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PARAMETERS FOR SELECTIVE INTRAOPERATIVE CHOLANGIOGRAPHY IN THE DIAGNOSIS OF COMMON BILE DUCT STONES

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In patients with gall bladder calculosis, the complication as common bile duct stones (CBDS) occurs in 10%-12% of cases and represents a serious disease which has to be recognized and treated in time. Diagnostic procedure that verifies the presence of CBDS is intraoperative cholangiography (IOC). Despite simplicity and safety of this method, solving technical and organizational details before its usage is required, and some percentage of failure and complications tend to occur. Hence, there is still a controversy whether this procedure should be used non-selectively or selectively.

The aim of our study was to examine in which cases of gall bladder calculosis IOC has to be used.

In a retrospective study, 150 patients operated for CBDS were analyzed. We formed a simple and unique scoring system with five parameters for prediction of this disease: diameter of common bile duct >8 mm, gall bladder calculosis <5 mm, high serum level of bilirubin, elevated levels of ALP and ALT in serum.

The value of scoring system was confirmed in a prospective group of 100 patients, operated for gall bladder calculosis and subjected to IOC. After scoring, all patients were divided into three risk groups for CBDS presence: low, medium and high.

Comparison of results for suspected CBDS (confirmed by scoring) and existing CBDS (confirmed by IOC) has demonstrated a high level of scoring system precision and its practical usage value in the election of patients with gall bladder calculosis who need IOC. *Acta Medica Medianae 2015;54(3):19-26.*

***Key words**: hepato-choledocholithiasis, intraoperative cholangiography, scoring system*

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Introduction

The number of surgical interventions on the bile ducts is constantly growing, and in many surgical units, cholecystectomy is one of the most common abdominal operations. Over two million cholecystectomy procedures are performed annually in the world. The most common disease of the biliary tract is calculosis of the gallbladder, which is in a certain percentage (7%-20%, on average, about 10%) followed by common bile duct calculosis – hepato-choledocholithiasis (HCHL), which is a serious disease that must be recognized and treated (1, 2). Modern diagnostic preoperative procedures (ultrasound, computed tomography (CT), eho-endoscopy, endoscopic retrograde cholangio-pancreatography (ERCP), magnetic resonance-MRCP) have enabled large morphological and functional precision in the preoperative diagnosis of this pathological condition (up to 98%), based on which the need for possible intraoperative application of some of the possible diagnostic procedures (intraoperative cholangiography, intraoperative ultrasound) can be determined (3, 4).

Intraoperative cholangiography (IOH) is a procedure based on which, during operation, the anatomic integrity of the entire biliary tree is determined (from intrahepatic bile ducts to the papillary region) and where the detection of possible pathological states of the system is done. The method was introduced in the early thirties of the 20th century (5) and has continuously been refined with the development of science and technology in the field of radiology.

The introduction of laparoscopic surgery in biliary surgery has not changed the already set principles and indications for IOH. IOH technique

in open and laparoscopic cholecystectomy is based on similar principles, with the help of a moving "C-arme" radiological device, to achieve the static and dynamic holangiograms of high precision (high-resolution) by using 10-40 mL of contrast. A large number of surgeons today unreservedly accept IOH as a mandatory and absolute diagnostic method, especially in the verification of hepatocholedochal calculosis, accepting the attitude that "there is no cholecystectomy without the mandatory application of IOH".

However, IOH, in addition to its value, has certain disadvantages:

- it extends the time of operation;
- technical problems are common during its implementation;
- the patient and the operating team are exposed to ionizing radiation;
- there is a possibility of allergic reactions to contrast agents;
- there is a risk of injury to the biliary tree;
- possible development of acute cholangitis and pancreatitis;
- there is a certain percentage of false positive and false negative results;
- there is a possibility of misinterpretation of the results;
- operation costs are on the increase;
- poor assessment of its application in patients with high surgical risk.

