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Diagnosis of Non-Tumor Stenosing Lesions of the Major Duodenal Papilla Using Endoscopic Ultrasonography

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Aim: to evaluate the possibilities of endoscopic ultrasonography in the diagnosis of benign stenosis of the major duodenal papilla and improve its results, including by identifying and objectifying the criteria of the disease.
Materials and methods. The results of the examination and treatment of 2146 patients treated at the Kursk Regional Multidisciplinary Clinical Hospital in the period from 2015 to 2022, who underwent transpapillary interventions and/or endoscopic ultrasonography on the basis of the endoscopy department, are presented. A therapeutic and diagnostic algorithm for the management of patients with dilation of the common bile duct has been introduced into clinical practice, based on the developed criteria for stenosis of the major duodenal papilla (MDP), for which endoscopic ultrasonography was used in combination with the methodology of synthesis of hybrid fuzzy decision rules. The algorithm was implemented in a group of patients, which included 217 people.
Results. Using the developed endosonographic criteria for MDP stenosis and the methodology for the synthesis of fuzzy decision rules, a production decision rule for the diagnosis of MDP stenosis was determined with a decision made according to a threshold set by experts at the level of 0.9. Guided by the selected information sources, 134 (61.7 %) patients with dilated common bile duct were diagnosed with MDP stenosis, requiring minimally invasive treatment aimed at relief of biliary hypertension and indications for endoscopic papillosphincterotomy were determined. In 83 cases of MDP stenosis, it was decided to abandon transpapillary interventions with subsequent follow-up of patients. Minimally invasive treatment using retrograde and antegrade techniques was performed in 134 patients. Complications were noted in 6 (4.4 %) patients, which is comparable to the number of complications with transpapillary interventions performed in patients without MDP stenosis. When monitoring 54 patients for one to three years, 85.2 % of patients showed regression of clinical, laboratory and instrumental symptoms of biliary hypertension.
Conclusions. The combination of endoscopic ultrasonography with fuzzy logic technologies based on hybrid artificial intelligence made it possible to objectify the diagnosis of MDP stenosis and optimize indications for transpapillary interventions.
Keywords: endoscopic ultrasonography, fuzzy decision rules, stenosis of the major duodenal papilla, endoscopic papillosphincterotomy
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Диагностика неопухолевых стенозирующих поражений большого сосочка двенадцатиперстной кишки с применением эндоскопической ультрасонографии

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Цель: оценить возможности эндоскопической ультрасонографии в диагностике доброкачественного стеноза большого сосочка двенадцатиперстной кишки и улучшить ее результаты, в том числе за счет определения и объективизации критериев заболевания.

Материалы и методы. Представлены результаты обследования и лечения 2146 пациентов, лечившихся в Курской областной многопрофильной клинической больнице в период с 2015 по 2022 г., которым на базе отделения эндоскопии выполнены транспапиллярные вмешательства и/или эндоскопическая ультрасонография. В клиническую практику внедрен лечебно-диагностический алгоритм ведения пациентов с расширением общего желчного протока, основой которого явились разработанные критерии стеноза большого сосочка двенадцатиперстной кишки (БС ДПК), для определения которых использовалась эндоскопическая ультрасонография в сочетании с методологией синтеза гибридных нечетких решающих правил. Алгоритм реализован в группе пациентов, которая включала 217 человек.
Результаты исследования. Используя разработанные эндосонографические критерии стеноза БС ДПК и методологию синтеза нечетких решающих правил, авторы определили продукционное решающее правило для диагностики стеноза БС ДПК с принятием решения по заданному экспертами порогу на уровне 0,9. У 134 (61,7 %) пациентов с расширением общего желчного протока диагностировали стеноз БС ДПК, требующий малоинвазивного лечения, направленного на купирование билиарной гипертензии, и были определены показания к эндоскопической папиллосфинктеротомии. В 83 случаях стеноза БС ДПК принято решение отказаться от транспапиллярных вмешательств с последующим наблюдением пациентов. Малоинвазивное лечение с использованием ретроградных и антеградных методик было проведено 134 пациентам. Осложнения отмечены у 6 (4,4 %) больных, что сопоставимо с количеством осложнений при транспапиллярных вмешательствах, выполненных у пациентов без стеноза БС ДПК. При наблюдении за 54 пациентами в течение от одного года до трех лет у 85,2 % пациентов отмечался регресс клинико-лабораторных и инструментальных симптомов желчной гипертензии.
Выводы. Сочетание эндоскопической ультрасонографии с технологиями нечеткой логики, основанной на гибридном искусственном интеллекте, позволило объективизировать диагностику стеноза БС ДПК и оптимизировать показания к транспапиллярным вмешательствам.
Ключевые слова: эндоскопическая ультрасонография, нечеткие решающие правила, стеноз большого сосочка двенадцатиперстной кишки, эндоскопическая папиллосфинктеротомия
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Introduction

