Clinical usefulness of ultrasonographic evaluation of common bile duct (CBD) size in cholecystectomized patients with suspected obstructive biliary pathology

Użyteczność kliniczna pomiaru średnicy przewodu żółciowego wspólnego w ultrasonografii u chorych po cholecystektomii podejrzewanych o zaburzenie odpływu żółci

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Słowa kluczowe: kamica żółciowa, ultrasonografia, diagnoza.

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Abstract

Introduction: While the direct visualization by ultrasonography (US) of the cause of biliary flow impairment is often difficult, the diameter of CBD is easily obtainable. There are controversies as to what diameter of CBD on US should be regarded as abnormal in cholecystectomized patients.

Aim: Evaluation of US measurement of CBD size (the clinically optimal cut-off value) in post-cholecystectomy patients, suspected for impaired biliary flow.

Material and methods: 795 post-cholecystectomy patients suspected for impaired biliary flow [657 women (83%); mean age 60.5; range 19-94 years], evaluated in years 1990-2005. CBD size was measured in antero-posterior transverse and left semilateral positions. The reference diagnostic method in every case was ERCP, completed by endoscopic sphincterotomy in 588 (74% of cases). Calculations of diagnostic sensitivity, specificity, NPV, PPV, likelihood ratios (LR+/–) and accuracy were used to find out the optimal cut-off value for CBD size.

Results: The most common pathology on ERCP was biliary lithiasis (500 cases), followed by benign CBD stricture combined with biliary lithiasis (14 cases), benign CBD stricture alone (5 cases) and malignant stricture alone (2 cases). In 274 cases no biliary pathology was found. There was a correlation between CBD diameter and choledocholithiasis (Z=–11,7 p=0.0001, Mann-Whitney U test). The best cut-off (the best diagnostic accuracy of 75% with sensitivity of 76% and specificity of 72%) was found for CBD size equal to or greater than 9 mm. NPV was 100% for CBD diameter less than 5 mm. PPV was 95% for CBD greater than 16 mm and PPV was 100% for CBD diameter greater than 22 mm.

Streszczenie

Wpowadzenie: Gdy bezpośrednie uwidocznienie przeszkody w drogach żółciowych podczas ultrasonografii (USG) jest często trudne, średnica przewodu żółciowego wspólnego (PŻW) może być zwykle łatwo zmierzona. Istnieją kontrowersje dotyczące tego, jaka średnica PŻW powinna być uznana za nieprawidłową u osób po cholecystektomii.

Cel: Ocena średnicy PŻW w USG (ustalenie klinicznie optymalnego wymiaru) u chorych po cholecystektomii, podejrzewanych o nieprawidłowy odpływ żółci z dróg żółciowych.

Materiał i metody: W latach 1990–2005 oceniono 795 chorych [657 kobiet (83%), średnia wieku 60,5 roku; przedział 19–94 lat] po cholecystektomii, podejrzewanych o zaburzenie odpływu żółci. Średnica PŻW w USG była oceniana w dwóch pozycjach badanego – na wznak i w lewym półskłonie. We wszystkich przypadkach metodę referencyjną stanowiła endoskopowa cholangiopankreatografia wsteczna (ECPW), uzupełniona sfinkterotomią endoskopową w przypadku 588 badanych (74% przypadków). Określenie czułości, swoistości, trafności, wartości prognostycznej wyniku dodatniego i ujemnego, współczynników prawdopodobieństwa wyniku dodatniego i ujemnego (LR+/–) dla każdej ze średnic PŻW w USG posłużyło do wyznaczenia optymalnego punktu odcięcia dla tego parametru.

Wyniki: Najczęściej rozpoznawaną chorobą w ECPW była kamica przewodowa (500 przypadków). Nienowotworowe zwężenie wraz z kamicą przewodową stwierdzono u 14 chorych, wyłącznie nienowotworowe zwężenie u 5, a nowotworowe zwężenie u 2 osób. W 274 przypadkach nie zaobserwowano choroby dróg żółciowych w czasie ECPW. Odnotowano korelację między średnicą PŻW a występowaniem kamicy przewodowej (Z=–11,7, p=0,0001, test U Manna-Whitneya). Naj-

Conclusions: In cholecystectomized patients the best sonographic discriminator between present and absent biliary pathology is CBD size ≥9 mm, but the clinical utility of this finding is far from expectations.

lepszym punktem odcięcia (najwyższa trafność diagnostyczna 75%, z czułością 76% i swoistością 72%) okazała się średnica PŻW ≥9 mm. Wartość prognostyczna wyniku ujemnego wyniosła 100% dla średnicy PŻW <5 mm, natomiast wartość prognostyczna wyniku dodatniego – 95% dla średnicy PŻW >16 mm, a 100% dla średnic >22 mm.

