

The Eurasia Proceedings of Science, Technology, Engineering and Mathematics (EPSTEM), 2026

Volume 41, Pages 49-55

ICRETS 2026: International Conference on Research in Engineering, Technology and Science

Biomedical Engineering and Biomedical Technologies for Effective Prevention, Detection and Elimination of Choledocholithiasis

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Abstract: Currently, the issues of effective prevention, detection and high-quality elimination of choledocholithiasis remain open. These issues have changed radically over the past 30 years after the significant spread of visualization using endoscopic ultrasound and magnetic resonance cholangiography, endoscopy and laparoscopy, but still require additional clarification. We studied the possibilities of modern approaches and developments in biomedical engineering and biomedical technologies in patients with choledocholithiasis on the basis of the Department of Surgery and Urology of Dnipro State Medical University and the surgical departments of Clinical Hospital No. 6 of Dnipro (Ukraine). To detect choledocholithiasis, a whole arsenal of biomedical engineering and biomedical technologies is used: clinical and laboratory, biochemical, radiation and endoscopic research methods. The most informative diagnostic methods are ultrasound in combination with computed tomography or magnetic resonance imaging, which are non-invasive, and endoscopic retrograde cholangiopancreatography. Along with the generally accepted method of eliminating the problem, where laparoscopic cholecystectomy was performed, we used intraoperative fiberocholedochoscopy as a component of biomedical engineering and an auxiliary component of biomedical technologies in the effective elimination of choledocholithiasis. The result of using biomedical engineering components with biomedical technologies in our work, which was carried out for the period from 2018 to 2024, is: the duration of treatment when using modern diagnostic and minimally invasive technologies was 6.8 ± 0.52 bed-days, mortality - 0.2%, while with open operations - 12.8 ± 3.3 bed-days, mortality — 5.2%. The use of minimally invasive interventions allowed to reduce the number of traditional - "open" - operations for choledocholithiasis and significantly reduce the number of complications, mortality, and the duration of patient hospitalization, which emphasizes the great importance of using biomedical engineering developments together with biomedical technologies in the detection, prevention and elimination of choledocholithiasis in patients.

Keywords: Biomedical, Engineering, Technologies, Choledocholithiasis

Introduction

With the introduction of choledocholithiasis biomedical minimally invasive and endoscopic technologies, the diagnostic capabilities in the detection of are expanding, but often this complication is not diagnosed before cholecystectomy. Choledocholithiasis is the presence of gallstones in the common bile duct (CBD), causing bile obstruction. It often causes upper right abdominal pain, jaundice, nausea, and vomiting. Caused by stone

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- Selection and peer-review under responsibility of the Organizing Committee of the Conference

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migration from the gallbladder (secondary) or formation within the ducts (primary), it is treated via ERCP for stone removal. Despite the wide range of biophysical diagnostic methods available today, none of them is a completely reliable method for detecting stones in the bile ducts, so the question of effective diagnosis of choledocholithiasis remains open (Girón, et al., 2023). This complication requires general surgical intervention, and due to the rapid development of biomedical technologies, its diagnosis and treatment are gradually improving.

Diagnosis and treatment of choledocholithiasis have changed radically in recent years after the significant spread of visualization using biophysical endoscopic ultrasound and magnetic resonance cholangiography, "RendeVouz" procedure, endoscopy and laparoscopy (Costi et al., 2014). Discussions are ongoing regarding the selection of the most informative, less invasive and cost-effective methods for detecting different forms of choledocholithiasis. It is also important to determine the most effective treatment for this condition. Modern biophysical technologies in the diagnosis and treatment of choledocholithiasis and its complications may rely on various imaging techniques and minimally invasive treatment methods, but there is no consensus on the best treatment for choledocholithiasis and its complications. New questions arise regarding the most effective treatment of complex cases requiring conversion to open surgery when intraoperative complications arise during laparoscopic choledocholithotomy (Alkarboly, et al., 2016; Cianci et al., 2021).

The American Society of Gastrointestinal Endoscopy (ASGE) has proposed risk criteria for choledocholithiasis that are used worldwide. According to ASGE guidelines, patients are routinely classified according to their likelihood of developing choledocholithiasis as low risk (<10%), intermediate risk (10%-50%), and high risk (>50%). The risk of choledocholithiasis should be assessed in every patient who requires cholecystectomy to determine the appropriate treatment strategy (Maple et al., 2010; Buxbaum et al. 2019). Accurate risk assessment of choledocholithiasis before laparoscopic cholecystectomy is essential to determine the optimal treatment strategy. Over the past 30 years, a number of biophysical and technological strategies have been introduced to treat even the most complex bile duct stones, including large balloon papillary dilatation and intraductal laser and electrohydraulic lithotripsy under cholangioscopy guidance (Khoury et al., 2019). Diagnosis of choledocholithiasis includes the consistent use of modern biomedical technologies: transabdominal ultrasound, direct contrast methods of the biliary tract and the use of polarization microscopy of bile (Wei et al., 2020).