Obstruction of the extrahepatic bile ducts, major duodenal papilla (MDP) is often accompanied by biliary and pancreatic hypertension and is complicated by mechanical jaundice, cholangitis, acute pancreatitis. The most common etiology of obstruction is choledocholithiasis, after which, among the benign causes leading to impaired patency of the biliary ducts, the second place is occupied by MDP stenosis [1, 2]. In patients with pathology of the pancreatobiliary zone, the frequency of non-tumor stenoses of MDP reaches 40 % [2–6]. To date, no standardized approach to the diagnosis of MDP stenosis has been developed in clinical practice, there is no single diagnostic algorithm and informative diagnostic criteria [7]. Diagnosis is mainly based on the identification of secondary signs that are a consequence of the pathological process, and the applied research methods are able to effectively identify the fact of obstruction, its level, and extent. The main difficulty lies in determining the nature of the pathological process, which is of fundamental importance in choosing surgical tactics. Endoscopic topical diagnosis, assessment of the severity of stenosis and its extent is difficult, which explains the difficulty in determining indications for endoscopic papillosphincterotomy (EPST). The detection of stenosing papillitis is complicated by the widespread inflammatory changes in the MDP, which are detected in most patients suffering from gallstone disease and pancreatitis. The true stenosis of MDP is masked by the symptoms of these diseases, which further complicates diagnosis.

Conventional diagnostic tools for periampular obstruction include ultrasound, duodenoscopy, computed tomography (CT), and magnetic resonance imaging (MRI). However, the extremely small size of the anatomical structures under study, often the absence or minimum amount of fluid in their lumen, and the air in the duodenum create significant difficulties for radiation diagnostic methods. In this regard, the differentiation of benign stenosis of MDP is often a difficult task [2, 3, 5, 8, 9]. Among modern methods of radiation diagnostics, endoscopic ultrasonography (EUS) occupies a special place, which allows you to directly visualize the papillary zone of the duodenum and assess in detail not only the condition of the terminal part of the common bile duct (CBD) and MDP, but also the entire periampular region. According to various studies, the accuracy

of endosonography in the diagnosis of MDP diseases is 40–96 % [10, 11].

Thus, the lack of clearly formulated criteria for MDP stenosis and a unified strategy for its diagnosis using EUS determines the relevance of the study.

Aim: to evaluate the possibilities of endoscopic ultrasonography in the diagnosis of benign stenosis of the major duodenal papilla and improve its results, including by identifying and objectifying the criteria of the disease.

Materials and methods

The work is based on the results of examination and treatment of 2146 patients hospitalized in the departments of general surgery, purulent surgery and gastroenterology of the Kursk Regional Multidisciplinary Clinical Hospital in the period from 2015 to 2022. The criterion for inclusion in the study was the fact that EUS and transpapillary interventions for biliary and/or pancreatic hypertension were performed. The exclusion criteria were diagnosed focal pathology of the pancreas, tumors of the pancreas, tumors of the MDP and duodenum. Based on clinical, laboratory and instrumental examination data of the general cohort of patients, the signs of MDP stenosis and the diagnostic capabilities of EUS were studied. Based on the results of observations, a therapeutic and diagnostic algorithm has been introduced into clinical practice, based on the developed criteria for stenosis of MDP. From the number of patients hospitalized in 2018–2022, a group of patients with stenosis of MDP of non-tumor etiology, including 217 people, was identified. The age of the patients ranged from 34 to 72 years, the average age was 64 ± 5.4 years. The majority of patients were women — 55.1 %, men made 44.8 %. Among this group of patients, 155 (71.4 %) people suffered from gallstone disease, 62 (27.7 %) of whom had previously had cholecystectomy at various times, 62 (28.6 %) patients did not have gallstone disease.

After a complex of clinical and laboratory studies with detailed anamnestic data, the method of examination of the first level, due to accessibility, non-invasiveness, and informativeness, was transcutaneous US. The sequence and set of therapeutic and diagnostic manipulations in patients with suspected MDP stenosis varied depending on the results of previously performed diagnostic studies, as well as rationally combining diagnostic and therapeutic manipulations into one stage, in particular, EUS and therapeutic transpapillary interventions. In patients with biliary hypertension and the absence of a visible cause of obstruction, according to US data, endosonography as a clarifying method was performed already at the initial stage of the diagnostic search, which allowed avoiding less informative methods of radiation diagnosis, as well as diagnostic endoscopic retrograde pancreatocholangiography. EUS is regarded as a second-line examination method after transcutaneous US for the diagnosis of gallstone disease, unexplained pain syndrome in the right hypochondrium and acute pancreatitis of unknown etiology [12].