It is already proven that the number of residual (unrecognized, "rest" or "oublie") calculosis cases is reduced by IOH application; however, the routine use of this diagnostic procedure loses its absolute place for the following reasons:

- hepatocholedocholithiasis can be, in a certain percentage, recognized before surgery by using highly sensitive and specific diagnostic procedures;
- residual calculosis does not present with such difficult postholecystectomic sequelae, as previously thought, because a large number (over 50%) ends without any consequences (false positive results, spontaneous elimination of calculosis, "no" residual HCHL without consequences to biliary system and liver, etc.);
-contemporary possibilities of endoscopic treatment, which can be applied preoperatively, intraoperatively and postoperatively, greatly reduce the problem of residual calculosis and facilitate decision of surgeons about the selective application of IOH (6-8).

Surgery of the biliary system is extremely complex and requires a great knowledge of anatomy not only of the biliary tree, but of the adjacent anatomical regions as well, and each surgical error or unnecessary diagnostic or therapeutic intervention may endanger the patient's life. Reintervention biliary surgeries are very difficult, with a high operational risk, and their morbidity and mortality are considerably higher than those of a primary biliary surgery. Surgical precision and restraint are the basic elements on which this surgery is based. Excessive self-confidence and the application of unnecessary diagnostic and surgical manipulation can cause serious surgical oversights and errors (1).

For these reasons, some surgeons have put into question the routine use of IOH during each cholecystectomy and recommended it only in cases of clear indications.

Numerous studies have shown that preoperative biliary system status and assessment of operational risk for patients, in a large percentage of cases, may suggest the use of IOH (9-15).

The aim of our research is driven by the existing dilemma of when and in which cases of gallbladder calculosis IOH should be applied.

The analysis of data obtained from the literature and our daily practice helped us to establish the evaluation system (scoring system), whose routine use will facilitate preoperative decision of surgeons on whether to perform IOH or not and avoid its unnecessary use.

The proposed scoring system for preoperative risk assessment of the existence of the calculosis of the main biliary tract must have a statistically significant and high diagnostic value); it must be easy to perform by using standard diagnostic procedures that can be applied in all surgical institutions, i.e. it must be available and economical.

Materials and Methods

We retrospectively analyzed medical records of 150 patients (group A), who were due to hepatocholedocholithiasis (HCHL) operated at the Surgical Clinic in Niš by using classical or laparoscopic technique, in the period from May 1, 2001 to May 1, 2006. Regressive multivariate analyses of clinical, ultrasound and laboratory parameters were carried out in these patients and so were identified and proposed statistically significant factors, which can effectively evaluate the existence of biliary calculosis of the biliary tract.

Selection of parameters is carried out on the basis of knowledge of the etiopathogenesis of the biliary tract calculosis, its clinical manifestations and possible applications of diagnostic methods (morphologic diagnosis, laboratory findings), pursuant to which, in all probability, the existence of HCHL and its potential sequelae can be preoperatively determined.

The parameters evaluated in group A were as follows:

Gender and age: We examined the percentage of HCHL in both genders and age over 55, as a possible predictive factor for the existence of HCHL.

Medical history: Although there are asymptomatic forms of calculosis of the biliary tract, the existence of certain symptoms suggests, in many cases, the existence of HCHL. This applies in particular to icterus and symptoms of some form of pancreatitis (acute or chronic) in medical history, which are in our study determined as certain parameters of preoperative evaluation for HCHL.

Laboratory (biochemical) tests

Our assessment parameters were: bilirubin above normal levels, ALP above 280 U/l, transaminases (AST and ALT) above normal levels, GGT above 50 U/l LDH above 460 U/l.

Ultrasound examination: ultrasound examination is the most consistent morphological diagnostic procedure, which can be easily and safely applied and gives very useful information. As the parameters of preoperative evaluation, we used data on the diameter HCH (>8 mm) and prospective verification of stones in it. We also examined the stones in the gallbladder and determined the number (single or multiple) and size (micro: up to 3 mm, small: 3-5 mm, medium: 5-10 mm large: >10 mm). Kidney stones are, in respect to the development of HCHL, divided into "dangerous" and "harmless". "Dangerous" stones are multiple micro or small stones, or a combination of different sizes of stones. "Harmless" are multiple medium or large stones, or individual stones, regardless of the size (US finding of intrahepatic calculosis and pancreatitis were more influenced by the implementation of the operational strategy and tactics than by a scoring system).

