the pain symptoms of biliary-type SOD patients, with an effective rate of 87% to 100% [22]. Most scholars recommend that biliary-type SOD patients be directly treated with EST without SOM[18]. In this trial, EST has a significant effect on patients with type I, which is consistent with the previous reports.

For type II disease, it has been previously believed that patients should first undergo SOM to determine whether the base pressure of the papilla sphincter is elevated; then, whether to perform EST based on abnormal findings should be determined[23]. Factors such as limited availability, needing an experienced operator,

technical challenges in performing SOM and difficulty interpreting the results often put SOM out of reach. Ali[24] found that the remission rate (55%) of patients with type II disease who were treated with EST after SOM confirmation was not significantly different from that of those who were treated by experienced endoscopists (60%). The patients' clinical characteristics, aminotransferase levels and abdominal pain characteristics are not related to the SOM results. Furthermore, SOM is susceptible to interference by multiple factors such as abdominal pressure and anesthetic effects. The lack of objective and accurate measurement results may even lead to many unnecessary adverse events. In this study, 50 patients with type II disease were treated with EST; 43 cases (86.0%) were obviously effective, 3 cases (6.0%) were effective, and the overall effective rate was 92.0% (46/50). Although the measurement of SOM is an important method to determine the therapeutic effect of biliary-type SOD, the increase in the basal pressure of the sphincter of Oddi is not completely parallel to the clinical symptoms and treatment. It is not possible to determine the curative effect for type II alone. In this group of 51 patients, no SOM test was performed before EST, and the overall efficacy was satisfactory.

The test found that the treatment rate of EST for type IIa and type IIb patients was 100% (6/6) and 90.9% (38/44), which has good clinical effect for the two types. However, clinical practice is more inclined to carry out EST for type IIb patients. EST has a good effect for type IIa patients only with elevated liver enzymes, but a larger sample size is still needed for further verification.

Relationship between FGID and SOD

FGID is a group of chronic, recurrent symptomatic functional diseases without organic changes in the gastrointestinal tract. The diagnosis of the disease mainly relies on similar clinical symptoms and no other pathological diseases that can be explained [25]. Traditional medical treatment of FGID is mainly to change bowel habits or improve visceral pain, such as with antispasmodic drugs, laxatives and others[26]. In addition, regulation of gastrointestinal microorganisms and gastrointestinal nerve regulation and some psychological treatment methods can be used to alleviate the clinical symptoms of patients[27]. The treatment of biliary-type SOD is different from that of FGID. Endoscopic treatment to relieve the obstruction of the papilla sphincter can effectively relieve the patients' symptoms and improve biochemical indicators, but it has no obvious benefit on Rome III functional dyspepsia subdivision in postprandial distress syndrome and epigastric pain syndrome. There are few articles reporting the relationship and importance of biliary-type SOD and differential diagnosis of FGID [25].

In this study, 12 patients with recurrent abdominal pain after endoscopic treatment had a higher proportion of biliary-type SOD with FGID (11/12). There was no difference in VRS-5 scores between patients with biliary-type SOD (with FGID) and biliary-type SOD (without FGID) before EST ($P > 0.05$). Of the 12 biliary-type SOD (with FGID) patients, 11 patients had abdominal pain after EST; of 67 biliary-type SOD (without FGID) patients, 0 patients had abdominal pain after EST. Biliary-type SOD patients with FGID were more prone to experience abdominal pain after EST ($P < 0.05$). FGID and biliary-type SOD have similar functional abdominal pain associations, affecting the clinician's judgment of biliary-type SOD and affecting the performance of EST for SOD, which is an interfering factor for the curative effect of SOD. Clinical identification of FGID before EST is the key factor affecting the efficacy of EST for biliary-type SOD. After a clear diagnosis of this type of patient, only medication or endoscopic treatment has limited efficacy. It is recommended that appropriate medical treatment be given, while active endoscopic treatment is the key to improving the treatment of such patients. Similar to the conclusions of other studies, in biliary-type SOD patients with gastric emptying disorder, EST treatment was not effective (38%) in Freeman *et al*[28] study. Miyatani *et al*[4] retrospective study also showed that FD was a risk factor for recurrence of abdominal pain in patients with type I and type II disease.

Regarding the relationship between FGID and biliary-type SOD, there are few clinical related studies. This manuscript retrospectively assessed the effect of EST as a treatment for biliary-type SOD as well as the relationship between the comorbidity of FGID and treatment success. There are deficiencies in this study, but it is mainly a retrospective study. It is difficult to accurately diagnose SOD in patients with FGID, and more prospective randomized trials are needed to confirm.

CONCLUSION

In summary, this study suggests that EST is a minimally invasive, safe and effective treatment, and it has a definite curative effect on type I and type II biliary SOD. It is recommended to carefully identify the interfering factors of FGID for the diagnosis and treatment of biliary-type SOD. For patients with type I and II SOD combined with FGID, single EST or medical treatment has limited efficacy. It is recommended that EST and medicine be combined to improve the cure rate of such patients.

ARTICLE HIGHLIGHTS

Research background

Although endoscopic sphincterotomy (EST) has a positive therapeutic effect on biliary-type sphincter of Oddi dysfunction (SOD), some patients still have little relief after EST, which implies that other functional abdominal pain may also be present with biliary-type SOD and interfere with the diagnosis and treatment of it.

Research motivation

This study explored the efficacy of EST in the treatment of biliary-type SOD and analyzed the reasons for the uncertainty of the efficacy of EST in the treatment of this kind of patients, that is, with FGID. The combined treatment of this kind of patient is the key to improve the efficacy of EST in the treatment of biliary-type SOD.

Research objectives

The objective was to investigate the therapeutic effect of EST in biliary-type SOD and analyze the reasons for the uncertainty of its curative effect to improve the curative effect of endoscopic therapy in this type patients.

Research methods

This study compared and analyzed the clinical remission of different types of SOD patients after EST, including indicators such as postoperative pain, transaminase recovery and so on. The follow-up time was long, and the number of cases was sufficient.

Research results

This study suggested that EST is a minimally invasive, safe and effective treatment. For patients with type I and II SOD combined with FGID, single EST or medical treatment has limited efficacy. It is recommended that EST and medicine be combined to improve the cure rate of such patients. There are deficiencies in this study, but it is mainly a retrospective study. It is difficult to accurately diagnose SOD in patients with FGID, and more prospective randomized trials are needed to confirm.

Research conclusions

EST is a minimally invasive, safe and effective treatment. For patients with type I and II SOD combined with FGID, single EST or medical treatment has limited efficacy. It is recommended that EST and medicine be combined to improve the cure rate of such patients.

Research perspectives

There is a close relationship between FGID and biliary-type SOD, and more prospective randomized trials are needed to clarify their relationship in the future.

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