Endoscopic examinations, including transpapillary interventions, were performed on the basis of the endoscopy department with the Evis Exera II video information system (Olympus, Japan), the TJF-150 video duodenoscope and a set of endoscopic instruments from Olympus and Medi-Globe (Germany). All transpapillary interventions were performed in the X-ray operating room using a mobile X-ray digital device with a C-shaped arc GE OEC Brivo 785 (General Electric Healthcare, USA). The EUS is performed with an EU-ME1 ultrasound processor (Olympus, Japan), endosonography — with ultrasonic video gastroscopes GF UM160 with a radial sensor and GF UC140P–AL5 with a convex sensor (Olympus, Japan). The technique of endosonography corresponded to the generally accepted endosonography of the pancreatobiliary zone.

Endosonography included the following stages: visual examination of the MDP and parapapillary zone, instrumental palpation of the MDP, detailed echo scanning of the organs of the hepatopancreatoduodenal zone with an emphasis on the periampular region to exclude pathology of adjacent organs, echo scanning of segments of the terminal CBD. When determining indications for duodenoscopy and transpapillary interventions according to EUS data, the latter were performed immediately, within the current study, combining diagnostic manipulations with therapeutic ones. At the same time, it became possible to use various tools and conduct a trial cannulation of the papilla mouth, obtaining additional information about the nature of the pathological process of the papilla to determine indications for EPST.

The main tasks of visual examination of the papillary region of the duodenum included assessment of the shape of the duodenum, the condition of its mucous membrane, localization of MDP, its size, shape, relief of the mucosa, assessment of the condition of the mouth, the presence of neoplasms, morphological verification of detected changes, instrumental palpation of the papilla, identification of concomitant pathology of the papillary zone. Echo scanning with visual inspection and the possibility of collecting material for morphological examination is one of the decisive advantages of EUS. It was considered possible to inspect the MDP and the parapapillary zone with an

echoendoscope without first performing duodenoscopy. In the vast majority of cases (in 192 (88.5 %) patients), the anatomical structures of the papillary region were examined in detail. In other cases, the examination of the papillary zone was carried out with devices with lateral optics, including within the same stage, replacing the echoendoscope with a duodenoscope. The examination was performed both as standard on the "short loop" of the endoscope and on the "long loop" for inflammatory changes in the duodenum with a sharp thickening and swelling of the folds of the mucous membrane in 7 patients, with a low location of MDP — in 6 patients, deformity of the duodenum — in 5 cases, very small papilla — in 4 cases, parapapillary diverticulum of large sizes — in 3 patients.

When echo-scanning the MDP area, attention was focused on the size of the papilla and longitudinal fold, segments of the terminal CBD, the structure of the duodenal wall, echogenicity of MDP tissues were visualized in detail, the state of the main pancreatic and extrahepatic bile ducts, the state of pancreas and regional lymph nodes were ascertained. In all cases, a complete examination of the pancreatobiliary zone was performed from all standard positions of the echoendoscope. The periampular area was examined from the bulb of the duodenum and the second part of the duodenum, often with repeated insertion and removal of an echoendoscope, while keeping the sonographic visualization of CBD and MDP in the field of view, repeatedly changing the scanning planes between the transverse and longitudinal visualization of these structures. Particular attention was paid to the nature of duct expansion and the detail of the stenosis zone itself relative to the muscular layer of the duodenal wall, with an assessment of its level, extent, nature of narrowing, the structure of the walls of the terminal CBD in the narrowing zone, and the contents of the bile ducts. To improve the sonographic visualization of the stenosis zone, the contact of the ultrasonic sensor with the wall of the duodenum and MDP was provided by the introduction of liquid into the intestinal lumen, replacing the balloon technique, which was especially effective for visualizing small anatomical structures of the papillary region. In the presence of choledocheal drains, they were used to fill the bile ducts with fluid. All this made it possible to improve the visualization of the papilla area in a physiological state, without compression with a balloon.

Results

In all 217 patients, the papillary zone was examined in detail and MDP and longitudinal fold were visualized. Upon visual examination, no papilla changes were detected in 112 (51.6 %) patients. MDP was defined as an oval flattened or cone-shaped elevation near the longitudinal and covering transverse fold on the posteromedial wall of the second part of the duodenum. When describing the MDP form, we used a classification that, from our point of view, is the most practical in terms of the technical features of performing transpapillary interventions. Hemispherical (most common), flattened, cone-shaped and dot-shaped MDP were distinguished [7, 9]. Although there is a much greater variety of forms in the literature: up to eight or more when describing the papilla [8, 13, 14].

According to our data, the flat and cone-shaped forms of MDP prevailed — 77 (35.5 %) and 68 (31.3 %) patients, respectively. The hemispherical shape accounted for 60 (27.6 %) patients. The remaining 12 patients had a dot-shaped form of MDP. These indicators differ from the average prevalence of MDP forms in the population, which is logical for the pathology under study. The average length of the longitudinal fold according to visual inspection was 8.1 ± 4.2 mm.