Wnioski: U chorych po cholecystektomii najlepszym ultrasonograficznym dyskryminatorem obecności przeszkody w odpływie żółci z dróg żółciowych jest średnica PŻW ≥9 mm, ale jej kliniczna użyteczność jest daleka od oczekiwań lekarzy.

Introduction

In cholecystectomized patients pain or discomfort in the right hypochondrium is referred to as post-cholecystectomy syndrome (PCS) [1]. Recurrent biliary colic is the most prevalent symptom of PCS and common bile duct (CBD) stone disease, which is diagnosed in 2-5% of cholecystectomized patients, is the most common cause of this syndrome [2, 3]. As compared with the known incidence rate of choledocholithiasis in patients with gallbladder *in situ*, the data on occurrence of CBD stones in cholecystectomized patients are scarce [4-7].

Prolonged bile duct obstruction leads to biliary cirrhosis and portal hypertension [8-10]; therefore any pathology hindering biliary outflow should be promptly eliminated. It is estimated that symptomatic post-cholecystectomy CBD stone disease may occur in only 15-25% of patients with calculi present in CBD [8]. Diagnosis of CBD stones or other causes of extrahepatic cholestasis in cholecystectomized patients is based on case history, biochemical blood tests and imaging techniques. Widespread use and convenience make transabdominal ultrasound (US) the first line imaging technique. Before the advent of non-invasive imaging methods ERCP was the "gold standard" for diagnosis of unclear biliary pathology. This examination is characterized by very high diagnostic sensitivity. Other imaging techniques, such as magnetic resonance (MR) or endoscopic ultrasonography (EUS), show comparable diagnostic accuracy. Predictability of US examination of CBD stones in patients with gallbladder stone disease is well known, whereas only a single study on prediction of CBD pathology in cholecystectomized patients has been published [11]. The aim of the study was to evaluate in cholecystectomized patients the clinical significance of US measurement of CBD size for finding biliary pathology.

Material and methods

The study was done retrospectively on 795 patients admitted consecutively to the Department of Gastroenterology and Hepatology of the Silesian Medical University in Katowice (years 1990-2005) because of pain or discomfort in the right hypochondrium, suggesting pathology of biliary ducts. Only patients with no gallbladder (post-cholecystectomy) and excellent visualization of CBD on US and endoscopic retrograde cholangiopancreatography (ERCP) were included in the study. Exclusion criteria were as follows: cholecystectomy performed earlier than 1 month before hospitalization (to rule out early post-cholecystectomy syndrome), surgical procedures on bile ducts (other than cholecystectomy or choledochotomy), previous endoscopic or surgical stenting of CBD and diagnoses of acute pancreatitis, acute cholangitis and neoplasms of bile ducts, pancreas or duodenal papilla.

Demographic data of patients are shown in Table I. The time interval between US and ERCP was not longer than 7 days to minimize the risk of spontaneous expulsion of stone from CBD. Ultrasound examinations were performed by experienced investigators, using the following ultrasound machines: Sigma 1AC (*Kontron*) in years 1990-2000 and Sonoace 6000C (*Kretz*) in years 2001-2005. In each patient the maximal transverse diameter of CBD was measured in both the supine and left lateral positions of the patient. ERCP was the validating examination. In our hospital magnetic resonance cholangiography (MRC) was introduced in 2002, and has served as the diagnostic standard since 2005.

Statistical analysis

The correlations of CBD size with sex, age, loss of weight and hepatic laboratory tests were tested by Pearson's coefficient correlation test.

To assess the prognostic efficiency of US evaluation, the number of results genuinely positive and negative, falsely positive and negative were determined (using 2×2 contingency table), followed by evaluation of diagnostic indicators: sensitivity, specificity, consistency (accuracy), prognostic value of positive and negative result, reliability index of positive and negative result and model prognostic value (Youden's index).