The presence of crystals in bile is a marker of choledocholithiasis, which, in the absence of pathognomonic signs, requires a thorough instrumental examination of patients, taking into account different informative and invasive methods of research, which will complete the diagnostic stage before surgical treatment (Baiu &Hawn, 2018) The results of microscopic examination of bile can be used as an important criterion for determining indications for endoscopic transpapillary intervention. According to literature data, the most common surgical intervention (up to 70%) in patients over 50 years of age was laparoscopic cholecystectomy with laparoscopic choledocholithotomy and T-tube drainage or primary closure.

The aim of the article is to identify a quantitative assessment of the prevalence of choledocholithiasis, identify reliable preoperative biophysical and technological factors for predicting choledocholithiasis, and improve the results of surgical treatment of patients with choledocholithiasis through the use of comprehensive effective preoperative and intraoperative diagnostics (Cai et al., 2017).

Method

In 2108 patients with gallstone disease who were treated in a surgical clinic of Dnipro City Hospital #6 from 2018 to 2024. Of these, 565 (26.8%) were diagnosed with choledocholithiasis. Including 193 (34.2%) were diagnosed with microcholedocholithiasis, and 147 (26%) of them required repeated operations for residual choledocholithiasis. Of the 565 patients with choledocholithiasis, 465 (82.3%) were women and 100 (17.7%) were men. Age over 50 years was observed in 502 (89%) patients. Clinical manifestations of choledocholithiasis were distinguished by the inconstancy of individual symptoms. In 78.7%, the absence of cholangitis was noted, in 26.5% - mechanical jaundice, in 28.9% choledocholithiasis proceeded without expansion of the diameter of the duct, in 17.2% without pronounced pain syndrome. Further, in all 565 patients with choledocholithiasis, during a comprehensive preoperative examination, calculi were found in the lumen of the bile ducts (Meeralam et al., 2017; Sebghatollahi et al., 2023). For the purpose of preoperative diagnostics to identify the risk of carrying choledocholithiasis, serological studies of the liver/pancreas, biomedical engineering instrumental methods were used: ultrasound examination, fibrogastroscopy, X-ray computed tomography of the bile ducts, M-retrograde cholecystopancreatography, E-retrograde cholecystopancreatography (Mandelia et al., 2013).

The complexity of preoperative diagnosis of choledocholithiasis lies in the diversity of clinical manifestations, the absence of a pathognomonic symptom complex, the presence of asymptomatic forms. Choledocholithiasis can be masked as other diseases. Methods of preoperative diagnosis of choledocholithiasis should be carried out according to the principle of "from simple to most complex" method.

Results and Discussion

In serological tests in choledocholithiasis, the direct fraction of total bilirubin was increased by 25 and 30.8 times, total cholesterol by 1.8 and 1.9 times, γ -glutamyl transpeptidase by 1.3 and 1.2 times, alkaline phosphatase by 3.9 and 4 times, and glutamate dehydrogenase by 1.2 and 1.3 times. Alkaline phosphatase had a sensitivity of 74.8%, total bilirubin had a sensitivity of 73.7%. (Isherwood et al., 2014). Thus, choledocholithiasis can be suspected based on markers of bile lithogenicity: $\uparrow$ cholesterol, $\downarrow$ cholatocholesterol coefficient, presence of $\uparrow$ level of direct bilirubin fraction in bile, $\uparrow\gamma$ glutamyl transpeptidase in blood serum. The presence of these markers of choledocholithiasis requires a thorough biotechnological instrumental examination and affects the choice of further treatment tactics (Toro-Calle et al., 2020; Kokoroskos et al., 2021).

Ultrasound was used as the initial imaging test for screening patients with suspected choledocholithiasis in 100% of patients. Of these, direct and indirect signs of choledocholithiasis were detected in 75%, and pseudo-negative results were obtained in 13%, and were explained by the severity of infiltrative changes in the hepatoduodenal ligament, which caused distortion of the echo signal, especially after repeated operations. No ultrasound signs of choledocholithiasis were detected in 193 (34.31%), in 107 (19%) patients, single stones from 2 to 4 mm were detected, and the diameter of the common bile duct was 0.7-0.8 cm. A direct sign of choledocholithiasis was considered to be the presence of a hyperechoic acoustic shadow in the lumen of the common bile duct. The acoustic shadow was detected in 176 (31.3%) patients. Indirect signs include the spread of intra- and extrahepatic bile ducts. According to ultrasound, it was found in 372 (65.9%) patients. The accuracy of preoperative ultrasound for the diagnosis of choledocholithiasis is low, however, an elevated level of alanine aminotransferase, concomitant acute cholecystitis, and an increased diameter of the common bile duct were identified as key factors affecting the accuracy of the diagnosis. Computed tomography, as one of the modern biomedical technological methods, was performed on 39 patients (28 women, 11 men) with choledocholithiasis. In 29 of them, choledocholithiasis was combined with chronic calculous cholecystitis, in 14 - with obstructive jaundice and cholangitis.