There is no uniform terminology of surgical anatomy of the terminal department of CBD in the literature [15]. Based on endosonographic, radiological, and endoscopic data obtained from the examination of patients in the study group, in order to implement the concept of a differentiated approach to the construction of a therapeutic and diagnostic algorithm for MDP stenosis and a clear definition of indications for minimally invasive intervention, as well as to determine the nature of the intervention, it was considered rational to divide the terminal CBD department into the following segments: ampullary (intraampular, papillary) — the segment corresponding to the section of the bile duct from the mouth of the MDP to the muscular layer of the wall of the duodenum; intramural segment, corresponding to the part of CBD at its junction with the muscular layer of the duodenal wall; intrapancreatic segment — a section of CBD before perforation of the duodenal wall, adjacent or partially covered by pancreas tissue, depending on anatomical features. The segmental structure of the terminal department of CBD is shown in Figure 1.

This approach is rational for the interpretation of EUS data, which allows you to visualize the described segments in detail within their boundaries, focusing on the hypoechoic muscular layer of the duodenal wall, and, accordingly, determine the location and extent of pathological changes. The described classification does not contradict the literature data [16]. This division is also reflected

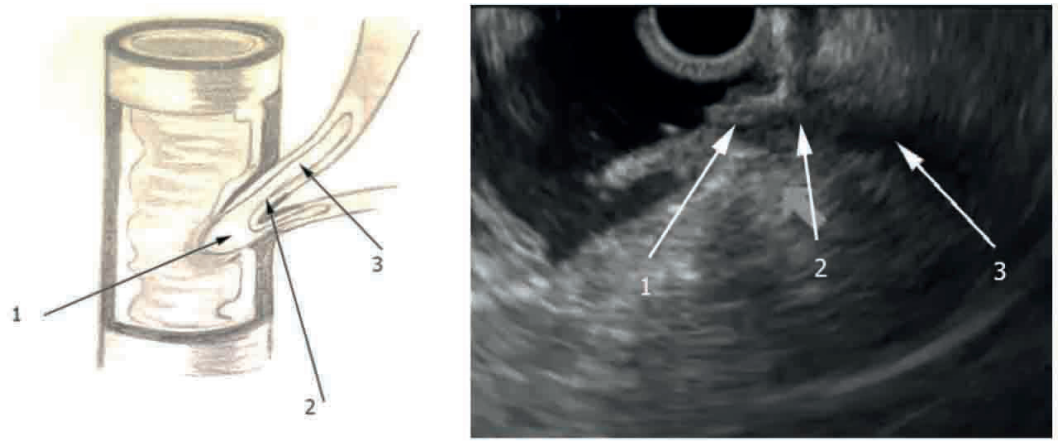

Figure 1. Segmental structure of the terminal part of the common bile duct: A — a scheme; B — endosonogram (*1* — ampullary section, *2* — intramural section, *3* — intrapancreatic section)

Рисунок 1. Сегментарное строение терминального отдела ОЖП: А — схема; В — эндосонограмма (*1* — ампулярный отдел, *2* — интрамуральный отдел, *3* — интрапанкреатический отдел)

in the methodological recommendations on endoscopic sphincterotomy developed by the Japanese Society of Gastroenterological Endoscopy (JGES), where the phrase "bile duct at the major papilla" is used, the correct translation of which means the intrapapillary part of the bile duct, i.e. the intraampular part is isolated from the intramural part. However, there is another point of view, which consists in the absence of sufficient grounds for revising the generally accepted classification of anatomical fragments of CBD. The authors adhere to the generally accepted classification, which provides for the allocation of supra-, retroduodenal, intrapancreatic and intramural departments of the choledochus without accentualization to the ampullary segment [6, 17]. Although the same authors describe the terminal section with the identification of not only the intramural section (duodenal part), but also, in fact, the MDP [6, 15], which suggests the presence of a section of the intraampullary duct in it.

Visually pathological changes in MDP were detected in 105 (48.4 %) patients. Among them, in the majority of cases, pathological reduction in the size of MDP prevailed with various variants of deformation of the longitudinal fold, the papilla itself, and poor visualization of the mouth or its visual absence — 52 (49.5 %) patients. Benign single or multiple polypoid formations in the mouth area were in second place in frequency — 30 (28.6 %) patients. In 21 (20.0 %) cases, a pathological increase in papilla size of more than 1 cm was noted. In 11 (10.5 %) patients, the phenomena of papillitis with edema and hyperemia of the mucous membrane were detected, and in some cases, the mucous membrane of the papillary zone of the duodenum was also hyperemic and edematous.

A biopsy was performed in 72 (33.2 %) patients with MDP stenosis. At the same time, 96.1 % of biopsies were informative, which is explained by the priority of material collection after EPST, if it was performed. At the same time, a targeted biopsy from the mouth of the MDP was performed in 34 (47.2 %) patients, in 38 (52.8 %) from the ampullary part of the MDP after EPST. The adenomatous form of chronic papillitis was detected in 14 (19.4 %) patients, adenomyomatous — in 1 (1.4 %), atrophic-sclerotic — in 10 (13.9 %). The most common morphological conclusion was papillomatosis MDP, which is hypertrophy of the villi of the mucous membrane at the mouth of the papilla, resulting from chronic inflammation (22 (30.5 %) patients). Chronic inflammatory changes of varying severity were detected in 14 (19.4 %) patients. Among other histological findings, hyperplastic polyp, scar tissue, inflammatory granulations, tubular, papillary and villous adenomas were established.