Table I. Characteristics of studied group, N=795
Tabela I*. Charakterystyka badanej grupy, N=795*

Feature		Results
Demographics	women	657 (83%)
	age [years]	60.5 (range 19-94) (59.5-61.4 95% CI)
	time from cholecystectomy [years]	11.08 (range 0.2-65) (10.4-11.8 95% CI)
Prevalence of biliary pathology		521 (65%)
Intervention	ERCP	795 (100%)
	endoscopic sphincterotomy	588 (74%)
Ultrasound findings	diameter of common bile duct [mm]	11.2 (range 1-34) (10.9-11.5 95% CI)
	detectable biliary pathology	269 (34%)

Incidence probability was assessed as: positive likelihood ratio (LR+) and negative likelihood ratio (LR–), before and after the examination or test.

All these indicators were calculated for every size of CBD recorded (1 to 34 mm of CBD size). The results were entered into a 2 × 2 contingency table to calculate the above indicators. The calculations were done using Statistica 6.0 PL (Statsoft) software.

Results

The most common pathology observed on ERCP was choledocholithiasis (500 cases), followed by benign CBD stricture combined with biliary lithiasis (14 cases), benign CBD stricture alone (5 cases) and malignant stricture alone (2 cases). In 274 cases no biliary pathology was found. Ultrasound measurements are presented in Tables II and III and Figures 1-4. The correlations of CBD size with a number of independent variables are shown in Table III.

Discussion

This study comprises to our knowledge the largest group of cholecystectomized patients evaluated sonographically [11, 12]. The number of cases included in our study is comparable with the largest series of patients without cholecystectomy [13] and exceeds by several times the previously published post-cholecystectomy series [14-22].

In this study ERCP was considered the diagnostic gold standard. Such an approach can exclude some patients with low to moderate probability of biliary obstruction, but allowed reliable end points to be obtained. Magnetic resonance cholangiography, which was not available in our department till 2002, may provide in our experience more false negative and false positive results than ERCP. This is particularly true for small CBD stones [23-26].

The majority of patients were women and elderly persons, which is typical of cholecystectomized patients. We excluded less than 10% of patients due to poor visibility of extrahepatic bile ducts on US examination, which is a percentage comparable with the literature [14].

Increased size of CBD and noticeable CBD stone (s) are good predictors of definitive biliary pathology [27]. Increased CBD diameter is a more sensitive but less specific US feature of choledocholithiasis than the visible stone [27-36]. The accordances between CBD size measured with US, magnetic resonance and ERCP are acceptable [37]. Endoscopic retrograde cholangiopancreatography diameter is usually slightly bigger [17, 19], probably due to the pressure of contrast injected into CBD.

Extrahepatic bile ducts dilate more easily and earlier than intrahepatic ducts [38]; therefore CBD dilatation can be a sensitive marker of biliary outflow obstruction. Diagnostic sensitivity of US for visuali-zation of CBD stones in patients with gallbladder is 65-69% and specificity 81-92% [37-39, 40]. It is well known that sonographic finding of the biliary stone or delineating a stricture of CBD is much more difficult than measuring its size. The aim of our study was to find in cholecystectomized patients the best cut-off for CBD size, capable of predicting biliary outflow disturbances. Highly variable values of "normal" CBD size ranging from 6 to 12 mm were given for non-cholecystectomized patients with gallbladder stones [40-44]. Similar variability was found in cholecystectomized patients [14-22]. Our study performed on a large number of cases showed that after cholecystectomy the CBD diameter of 9 mm or bigger is the best discriminator between present and absent biliary pathology. The same observation was made by Terhaar et al.; however our study comprised almost 20 times more patients [11].

Table II. CBD size on US in the evaluation of biliary flow obstruction in post post-cholecystectomy patients

Tabela II. *Wymiar przewodu żółciowego wspólnego (PŻW) w USG w ocenie chorych po cholecystektomii podejrzewanych o zaburzenie odpływu żółci*

