ORIGINAL ARTICLE

Normal serum bilirubin level is the risk factor for post-ERCP pancreatitis in Sphincter of Oddi dysfunction types I and II

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ABSTRACT

Aim: To evaluate the risk factors for PEP in SOD types I and II.

Materials and Methods: We retrospectively analyzed 107 cases of SOD type I, II with undergoing ERCP. Potential risk factors for PEP were investigated: age<60 years, gender, history of cholecystectomy, history of EST, normal serum bilirubin level, common bile duct≤10 mm, gallbladder stones, periamullary diverticulum, papilla size ≥15 mm, initial ERCP success, selective biliary cannulation, pancreatic cannulation/injection, Precut and EST. Factors both significant (p<0.05) for univariate and multivariate analyses were identified as independent risk factor for PEP.

Results: The overall PEP rate was 14% (15/107). Univariate analysis ($\chi 2$) showed that only bilirubin level was significantly (p<0.05) associated with PEP. Multivariate analysis by multinomial regression showed that two factors were associated with PEP – normal bilirubin level (OR 9.574, 95% CI 1.869-49.034, p=0.007) and Precut (OR 0.116, 95% CI 0.014-0.979, p=0.048).

Conclusions: Normal serum bilirubin level is an independent risk factor for PEP in patients with Type I and Type II of SOD. In cases of suspected or confirmed Type I, II of SOD with normal bilirubin level, ERCP with EST should be avoided and replaced by medical treatment or, if ERCP had been chosen, advanced PEP prophylactic measures should be done.

KEY WORDS: Endoscopic retrograde cholangiopancreatography, sphincter of Oddi dysfunction, ERCP, post-ERCP pancreatitis, risk factor

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INTRODUCTION

Sphincter of Oddi dysfunction (SOD) is a benign motility disorder caused by either dyskinesia or stenosis of the sphincter of Oddi. The pathogenesis of the SOD is not well understood. It may have multiple clinical features often simultaneous: episodic pain in the epigastrium or the right upper quadrant, nausea, vomiting, jaundice and recurrent pancreatitis. Depending on clinical features and laboratory findings it has been categorized into biliary and pancreatic SOD [1,2].

According to the modified Milwaukee classification system, biliary SOD is classified into 3 types based on symptoms, biochemical abnormalities, and imaging results [3, 4]. Type I SOD is defined as biliary-type pain with both elevated liver enzymes and a dilated bile duct. Type II SOD presents with biliary-type pain with either elevated liver enzymes or a dilated bile duct. Type III SOD patients have biliary-type pain only without biochemical or imaging abnormalities [1].

Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (EST) plays an important role in SOD management. It was confirmed by retrospective and prospective randomized trials that EST is an effective treatment for biliary SOD types I and II, as [5-7]. However, in SOD type III, EST has no advantage over placebo [7].

On the other hand, SOD is a well known risk factor for post-ERCP pancreatitis (PEP) [8-12]. But there is a lack of studies dedicated on analysis of PEP risk factors in a particular group of patients with SOD.

AIM

The aim of this study is to evaluate the risk factors for PEP in SOD type I, II.

MATERIALS AND METHODS

We retrospectively analyzed the medical data of 107 cases of biliary SOD type I, II with undergoing ERCP between January 2013 and December 2020 at Municipal non-profit enterprise city clinical hospital №2 named after prof. O.O. Shalimov of Kharkiv City Council.

Table 1. Baseline and Clinical Characteristics of the Patients with SOD

	Value
Age (range), yrs	63.7±13.8 (21-88)
Male/Female	21(19.6%)/86(80.4%)
Total bilirubin level (range), mg/dL	2.32±2.32 (0.47-14.5)
Common bile duct, mm	10.4±2.7
Cholecystectomy in history	26 (24.3%)
EST in in history	6 (5.6%)
Periampullary diverticulum	13 (12.2 %)
Initial ERCP success	103 (96.3 %)
Selective biliary cannulation	68 (63.5%)
Pancreatic cannulation/injection	21 (19.6%)
EST	86 (80.4 %)
Precut	38 (35.5 %)
PEP	15 (14 %)

Source: compiled by the authors of this study

ERCP

ERCP was performed by two experienced operators. Before the procedure all patients received diclofenac (100 mg) per rectum for PEP prevention. Premedicated with an injection of scopolamine butylbromide (10–20 mg) and local anesthesia of the pharynx with 8 % lidocaine were done.

Procedure usually was started with a guided sphincterotom or canula. Priority was given to obtain selective biliary cannulation which is defined as deep canulation of common bile duct (CBD) through naïve papilla followed by cholangiography without canulation of pancreatic duct or wirsungography. Needle-knife precut sphincterotomy (Precut) was used to achieve biliary access in case of failure of selective biliary cannulation after 5-10 attempts or approximately 5 min of trying.

We have never used transpancreatic precut as well as sphincter manometry. And we have not used prophylactic pancreatic stents placement in patients of this series.