The next step in performing EUS was a detailed ultrasound imaging of all anatomical structures of this area, confirming the absence of other obstructive pathology of the pancreas, terminal CBD, duodenum [18].

AT the same time, EUS makes it possible not to resort to performing other imaging research

methods (CT, MRI), which avoids unjustifiably complicating the diagnostic algorithm. Thus, in the Roman criteria of functional pathology of the gastrointestinal tract, one of the criteria for diagnosing a functional disorder of the sphincter of the pancreatic type Oddi is "negative EUS", which indicates its high diagnostic effectiveness [19].

Diagnostic criteria for MDP stenosis are not clearly formulated [5]. The differential diagnosis of diseases that can lead to cicatricial stenosis of MDP (parapapillary diverticula, MDP polyps, choledocholithiasis, papillitis) and functional disorders of the Oddi sphincter is based on an integrated approach that should include clinical, laboratory and instrumental methods of examination of patients [20]. The main criterion for bile duct obstruction at the MDP level is the expansion of CBD. At the same time, the question arises about the size of the boundary diameter of the CBD, indicating a violation of the bile outflow [20]. It is reported that even a slight expansion of CBD is still not a variant of the norm but may be a symptom of the disease — MDP stenosis [7]. There are also alternative judgments indicating dilation of the bile ducts due to dysfunction of the biliary system during inflammation and loss of reservoir function of the gallbladder [21]. The diameter of the bile duct depends on age, body mass index, medication intake and diseases of the pancreatobiliary zone [22]. The diagnosis of papillostenosis is established "by contradiction": only complete confidence in the absence of another obstructive pathology of MDP makes papillostenosis a valid diagnosis [8].

Visual signs of MDP stenosis in the study group were the following: abnormal increase or decrease in the size of the papilla; deformation of the longitudinal fold; complete absence or low severity of the longitudinal fold; absence of a clearly defined mouth of MDP; epithelial growths in the mouth area. During instrumental palpation and trial cannulation with various instruments, signs of stenosis were considered: increased papilla density and "slipping" of instruments, difficulty in cannulating the mouth, lack of free mobility of the papillotome string during mouth cannulation in the case of duodenoscopy.

Informative ultrasound criteria for MDP stenosis are shown in the Table. When performing endosonography, the following results were obtained. The diameter of CBD in the study group varied within 13.2 ± 4.2 mm. Choledocholithiasis was detected in 41 (18.9 %) cases in patients suffering from gallstone disease. Loose concretions and biliary sludge were found in another 34 (15.7 %) patients, taking into account all diagnosed hyperechogenic inclusions of the common bile duct, including those whose dimensions were no more than 2 mm, the proportion of patients with heterogeneous contents of the bile ducts reached 46.0 %. This is confirmed by the literature data indicating the high sensitivity of EUS in the diagnosis of choledocholithiasis [5], high resolution in some cases makes it possible to visualize even individual bile acid crystals [23, 24]. A hyperplastic variant of stenosing papillitis with an increase in MDP in size was detected in 20 (9.2 %) cases. Direct endosonographic criteria for sclerosing papillitis — a narrowed segment of the terminal choledochus; thickened MDP walls (emphasized layering with a predominance of hyperechoic signals) — were detected in 41 (18.9 %) patients.

The elasticity of the terminal CBD was assessed by its contractile activity. In the literature, this phenomenon is described as a "game of the sphincter apparatus" [16] or contractility in the area of the closing terminal sphincters [25]. In the fibrotic-sclerotic process, contractility is preserved, but significantly reduced. In EUS, multiple active changes in the diameter and shape of the lumen of the terminal choledochus are visualized at the level of interest to the researcher, while the object of comparison was duodenal peristalsis. Changes in the diameter and shape of the lumen of the terminal section can be most clearly traced when using a convex sensor during transverse scanning in the position of the distal end of the echoendoscope in the second part of the duodenum at the MDP level (Fig. 2).

The work of the sphincter apparatus was visualized in the majority of patients in the study group — 163 (75.1 %), and a decrease or absence of contractility of the terminal choledochus at the level of the stenosed segment was confidently stated in 72 (44.2 %) patients.