CBD diameter [mm]	**1**	**2**	**3**	**4**	**5**	6	7	8	**9**	10	11	12	13	14	15	16	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**
Results of the method																																		
True positive	521	521	521	521	518	500	472	430	397	332	287	222	181	155	98	81	65	52	41	23	18	13	12	11	3	2	2	2	2	1	1	1	1	1
False positive	273	273	272	270	248	211	153	111	78	58	38	24	16	12	8	6	3	2	2	2	1	1	0	0	0	0	0	0	0	0	0	0	0	0
True negative	1	1	2	4	26	62	121	164	196	216	236	250	258	262	266	268	271	272	272	272	273	273	274	274	274	274	274	274	274	274	274	274	274	274
False negative	0	0	0	0	3	21	49	91	124	189	234	299	340	366	423	440	456	469	480	498	503	508	509	510	518	519	519	519	519	520	520	520	520	520
Sum	795	795	795	795	795	794	795	796	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795	795
Statistical evaluation																																		
Sensitivity	1.00	1.00	1.00	1.00	0.99	0.96	0.91	0.83	**0.76**	0.64	0.55	0.43	0.35	0.30	0.19	0.16	0.12	0.10	0.08	0.04	0.03	0.02	0.02	0.02	0.01	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Specificity	0.00	0.00	0.01	0.01	0.09	0.23	0.44	0.60	**0.72**	0.79	0.86	0.91	0.94	0.96	0.97	0.98	0.99	0.99	0.99	0.99	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Accuracy	0.66	0.66	0.66	0.66	0.68	0.71	0.75	0.75	**0.75**	0.69	0.66	0.59	0.55	0.52	0.46	0.44	0.42	0.41	0.39	0.37	0.37	0.36	0.36	0.36	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35
Youdens' index	0.00	0.00	0.01	0.01	0.09	0.19	0.35	0.42	**0.48**	0.43	0.41	0.34	0.29	0.25	0.16	0.13	0.11	0.09	0.07	0.04	0.03	0.02	0.02	0.02	0.01	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PPV	0.66	0.66	0.66	0.66	0.68	0.70	0.76	0.80	**0.84**	0.85	0.88	0.90	0.92	0.93	0.92	0.93	**0.96**	**0.96**	**0.95**	**0.92**	**0.95**	**0.93**	**1.00**	**1.00**	**1.00**	**1.00**	**1.00**	**1.00**	**1.00**	**1.00**	**1.00**	**1.00**	**1.00**	**1.00**
NPV	**1.00**	**1.00**	**1.00**	**1.00**	**0.90**	0.75	0.71	0.64	**0.61**	0.53	0.50	0.46	0.43	0.42	0.39	0.38	0.37	0.37	0.36	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35
Prevalence																0.66																		
Pre-test odds																1.90																		
LR+	1.00	1.00	1.01	1.01	1.10	1.25	1.62	2.06	**2.68**	3.01	3.97	4.86	5.95	6.79	6.44	7.10	**11.39**	**13.67**	**10.78**	**6.05**	**9.47**	**6.84**	**ω**	**ω**	**ω**	**ω**	**ω**	**ω**	**ω**	**ω**	**ω**	**ω**	**ω**	**ω**
LR–	**0.00**	**0.00**	**0.00**	**0.00**	**0.06**	0.18	0.21	0.29	**0.33**	0.46	0.52	0.63	0.69	0.73	0.84	0.86	0.88	0.91	0.93	0.96	0.97	0.98	0.98	0.98	0.99	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Post-test odds	1.91	1.91	1.92	1.93	2.09	2.37	3.08	3.91	**5.09**	5.72	7.55	9.25	11.31	12.92	12.25	13.50	21.67	26.00	20.50	11.50	18.00	13.00	ω	ω	ω	ω	ω	ω	ω	ω	ω	ω	ω	ω
Post-test probability	0.66	0.66	0.66	0.66	0.68	0.70	0.76	0.80	**0.84**	0.85	0.88	0.90	0.92	0.93	0.92	0.93	0.96	0.96	0.95	0.92	0.95	0.93	ω	ω	ω	ω	ω	ω	ω	ω	ω	ω	ω	ω

Table III. Pearson's correlation test between CBD size and independent variables
Tabela III. *Korelacja wymiaru przewodu żółciowego wspólnego (PŻW) ze zmiennymi niezależnymi*

	Sex	Age	Height	Weight	Time since cholecystectomy	CBDS ON US	L_{10}ALP	L_{10}GTP	BIL	L_{10}ALT	L_{10}AST	WBC
CBD diameter	–0.0358	0.2686	–0.1118	0.0257	0.0676	0.3857	0.3413	0.2378	0.2648	0.0876	0.1429	0.1036
	p=0.334	p=0.000	p=0.002	p=0.487	p=0.067	p=0.000	p=0.000	p=0.000	p=0.000	p=0.018	p=0.000	p=0.005