The combination of ultrasound examination with computed tomography increases the accuracy of choledocholithiasis diagnosis to 97.4%. In severe cases with the development of complications, with suspected infection, computed tomography allowed to diagnose the presence of pancreatic necrosis and the volume of organ damage, as well as to determine the presence of infiltration of adjacent tissues and fluid accumulations, their distribution in anatomical spaces. Computed tomography with bolus contrast, unlike ultrasound, allowed to more accurately assess the extrapancreatic spread of the inflammatory process.

Fibrogastroduodenoscopy was performed on a mandatory basis in all 565 patients with suspected choledocholithiasis. This technique helped to detect bedsores in the area of the major duodenal papilla, due to the impaction of concretions in 8 patients, in 8 patients after fibrogastroduodenoscopy, spontaneous passage of concretions into the duodenum was observed and, as a result, mechanical jaundice decreased and urine color lightened.

As a biomedical engineering technology, direct contrast of the extrahepatic bile ducts before surgery was used, and it was carried out using E-retrograde cholecystopancreatography, which was performed in 198 (35%) patients. The indications for its implementation were: 1) suspicion of choledocholithiasis according to ultrasound; 2) biochemical disorders (increased bilirubin and other indicators); 3) the need to remove common bile duct stones. The informativeness of E-retrograde cholecystopancreatography in choledocholithiasis was 96.7%. The data obtained indicate the presence of choledocholithiasis in 28%, however, in 5% only the pancreatic duct was contrasted, and in 2% pseudo-negative results of the study were obtained.

In 83 patients, M-retrograde cholecystopancreatography was used to diagnose choledocholithiasis. Common bile duct stones were visualized on MR images as single or multiple filling defects with loss of MR signal from them against the background of a bright signal from the surrounding bile. The common bile duct was more than 0.8 cm in 61 patients and 0.7-0.8 cm in 22 patients. In 15, single small stones were located in the ampullary part of the common bile duct, in 30 choledocholithiasis was combined with stenosis of the major duodenal papilla (Polistina et al., 2015).

Our results showed the informativeness of M-retrograde cholecystopancreatography in the diagnosis of various forms of choledocholithiasis. This study is a non-invasive diagnostic method for visualization of the bile ducts. The technique does not require the administration of contrast agents, does not involve intervention in the biliary system, and does not involve radiation exposure. The informativeness of M-retrograde cholecystopancreatography in choledocholithiasis was 93% (Qiu et al., 2015; Giljaca et al., 2015; Reid et al., 2017).

There were 1 false-positive and 1 false-negative results. The reason for the false positive result of M-retrograde cholecystopancreatography was the mistaken perception of edema of the ampullary sphincter for a stone of the distal common bile duct. False negative diagnosis associated with the lack of contrast between multiple small intrahepatic duct stones and the surrounding liver, without high signal of bile, which outlines the stones. Stones with a diameter of <5 mm are almost not visualized on M-retrograde cholecystopancreatography. Choledocholithiasis diagnosed by M-retrograde cholecystopancreatography in this category of patients is an indication for laparoscopic, endoscopic, or other surgical intervention, to prevent repeated surgical interventions on the biliary tract.

This biomedical technological method should not be used as a screening method due to the high cost and the need for hardware, but it is very necessary when ultrasound examination does not provide sufficient diagnostic information. The lack of invasiveness, visualization of the bile ducts above or below the intersection allows in many cases to replace invasive E-retrograde cholecystopancreatography. Preoperative diagnostic methods together with clinical, laboratory and functional examination results allow to justify indications for surgery. However, it is possible to determine all the subtleties of the nature and extent of the pathological process only when conducting a comprehensive intraoperative examination.

The main method of treatment of choledocholithiasis and its complications was surgery. Preoperative conservative therapy began with intensive infusion therapy in combination with antisecretory therapy. All patients received standard infusion therapy, which included antispasmodic, antisecretory, detoxification, anticoagulant therapy, correction of water and electrolyte imbalance and, if necessary, antibacterial therapy.