When performing EPST, well-known anatomical landmarks regulating the length of the incision are the shape of the MDP and the size of the longitudinal fold, as well as the localization of the transverse fold [6, 16, 26]. However, the formation of a longitudinal fold may be caused not only by the terminal department of the CBD, but also by lymph nodes [6]. At the same time, it should be borne in mind that the upper boundary of the longitudinal fold may not always be a reliable anatomical reference point for determining the length of the papillary segment and the length of the papillotomic incision [27]. In connection with the above, clarifying the boundaries and length of the segments of the terminal part of the common bile duct during endosonography, as well as comparing them with endoscopic landmarks, is of great practical importance for accurate topical diagnosis of MDP pathology, predicting the length of the

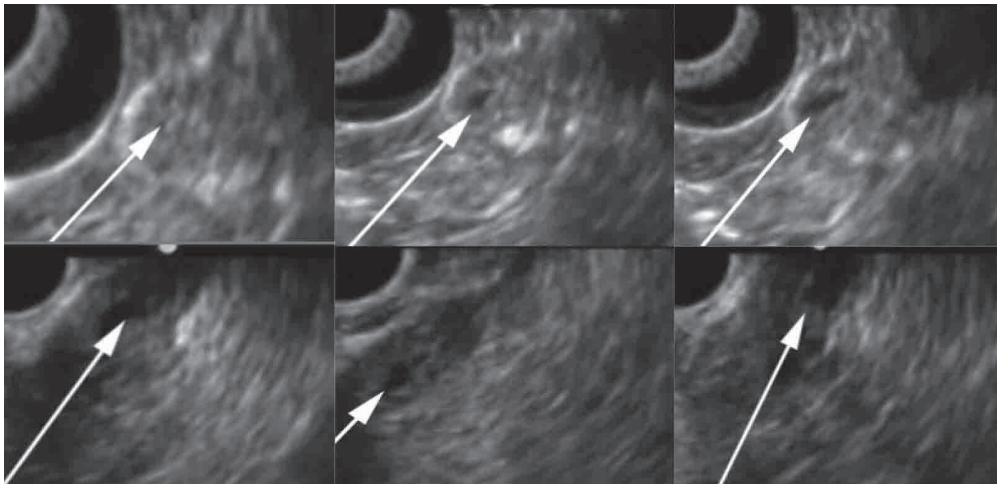

Figure 2. Assessment of the elasticity of the terminal portion of the common bile duct: on a series of endosonograms, the ampullary segment of the terminal portion of the common bile duct (indicated by arrows) is visualized with multiple changes in the diameter and shape of the lumen

Рисунок 2. Оценка эластичности терминального отдела ОЖП: на серии эндосонограмм визуализируется ампулярный сегмент терминального отдела холедоха (обозначен стрелками) с многократным изменением диаметра и формы просвета

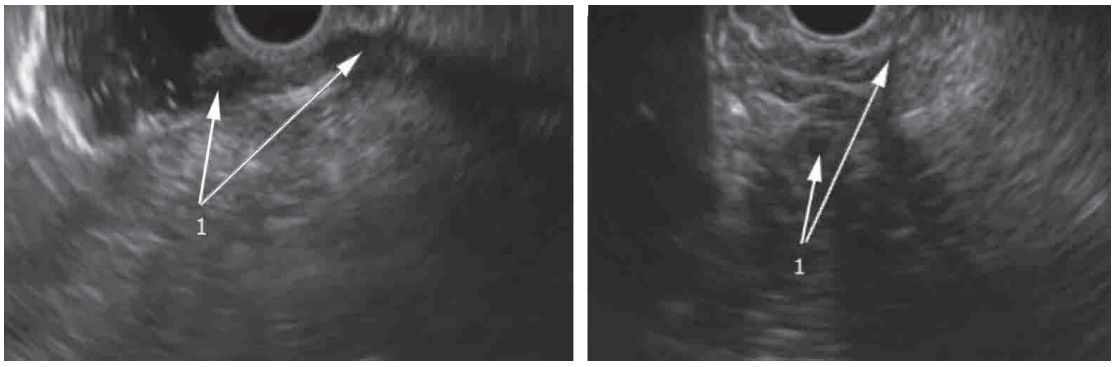

Figure 3. Assessment of the length of the ampullary segment of the terminal part of the common bile duct: A — longitudinal scan; B — transverse scan (1 — arrows indicate the length of the ampullary segment)

Рисунок 3. Оценка протяженности ампулярного сегмента терминального отдела общего желчного протока: А — продольный скан; В — поперечный скан (1 — стрелками обозначена протяженность ампулярного сегмента)

incision during papillotomy and determining options for minimally invasive interventions. For an accurate topical diagnosis, it is important to:

— perform a study using intravenous sedation;

— the use of an echoendoscope with a convex sensor, which allows to obtain a detailed joint visualization of the segments of the terminal department and the muscular layer of the duodenum in one scan;

— combination of balloon endosonography technique and duodenal filling technique with liquid;

— assessment of the length of the ampullary segment of the terminal CBD in longitudinal and transverse scans, the results of which should be comparable (Fig. 3).