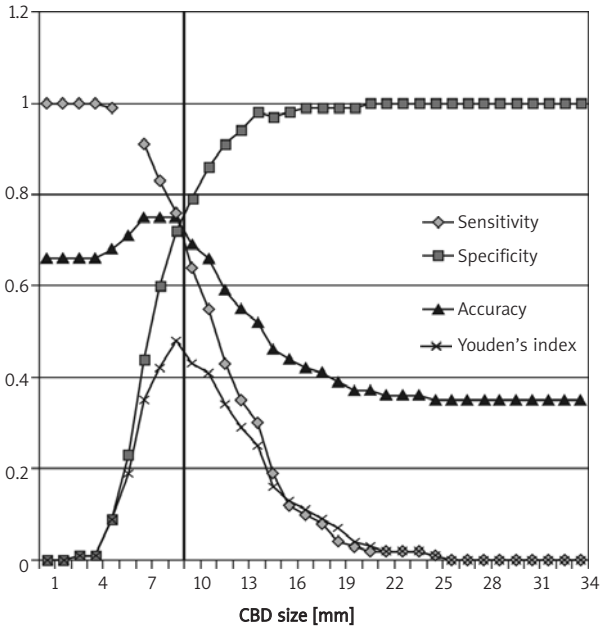

Fig. 1. Diagnostic value (sensitivity, specificity, accuracy, Youden's index) of CBD size in evaluation of post-cholecystectomy patients [1]
Ryc. 1. *Znaczenie diagnostyczne (czułość, swoistość, trafność, wskaźnik Youdena)* [1]

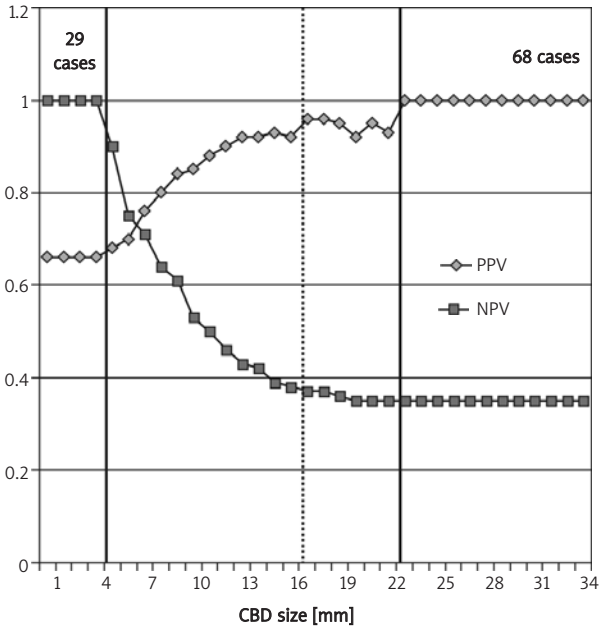

Fig. 2. Diagnostic value (positive predictive and negative value) of CBD size in evaluation of post-cholecystectomy patients [2]
Ryc. 2. *Znaczenie diagnostyczne (wartość rokownicza wyniku dodatniego i ujemnego) wymiaru przewodu żółciowego wspólnego (PŻW) u chorych po cholecystektomii* [2]

Another message from our study is that excellent NPV and PPV values are reserved for a small portion of patients with either narrow or large CBD (Figure 2).

Significant biliary pathology can be found even in patients with normal CBD size [26]. In 20-30% of patients with CBD stones the biliary ducts are not dilated [42, 45-47]. The situation when CBD size is enlarged without discernible cause of biliary obstruction is less common [45]. These limitations may explain why biliary US is unsatisfactory with respect to diagnostic sensitivity and specificity.

Previous studies suggested that rising age is associated with increase in CBD size, approximately by 1 mm for every 10 to 20 years [48-50]. Our data support the correlation between CBD size and age; however, Pearson's coefficient of 0.27 indicates that this relationship is not strong (Table III). On the other hand, in our study as in other reports the sex and body weight were not related to CBD size [48]. In the opinion of many investigators the cholecystectomy itself is responsible for slight enlargement of CBD size, which can be attributed to loss of the bile reservoir role of the gallbladder [15, 19, 21, 51]. However, CBD dilatation associated with persistent or temporary cholestasis is often caused by organic diseases e.g. CBD stones or its iatrogenic, inflammatory or malignant stricture [52-55].