Other tests (ERCP, CT, MRCP, PTC)

These tests were not used as standard, so that they were not used for the formation of the scoring system.

Based on the assessment of the above parameters, we created our own scoring system, which enables, in a high percentage of cases, the identification of possible preoperative calculosis of the main biliary tract.

In the prospective part of the study, 100 patients (group B), in whom cholecystectomy for gall bladder calculosis was performed in the period from 1 May 2006 onwards, were ranked in three risk groups for the existence of HCHL, under the proposed scoring system. Intraoperative cholangiography, as the most consistent and accurate method for identification of calculosis in the main biliary tract, was performed in all the patients. The results were compared (positive or negative intraoperative cholangiography) with preoperative assessment (based on the scoring system) for the existence of HCHL in the study patients. Hiquadrant test i.e., Fisher's modification and the Student's t-test were used to determine the statistical significance and difference in parameters. Correlation analysis was used to determine the statistical dependence between certain characteristics of observation.

Results

Results of the retrospective part of the study (group A)

The results of univariate logistic regression (Table 1) showed that the following items are significant for the occurrence of HCHL: cholecystitis, cholangitis, icterus in medical history, diameter of HCH and/or ultrasound verified choledocholithiasis, dangerous calculosis, elevated bilirubin, ALP, AST, ALT and GGT.

According to the results of multivariate logistic regression where independent risk factors for HCHL occurrence were cholecystitis, cholangitis, icterus in medical history, diameter, dangerous calculosis (Table 2), only two factors were singled out: the diameter and/or ultrasound verified choledocholithiasis and dangerous calculus of the gallbladder. Patients with HCH diameter greater than 8 mm or directly visualized calculosis in HCH have 5.307 times higher risk of hepato-choledocholithiasis, while in patients with dangerous calculosis that risk is 10.712 times higher. The model explains the effect of these parameters on the dependent variable by Cox and Snell's determination coefficient of 54.7% and Nagelkerke's determination coefficient of 73.0%.

Table 1. Results of a univariate logistic regression analysis

Variables	Odds ratio	95% CI Odds ratio	P	SS
Gender	1.130	0.540 - 2.390	0.860	-
Cholecystitis	3.060	0.910 – 11.260	0.044*	SS
Cholangitis	12.500	4.880 – 32.000	$<1x10^{6}$***	SS
Pancreatitis	1.420	0.390 – 5.640	0.773	-
Dyspepsia	1.200	0.550 – 2.640	0.756	-
Icterus	147.000	20.010 – 3010.850	$<1x10^{6}$***	SS
Diameter of HCH and/or ultrasound verified choledocholithiasis	506.560	82.770 – 4188.180	$<1x10^{6}$***	SS
Age	1.930	0.910 – 4.070	0.089	-
Dangerous calculosis	367.000	64.140 – 2966.46	$<1x10^{6}$***	SS
Bilirubin	21.360	6.610 – 76.470	$<1x10^{6}$***	SS
ALP	24.570	8.910 – 70.750	$<1x10^{6}$***	SS
AST	16.630	6.390 – 44.740	$<1x10^{6}$***	SS
ALT	49.610	15.770 – 165.940	$<1x10^{6}$***	SS
LDH	3.210	0.820 – 14.580	0.107	SS

GGT	3.040	1.410 – 6.580	0.003**	SS

Table 2. Results of a multivariate logistic regression analysis of a block consisting of cholecystitis, cholangitis, icterus, diameter and dangerous calculosis

Variables	Odds ratio	95% CI Odds ratio	P
Diameter	5.307	1.078 – 26.122	0.040*
Dangerous calculosis	10.712	1.606 – 71.478	0.014*