After the procedure, the patient fasted until the next morning, received an intravenous infusion and ceftriaxone (2 g). Blood tests – hemoglobin, bilirubin and amylase levels were measured at baseline, 4-8 hours after the procedure, and next morning. ERCP-related adverse events were recorded; PEP was defined as upper abdominal pain with amylase levels more than three times the normal rate [13]. The severity of PEP was defined as mild (no organ failure, no local or systemic complications); moderate (transient organ failure, local or systemic complications without persistent organ failure); severe (persistent organ failure) [13].

The primary endpoint of this study was the occurrence of PEP.

STATISTICS

A number of potential risk factors for PEP were taken into analysis: age, gender, history of cholecystectomy, history of EST, serum bilirubin level, CBD size, gallbladder stones, parapapillary diverticulum, papilla size, initial ERCP success, selective biliary cannulation, pancreatic cannulation/injection, Precut and EST. All variables were made as categorical. For the univariate analysis, the Chi-square test (χ^2) was performed to identify differences in characteristics between patients with or without PEP. All variables were also taken for entry into multivariate analysis by multinomial logistic regression. Factors with $p<0.05$ both for univariate and multivariate analyses were identified as independent risk factors for PEP. All calculation were performed with SPSS® version 19 (IBM, USA).

ETHICS

This work complies with the principles of the Declaration of Helsinki.

RESULTS

Characteristics of the patients are shown in Table 1.

The overall PEP rate was 14% (15/107). Among these 15 patient with PEP there was no severe case, 1 moderate and 14 mild pancreatitis. No procedure-related deaths, no hospital deaths occurred in any of the patients with PEP.

Univariate analysis showed that among 14 investigated factor only serum bilirubin level was significantly ($p<0.05$) assosiated with PEP (Table 2). Normal biliru-

Table 2. Univariate and multivariate analyses of risk factors for PEP in patients with SOD.

Variables	PEP (n=15)	Non -PEP (n=92)	Analysis				
			Univariate		Multivariate		
			χ^2	P	P	OR	CI (95%)
Female gender	14 (93.4%)	72 (78,2%)	1.857	0.173	0.069	0.735	0.073-7.366
Age < 60 years	5 (33,3%)	31 (33,6%)	0.001	0.979	0.620	1.481	0.313-7.010
Cholecystectomy in history	4 (26,6%)	22 (23,9%)	0.053	0.818	0.153	4.999	0.549-45.483
EST in in history	1 (6,6%)	5 (5,4%)	0.037	0.848	0.850	0.768	0.050-11.875
Normal Serum Bilirubin level	12 (80%)	39 (42,3%)	7.313	0.007	0.007	9.574	1.869-49.034
Common bile duct, mm ≤10	9 (60%)	52 (56,5%)	0.064	0.801	0.370	1.916	0.462-7.944
Gallbladder stones	9 (60%)	47 (51%)	0.411	0.522	0.113	4.709	0.692-32.049
Periampullary diverticulum	0 (0%)	13 (14,1%)	2.413	0.121	*	*	*
Papilla size, mm ≥15	1 (6,6%)	16 (17,3%)	1.110	0.293	0.543	.477	0.044-5.200
ERCP success	14 (6,6%)	89 (96,7%)	0.416	0.520	0.602	.438	0.020-9.702
Selective biliary cannulation	10 (66,6%)	58 (63%)	0.073	0.787	0.689	.633	0.067-5.951
Pancreatic cannulation/injection	5 (33,3%)	16 (17,3%)	2.078	0.150	0.318	2.800	0.372-5.951
Precut	3 (20%)	35 (38%)	1.833	0.176	0.048	0.116	0.014-0.979
EST	13 (80%)	73 (79,3%)	0.438	0.509	0.613	1.644	0.240-11.249

* Calculation is unfeasible because one of the comparable groups contains 0 cases
Source: compiled by the authors of this study

bin was in 80% (12/15) patient with PEP and in 42,3% (39/92) patients without PEP (p=0.007).

Multivariate analysis showed that two factors were associated with PEP – normal bilirubin level (p=0.007) and Precut (p=0.048).

Precut was used in 20% (3/15) patients with PEP while it was in 38% (35/92) patients without PEP (p=0.048).

As being significant both for uni- and multivariate analyses normal serum bilirubin level identified as the risk factor for PEP in patients with SOD.

DISCUSSION

PEP is the most common adverse event after ERCP and related endoscopic procedures [9, 10, 13, 14]. Being a serious complication in severe cases PEP may lead to mortality [9, 10, 15]. According clinical trials and studies the incidence of PEP ranges widely from 1% to 19,6% [8-10, 14-23]. SOD is a well known risk factor for PEP [8-10, 13, 15, 19]. Our previous study has also shown that SOD is an independent risk factor for PEP (OR 4.107; 95% CI, 1.726-9.771; p=0.001) [11]. But there are only a few studies describing risk factors for PEP in a particular group of patients with SOD [24]. That is why we dedicated our work to investigating PEP risk factors in such patients.