Our study clearly demonstrates the relationship between CBD size and biliary obstruction caused in

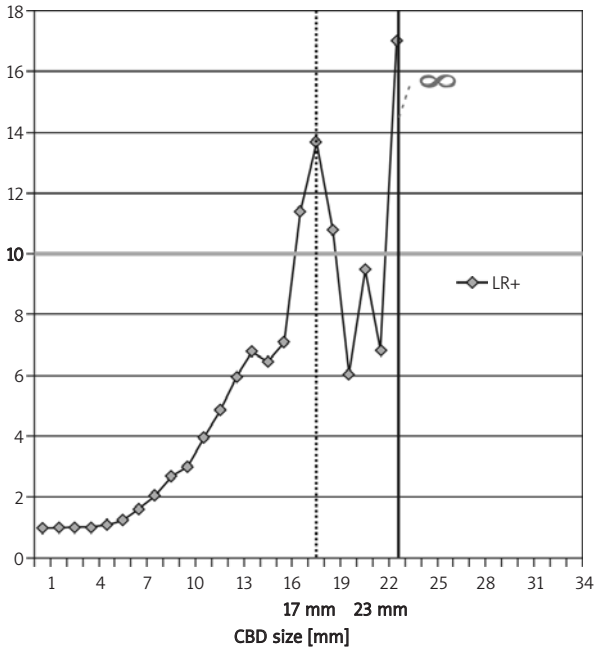

Fig. 3. Diagnostic value (LR+) of CBD size in evaluation of post-cholecystectomy patients [3]
Ryc. 3. *Znaczenie diagnostyczne (LR+) wymiaru przewodu żółciowego wspólnego (PŻW) u chorych po cholecystektomii* [3]

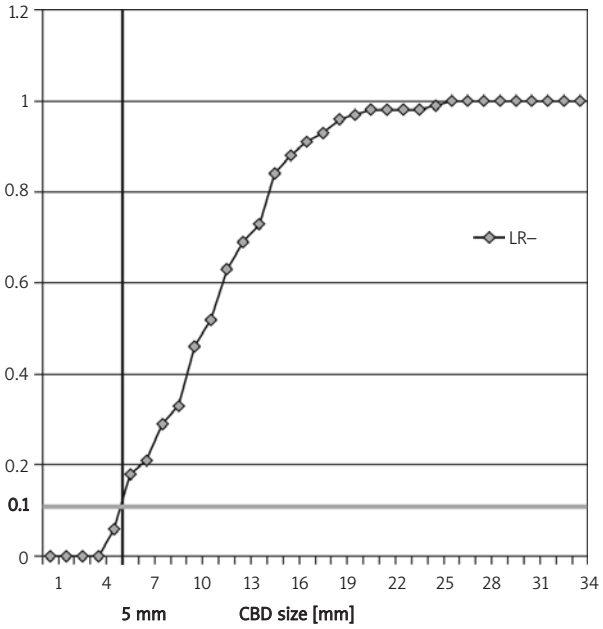

Fig. 4. Diagnostic value (LR–) of CBD size in evaluation of post-cholecystectomy patients [4]
Ryc. 4. *Znaczenie diagnostyczne (LR–) wymiaru przewodu żółciowego wspólnego (PŻW) u chorych po cholecystektomii* [4]

most cases by CBD stone (s). This finding fully agrees with the meta-analysis by Abboud et al. indicating a high likelihood ratio for CBD stones concluded from US-derived CBD enlargement [27].

The US is a first line examination usually used for preliminary diagnostic stratification of patients. In this study the cut-off for CBD size of 9 mm had in cholecystectomized patients the optimal 75% accuracy (with Youden's index of 48%) in detection of CBD pathology. Unfortunately, by taking 5 mm diameter of CBD as a guide for clinical decisions, one can exclude with high certitude only a minority of patients from further evaluation (NPV of 100%, likelihood ratio less than 0.1). Also a minority of patients could be directly advised to undergo invasive examination (e.g. ERCP), when CBD is larger than 17 mm (PPV of 95%; likelihood ratio more than 10). The vast majority of patients still remain in the "grey zone" and should be evaluated with more sophisticated modalities. Therefore, diagnostic accuracy based on US biliary evaluation is limited and clinico-biochemical presentation should always be contemplated together with US evaluation.

Conclusions

Increasing CBD diameter in cholecystectomized patients strongly correlates with the presence of CBD obstruction, caused usually by biliary stones. In cholecystectomized patients the diagnostically optimal cut-off value for the CBD diameter is 9 mm, but its practical value is far from clinical expectations.

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