When determining the localization of MDP stenosis, we focused on direct sonographic signs, the level of expansion of the bile ducts, contractile activity of the terminal CBD, visual endoscopic signs, and the results of instrumental "palpation". In the majority of cases, 133 (61.3 %) patients

Table. Informative criteria for MDP stenosis with diagnostic confidence coefficients
Таблица. Информативные критерии стеноза БС ДПК с диагностическими коэффициентами уверенности

Feature *Признак*	Description of the feature *Описание признака*	Confidence coefficient *Коэффициент уверенности*
X1	Expansion of the common bile duct over 12 mm *Расширение общего желчного протока свыше 12 мм*	0.6
X2	Expansion of the common bile duct over 9 mm *Расширение общего желчного протока до 9 мм*	0.55
X3	Visualization of threadlike segments of the terminal part of the common bile duct following suprastenotic expansion *Визуализация нитевидных сегментов терминального отдела общего желчного протока, следующих за супрастенотическим расширением*	0.75
X4	Segmental thickening of the walls of the ampullary part of the MDP with the formation of an accentuated layered structure of mixed echogenicity or with the predominance of hyperechoic signals *Сегментарное утолщение стенок ампулярного отдела БС ДПК с формированием подчеркнутой слоистой структуры смешанной эхогенности или с преобладанием гиперэхогенных сигналов*	0.75
X5	Decreased elasticity of the terminal part of the common bile duct *Снижение эластичности терминального отдела общего желчного протока*	0.65
X6	Smooth contour of the narrowing of the duct to the stenosis zone *Плавный контур сужения протока к зоне стеноза*	0.45
X7	Pathological reduction in the size of the MDP with various variants of deformation of the longitudinal fold *Патологическое уменьшение размеров БС ДПК с различными вариантами деформации продольной складки*	0.45
X8	Homogeneous hypoechoic enlarged MDP, the dimensions of which do not exceed 1 cm *Однородный гипоэхогенный увеличенный БС ДПК, размеры которого не превышают 1 см*	0.35
X9	Presence of biliary sludge *Наличие билиарного сладжа*	0.30
X10	Polypoid formations in the mouth area *Полиповидные образования в области устья*	0.35
X11	Papillitis without changing the size of MDP *Папиллит без изменения размеров БС ДПК*	0.25

Note: MDP — major duodenal papilla.
Примечание: БС ДПК — большой сосочек двенадцатиперстной кишки.

had local stenosis within the ampullary segment, while the mouth of the MDP remained free. At the same time, the CBD was expanded to the intramural department. Sonographically, there were no changes in the intramural department, the contractile activity of the intramural department was preserved. Local ampullary stenosis spreading from the mouth of the MDP occurred in 20 (9.2 %) patients. At the same time, the mouth could not be cannulated, and in 12 patients it did not differentiate. Extensive ampullary stenosis extending to the intramural department was found in 18 (8.3 %) cases. At the same time, in addition to visualization of direct signs of stenosis, there was a decrease or absence of contractility in the intramural region of the CBD. MDP stenosis with the spread of stricture to the intrapancreatic department was detected in 21 (9.7 %) patients. Its main feature was a cone-shaped stricture visible in EUS with suprastenotic expansion. In 25 (11.5 %) patients, it was not possible to convincingly determine the localization and extent, mainly due to the small size of the MDP and longitudinal fold, pronounced peristalsis, fuzzy visualization of the

papillary zone due to edematous changes in the duodenal wall, etc.

Analysis of the signs of MDP stenosis showed that they are characterized by a heterogeneous description. A reliable diagnosis is established only by a set of signs, for each of which it is individually impossible to establish reliable links with papillostenosis. In accordance with the recommendations of [28–30], to obtain a diagnostic decision rule, it is advisable to use a methodology for the synthesis of hybrid fuzzy decision rules, according to which, for the resulting data structure, the basic element of diagnostic models are confidence coefficients in the diagnosis of "MDP stenosis" obtained by expert evaluation for each informative feature. The Table shows informative features with corresponding confidence coefficients obtained using the methodology of synthesis of hybrid fuzzy decision rules when working with experts using the Delphi method.

Direct signs of MDP stenosis (X3, X4) are shown in Figures 4 and 5.

Considering the need to pre-exclude a number of diagnoses and properties of selected informative features, a fuzzy production diagnostic rule is obtained:

IF [NOTQ1 OR NOTQ2 OR, …, OR NOTQn] THEN {S(i + 1) = S(i) + KU(i + 1) [1 – S(i)]} OTHERWISE (S = 0),

where Q1, Q2, …, Qn are excluded diagnoses; S(i) – the confidence in the stenosis of the MDP at the i-step of calculation; KU(i + 1) – the confidence coefficient in the desired diagnosis for an informative feature with the number i + 1; S(1) = KU(1).

Excluded diagnoses include pathology of periampular localization, causing CBD obstruction: Q1 – pancreatic tumors; Q2 – focal forms of chronic pancreatitis; Q3 – CBD tumors; Q4 – benign CBD strictures; Q5 – extracholedocheal obstructive pathology (retroperitoneal tumors, lymph nodes, cysts, etc.); Q6 – MDP tumors; Q7 – parapapillary diverticulum; Q8 – duodenal tumors; Q9 – duodenal deformity (ulcerative, postoperative, etc.).