Table 3. Results of a multivariate logistic regression analysis of a block consisting of bilirubin, ALP, AST, ALT and GGT

Markings	Odds ratio	95% CI Odds ratio	P
Bilirubin	4.474	1.371 – 14.594	0.013*
ALP	4.796	1.487 – 15.463	0.009**
ALT	2.728	1.011 – 7.362	0.048*

According to the results of multivariate logistic regression, independent risk factors for HCHL occurrence were bilirubin, ALP, AST, ALT, GGT (Table 3), and three factors were singled out: bilirubin, ALP and ALT. Patients with elevated bilirubin have 4.474 times higher risk of choledocholithiasis, with elevated ALP by 4.796 times, while in patients with elevated ALT infection that risk is 2.728 times higher. The model explains the effect of these parameters on the dependent variable by Cox and Snell's determination coefficient of 45.2% and Nagelkerke's determination coefficient of 60.3%

Our proposal for preoperative scoring system based on univariate and multivariate analysis is the following (Table 4): This table shows the parameters obtained by statistical processing of the preparatory group A, which together form the proposed scoring system. Using the multivariate analysis, independent prognostic factors of hepatocholedocholithiasis were determined. Each of the parameters is given a certain value. Those parameters with maximum odds ratio were given a higher point value than the others. The total sum of the points has a scoring value of 10.

The scoring system with the above parameters was applied in a prospective study in group B, during preoperative risk assessment of HCHL. In all 100 patients of the control group B, a routine IOH was performed during the surgical intervention.

By preoperative and intraoperative cholangiography scoring, the validation of the scoring system was performed and its positions on the selective use of intraoperative cholangiography were defined in patients with gallbladder calculosis.

Table 4. Proposal for preoperative scoring system on the basis of which we can decide on selective application of IOH

Parameter	Criteria	Score
Bilirubin	elevated values	3
Alkaline Phosphatase(ALP)	elevated values	1
ALT	elevated values	1
US of thebiliary ducts	diameter >8 mm and/or stones in the biliary duct	3
US of the gallbladder	"dangerous" stones in the gallbladder	2
Score		10

Table 5. Results of the score in 100 patients before cholecystectomy

Score	0	1	2	3	4	5	6	7	8	9	10
Number of patients	41	19	24	6	2	0	0	3	3	1	1

Table 6. The relation between the results of the score and choledocholithiasis in 100 patients undergoing cholecystectomy

Score	The number of patients with choledocholithiasis	The number of patients without choledocholithiasis	Percentage	χ^2	χ^2 Mantel-Haenszel's with Yates' correction	p
< 3	1	83	84	45,27	44,82	$<1x10^6$
≥3	9	7	16			

Results of a prospective part of the study (group B) (Table 5)

During cholecystectomy, by intraoperative cholangiography and exploration of bile ducts, choledocholithiasis was observed in 10 patients. The relation between the score and choledocholithiasis is shown in table (Table 6).

There was a significant correlation between the value of the scoring system 3 and higher and choledocholithiasis (Mantel-Haenszel's test with Yates' correction, $p < 0.0001$).

Discussion

The current dilemma on the implementation of IOH has been the subject of many randomized trials, which attempted to determine the degree of applicability of IOH in the surgery of the biliary tract. Two opposing viewpoints are: required IOH in the surgery of the biliary tract (not just calculosis) or its selective application, depending on the preoperative evaluation and attitude of the surgeons (15-36).

Selective application of IOH must be based on the knowledge of specific diagnostic data which can be obtained during the preoperative preparation of patients with calculosis of the biliary tract. Numerous studies have been conducted to establish independent and objective parameters, based on which the existence of HCHL can be determined, including the IOH applying. On the other hand, preoperative diagnostic data obtained, together with intraoperative finding, can, with a high probability, exclude the existence of HCHL, thus avoiding standard (routine) application of IOH, with all its deficiencies and possible complications.

The aim of our research is driven by the existing issue: when and in which cases of gallbladder calculosis can we apply IOH in HCHL detection?