With implementing of CT, MRI, and endoscopic ultrasound the diagnostic role of ERCP has almost gone. And nowadays ERCP is used mainly as therapeutic procedure in malignant or benign biliary obstruction, CBD stones and other bilio-panreatic pathology. Suspected cases of SOD requiring ERCP are gradually decreasing [24]. Nonetheless ERCP with EST is an effective treatment modality in biliary SOD types I and II while having no advantage in SOD type III [5-7]. That is why in present study we analysed only Type I and II of biliary SOD and have not included cases of Type III of biliary SOD as well as pancreatic SOD.

We have evaluated 14 protentional risk factors for PEP in SOD – both patient related (age < 60 years, gender, CBD size ≤10 mm, normal bilirubin level, history of cholecystectomy, history of EST, gallbladder stones, parapapillary diverticulum, papilla size ≥15 mm) and procedure related (initial ERCP success, selective biliary cannulation, pancreatic cannulation/injection, Precut, EST). We have carefully chosen these variables to be studied and intentionally have not taken such factors as smoking, drinking and comorbidities, which appear in other studies [25, 26]. We consider them irrelevant to PEP. We have not considered the factor of difficult cannulation as in our technique manner precut papillotomy was done in case of it. All the variables were taken both

into univariate analysis and into multivariate regression as there is an opinion that such a model may give more reliable results [16, 27].

The incidence of PEP in patients with SOD reported to be from 9.1 % to 37.9 % [19, 21, 28-31]. Even after prophylactic pancreatic stenting PEP reported to be high – up to 25 % [30]. In our study the PEP occurred in 14 % of patient. That is higher than PEP incidence in non-selected studies (3.6%-9,5%) [8-11, 14-16, 18, 20-23].

Our investigation showed that the only risk factor significant both for univariate and multivariate analysis was normal serum bilirubin level (OR 9.574, 95% CI 1.869-49.034, p=0.007).

In one of the first work with a prospective, multicentre design by M. L. Freeman et all normal serum bilirubin was an independent risk factor for PEP (OR 1.89, 95% CI 1.22-2.93, p=0.0023) [28]. In a work from Japan including 1,273 patients with native papillae who underwent ERCP for bile duct stones normal serum bilirubin was also an independent risk factor for PEP (OR 1.9, CI 1.01–3.6, p=0.047) [20]. In others studies where serum bilirubin level was investigated it turned out not to be a risk factor [14, 19, 21, 22, 25, 29]. There is an interesting paper describing risk factors of PEP in high-risk patients and normal serum bilirubin did not prove to be an independent risk factor for PEP [19]. Most of these studies whether bilirubin level turned out to be a risk factor or not were unselected and so obtained data could not be totally implemented on patient with SOD [14, 19, 21, 22, 25, 29]. In many studies this factor was not analysed at all [8, 16, 17, 20, 24, 26, 28, 30, 31]. We find serum bilirubin level very important factor to be investigate as hyperbilirubinemia is one of the signs of biliary obstruction so serum bilirubin level in combination with biliary dilatation plays a significant role in determining the indication for ERCP. And so we suppose that in case of SOD heperbilirubinemia could be a reliable criterion for ERCP usage both for potentiational therapeutic benefit and for PEP safety.

Aggressive prophylaxis of PEP is particularly important in patient with risk factors [13, 14, 20, 31]. For patients with SOD being in group of risk prevention of PEP is extremally important [13, 24]. The best way to prevent PEP is to exclude unnecessary ERCP in SOD. That is why a case with normal serum bilirubin should be carefully examined and medical treatment should be considered. In case when ERCP has been chosen several options are available for PEP prevention.

Pancreatic stent placement was reported to be effective in the reduction of PEP includung patients with SOD [32-34]. In contrast to these papers, there are some reports that pancreatic stenting cannot reduce the incidence of PEP [35-36].

Rectal nonsteroid anti-inflammatory drugs (NSAIDs) showed the efficiency in reduction of PEP incidence in majority of randomised controlled trials (RCT) and meta-analyses [13, 37, 38]. That is why in different guidelines there is a recommendation to use routine rectal administration of 100 mg diclofenac or indomethacin immediately before ERCP in all patients without contrindications to NSAIDs [13].

Also aggressive hydration was reported to be effective in prevention of PEP [13]. In patient with contraindications to NSAIDs it may be an alternative prevention measure [13]. According to a network meta-analysis, the combination of aggressive hydration and rectal NSAIDs is the most effective PEP prevention strategy. Its preventive efficacy was observed to be 70% to 99% higher than that of single prophylactic measures [39]. Therefore, aggressive prophylaxis for PEP with these strategies should be considered in patients with SOD especially with normal serum bilirubin.

This study has some limitations: first, this was a retrospective and single-center study; second, the number of cases is relatively small. The last one may lead to a bias to insignificance of certain factors which might be significant in lager sampling. That is why a large multicenter study is needed to confirm and clear-up the risk factors for PEP in Type I and II SOD.

CONCLUSIONS

In conclusion, normal bilirubin level is an independent risk factor for PEP in patients with Type I and Type II of biliary SOD. So in cases of suspected or confirmed Type I, II of biliary SOD with normal bilirubin level, ERCP with EST should be avoided and replaced by medical treatment or, if ERCP had been chosen, advanced PEP prophylactic measures should be done.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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