In mathematical modeling, for the obtained partial confidence coefficients at their maximum values, the confidence in the correct classification according to the class "MDP stenosis" exceeds 0.99, and for the most common values of informative signs – 0.92.

According to the most common values of informative signs, confidence in the correct classification according to the MDP stenosis class exceeds 0.90. This value was considered the threshold for triggering the decisive rule. Indications for minimally invasive treatment were determined for all patients included in the

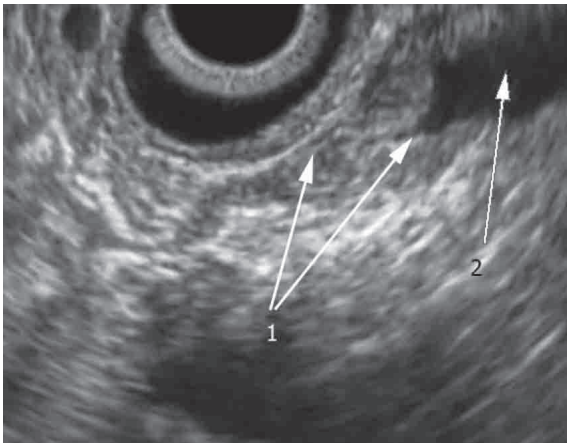

Figure 4. Threadlike segment of the terminal part of the common bile duct, following the suprastenotic dilatation (X3): *1* – threadlike segment, *2* – suprastenotic dilatation of the common bile duct

Рисунок 4. Нитевидный сегмент терминального отдела общего желчного протока, следующий за супрастенотическим расширением (признак X3): *1* – нитевидный сегмент, *2* – супрастенотическое расширение холедоха

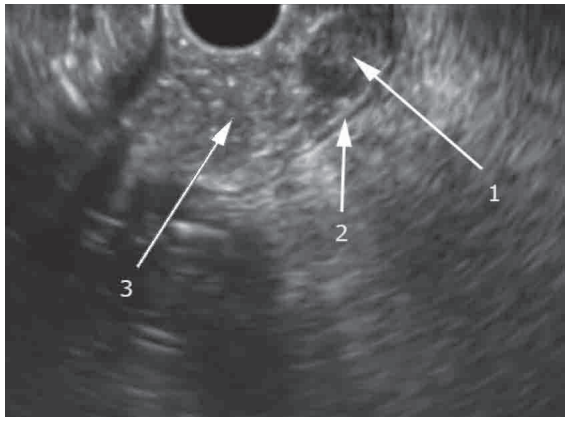

Figure 5. Segmental thickening of the walls of the ampullary portion of the major duodenal papilla with the formation of an accentuated layered structure of mixed echogenicity or with a predominance of hyperechoic signals (X4): *1* – major duodenal papilla, *2* – muscular layer of the duodenum, *3* – duodenal lumen

Рисунок 5. Сегментарное утолщение стенок ампулярного отдела БС ДПК с формированием подчеркнутой слоистой структуры смешанной эхогенности или с преобладанием гиперэхогенных сигналов (признак X4): *1* – БС ДПК, *2* – мышечный слой ДПК, *3* – просвет ДПК

group with reliable criteria for MDP stenosis and a threshold for triggering the decisive rule above 0.90.

Transpapillary interventions were performed in 134 (61.7 %) patients with MDP stenosis. The results of retrograde and antegrade cholangiography, EPST, instrumental revision of the bile ducts, and morphological examination of biopsy material were considered to confirm the correctness of the diagnosis of MDP stenosis. The main ultrasound sign of successful resolution of stenosis was considered to be a decrease in the diameter of CBD by at least 20–30 % in the control study starting from the third day after the intervention. There were no fundamental contradictions and discrepancies between the EUS data and the results of minimally invasive treatment. Complications were noted in 6 (4.4 %) patients, which is comparable to the number of complications with transpapillary interventions performed in patients without MDP stenosis. In one case, retroduodenal perforation of the duodenum was detected, in two cases — bleeding from a papillotomy wound, which required the use of repeated endoscopic hemostasis, in three cases — acute pancreatitis of varying severity.

In 39 (72.2 %) patients out of 54 observed for one to three years after papillotomy, there was an almost complete regression of clinical symptoms (pain syndrome of a biliary and/or pancreatic nature), and in 7 more patients there was a significant decrease in the intensity and frequency of pain, which indicates a correctly established diagnosis and determination of indications to the EPST.

Conclusion

Thus, the developed criteria for MDP stenosis in combination with the methodology for the synthesis of hybrid decision rules make it possible to objectify the diagnosis of this pathology and reasonably clarify the indications for transpapillary interventions. The use of EUS, as well as the integration of fuzzy logic methods into a set of diagnostic measures in patients with non-tumor stenosis of MDP, allows us to bring the diagnosis of this pathology to a qualitatively new level, to obtain objective information about the features of the anatomy of the terminal department of CBD already at the preoperative noninvasive stage.

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