By using the standard diagnostic agents which are widely available, without the involvement of highly sophisticated medical technology, it was necessary to form a group of predictive preoperative diagnostic parameters (for and against the application of IOH), which can be successfully applied in all hospitals in which the surgery of the biliary tract is performed.

ERCP and MRCP are used very rarely, so they are not included into the parameters for the preoperative assessment in our study, among other things, because they are only used in better equipped hospitals. Although ERCP is considered to be very precise, with high specificity and sensitivity to HCHL, there are a lot of patients with HCHL who have ERCP negative findings, and the percentage of residual calculosis is not negligible, while the method itself is associated with a certain morbidity and mortality. MRCP in recent times is increasingly emerging as an excellent diagnostic agent, and some authors recommend it in a HCHL preoperative diagnosis, which could completely replace IOH in the future. However, as an expensive and technically demanding method, it can be found only in the better-equipped hospital centers (36-43).

In this retrospective analysis of case histories of 150 patients operated on for HCHL, we identified 16 parameters which can be preoperative predictors for the existence of this pathological condition. Statistical processing determined their significance as prognostic factors of HCHL existence. A simple scoring system, clinically applicable and easy to interpret, was formed this way and it suggests or rejects the application of IOH in gallbladder calculosis.

A final decision on the significance of certain parameters for preoperative scoring system and their value in points was brought only after the verification of the proposed system in the prospective group B. All the patients in this group had gallbladder calculosis, and the assessment of the existence of HCHL was based on the preoperative set of scoring systems and the mandatory application of IOH. We then compared the results of susceptibility to HCHL (obtained by preoperative scoring system) and the actual existence of HCHL (confirmed by IOH and operative findings).

Our results showed that the indicator of susceptibility to HCHL obtained by using the preoperative scoring system showed its practical usefulness. Namely, it was confirmed that the percentage of presumed HCHL, obtained by using the scoring system, was statistically significant for the group of patients with 3 or more points ($\chi 2$-45.27, Mantel-Haenszel $\chi 2$ with Yates's correction - 44.82, $p < 1x106$), or that the results of preoperative assessment, in most cases, coincided with the results of IOH. Hence, the fact is that IOH is an important diagnostic tool in the verification of HCHL, but its use (due to the already mentioned disadvantage) can be limited only to those cases in which the scoring system is used (with intraoperative findings), suggesting the possible existence of HCHL. In this way, an attitude committed to the selective application of IOH in those cases when indicated by the scoring system, is formed.

The literature is controversial, and the difference in the attitudes of some authors is evident (from the unreserved application of IOH along with any operation on the bile ducts to its selective application). Some studies showed (22) that there was no difference in results between routinely and selectively applied IOH and the procedure of the latter, on the whole, is safer, less complicated and considerably cheaper (21). There are numerous scoring systems that help whether IOH will be performed or not (14, 19, 37). By ap-plying these scoring systems, i.e. by the selective application of IOH, Charfare et al. 2003, in their prospective study of 600 cholecystectomies, came to the result of the 8% of residual calculosis, which is not far from the percentage of the cases where the scale was not identified by a routinely performed intraoperative cholangiography (9). Abboud et al. (1996) also demonstrated that the use of preoperative parame-

ters (cholangitis, icterus, enlarged diameter of hepatocholedochus or US verified stones of the same,

Table 7: Three groups of patient classified by the scoring system (in relation to the risk of the biliary tract calculosis)

GROUP	SCORE	RISK	RECOMMENDATION
I	0, 1, 2	LOW	Without IOH
II	3	MEDIUM	The decision on IOH application is made by a surgeon on the basis of intraoperative findings
III	4-10	HIGH	Mandatory IOH application

elevated bilirubin, alkaline phosphatase, amylase, then the existence of pancreatitis and cholecystitis), is a sufficient indicator for the existence of HCHL (4).

Borie and Millat (2003) with their work proved the necessity for the routine IOH, citing two main reasons: prevention of HCH lesions and identification of stones of the main billiary tract (38). However, C. Vons considers that the two reasons for the routine performing of IOH are neither sufficient nor justified (39). Firstly, lesions of the bile ducts usually occur at the beginning of the surgical intervention, before IOH procedure, which itself can contribute to their occurrence. Secondly, there are many predictive factors which can make the selection of patients who will have IOH performed (43-48).

Our results, obtained by using univariate and multivariate logistic regression analysis indicated five predictive factors: HCH diameter of over 8 mm and the so-called dangerous gallbladder calculosis, elevated bilirubin, ALP and ALT. Based on these morphological and laboratory parameters, which have a statistical significance, we created our proposal of the scoring system, which can be used preoperatively, and on the basis of which, in all probability, it can induce an IOH applying in suspected hepato-choledocholithiasis. On this basis, preoperatively, all patients with calculosis of the gallbladder, in relation to the risk of the biliary tract calculosis, can be classified into three groups: patients of low, medium and high risk (Table 7).

In the first group of a low preoperatively determined score (84 patients), only one patient (1.19%) had HCHL. We believe that in group I (Score 0,1,2), IOH is not necessary.

Since HCHL is detected in 9 out of 10 patients (90%), (score greater than 4) that make up group III, we believe that IOH is here required.

In group II (score 3) (6 patients) HCHL was not verified. Since there were some dilemmas about the presence of stones, the decision on IOH applying is left to the surgeon, based on the intraoperative findings.

Due to the ease of implementation and a high coefficient of accuracy, it is our opinion that the proposed scoring system has a practical utility value, which justifies our hypothesis about the selective application of IOH in gallbladder calculosis.

By the selective use of IOH, all the disadvantages of its implementation can be avoided and the procedure can be applied only in cases where needed it and where IOH advantages are obvious.

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PARAMETRI ZA SELEKTIVNU PRIMENU INTRAOPERATIVNE HOLANGIOGRAFIJE U DIJAGNOZI KALKULOZE ŽUČNIH VODOVA

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Hepatikoholedoholitijaza (HCHL) komplikuje stanje kod 10 do 12% bolesnika sa kalkulozom žučne kese i predstavlja ozbiljno oboljenje koje se mora na vreme prepoznati i lečiti. Dijagnostička metoda kojom se sa velikom preciznošću utvrđuje prisustvo HCHL je intraoperativna holangiografija (IOH). Iako relativno jednostavna i bezbedna, opterećena je tehničkim i organizacionim zahtevima i određenim procentom neuspeha i komplikacija. O njenoj primeni postoje dva stava: rutinska ili selektivna IOH.

Cilj našeg istraživanja bio je podstaknut postojećom dilemom: kada i u kojim slučajevima kalkuloze žučne kese treba primeniti IOH.

Retrospektivnim ispitivanjem preoperativnih parametara kod 150 bolesnika koji su operisanh zbog HCHL formiran je jednostavan skoring sistem (5 parametara) za predikciju ove bolesti: dijametar glavnog žučnog voda >8 mm, kalkuloza žučne kese <5 mm, povišen nivo bilirubina, ALP i ALT u serumu.

Njegova vrednost je potvrđivana kod 100 bolesnika prospektivne grupe, operisanih zbog kalkuloze žučne kese, a na osnovu skoringa svrstanih u tri grupe: bolesnike niskog, srednjeg i vosokog rizika za prisustvo HCHL. Svim bolesnicima prospektivne grupe urađena je IOH.

Upoređivanjem rezultata suspektnosti HCHL (utvrđenih skoring sistemom) i stvarnog postojanja HCHL (utvrđenih IOH), potvrđen je visok koeficijent tačnosti skoring sistema i njegova praktična upotrebna vrednost u selekciji bolesnika sa kalkulozom žučne kese kod kojih treba primeniti IOH. *Acta Medica Medianae 2015; 54(3):19-26.*

***Ključne reči**: hepatikoholedoholitijaza, intraoperativna holangiografija, skoring sistem*