In primary choledocholithiasis, 408 (72.2%) underwent one-stage treatment using the necessary modern biomedical engineering and technological complex: laparoscopic cholecystectomy, intraoperative fibrocholedochoscopy, choledochotomy, choledocholithotomy, external drainage of the common bile duct with T-tube drainage. We believe that drainage of the bile duct is mandatory because manipulations on the bile ducts can cause the development of severe pancreatitis, which is more common in women (Tan et al., 2023).

In secondary choledocholithiasis, 143 (25.3%) underwent intraoperative fibrocholedochoscopy, choledochotomy, choledocholithotomy, and external drainage of the common bile duct. Intraoperative fibrocholedochoscopy was performed in 408 (72.2%) patients with primary choledocholithiasis and in 143 (25.3%) with secondary choledocholithiasis. Choledochoscopy was performed using a new generation thin endoscope from Cirkon (USA) with an external diameter of 9.8F and a working channel diameter of 3.6F. The fibrocholedochoscope was inserted into the lumen of the common bile duct through the cystic duct in 121 (22%) and through the choledochotomy opening in 430 (78%) (Virzi et al., 2018).

After that, the distal parts of the common bile duct, the internal canal of the major duodenal papilla were examined and its patency was checked. Then, the proximal part of the hepaticocholedochus and intrahepatic ducts were revised. The detected stones were removed using Dormia baskets manufactured by Cirkon (USA). Fogarty catheters of various diameters were also used to remove stones. Signs of cholangitis (fibrin flakes, edema, hyperemia, erosion of the duct mucosa) were detected in 120 (20%) patients, and these patients underwent biopsy with histology and bacteriological examination. According to our data, intraoperative fibrocholedochoscopy is the most informative method of intraoperative diagnosis of choledocholithiasis and its complications (Badger et al., 2014).

The diagnostic value of choledochoscopy performed through the cystic duct stump is 89.8%. The diagnostic value of choledochoscopy through the choledochotomy opening is 100% and allows for a detailed examination of the proximal and distal parts of the bile ducts. The completeness of stone removal was assessed by control fibrocholedochoscopy. According to its data, fragments of stones with a diameter of 4 to 6 mm were detected in 3 (16%) patients, which prevented the development of residual choledocholithiasis. The special importance of fibrocholedochoscopy in the diagnosis of intrahepatic lithiasis. According to its data, intrahepatic lithiasis was detected in 20 (3.7%) patients. These patients had no data on intrahepatic lithiasis before choledochoscopy. The

found concrements were removed using Dormia baskets, Fogarty catheters under the control of a fibrocholedochoscope.

After the surgical intervention, patients experienced a decrease in pain syndrome, intoxication, improvement in general condition, and disappearance of symptoms of mechanical jaundice. All patients underwent early activation. Simultaneous elimination of complications of choledocholithiasis allows reducing the severity and duration of organ and multiorgan failure and avoiding probable death in the elderly and senile age with severe concomitant pathology (Aleknaitė et al., 2018). The drain was removed 14–21 days after surgery based on the results of E-retrograde cholecystopancreatography or fistulography. One patient died after surgery, with a mortality rate of 0.6%. Minimally invasive interventions (as primary surgery) were performed in 418 (74%) patients - in 408 (72.2%) laparoscopic cholecystectomy, intraoperative fibrocholedochoscopy, choledochotomy, choledocholithotomy and 10 patients (1.8%) underwent endoscopic papillosphincterotomy during E-retrograde cholecystopancreatography. They proved to be an effective and sufficient method of surgical intervention in 74% of patients. The duration of treatment when using minimally invasive technologies was 6.8 ± 0.52 bed-days, mortality – 2.6%, with open operations – 12.8 ± 3.3 bed-days, mortality – 5.2% (Bergeron, et al., 2021).

Conclusion

1. Choledocholithiasis occurs, according to our data, in 26.8% of patients with gallbladder diseases.
2. Predictors of choledocholithiasis were: age over 50 years in 89% of patients, female gender in 82.3%, markers of bile lithogenicity: $\uparrow$ cholesterol, $\downarrow$ cholatocholesterol coefficient, $\uparrow$ level of direct bilirubin fraction, $\uparrow$ level of alkaline phosphatase in blood serum, diameter of the common bile duct (0.7 cm and $\uparrow$).
3. For the diagnosis of choledocholithiasis, it is advisable to use modern biomedical engineering and technological transabdominal ultrasound examination in combination with E-retrograde cholecystopancreatography or M-retrograde cholecystopancreatography.
4. The final decision is made during a comprehensive intraoperative examination.
5. An effective and sufficient method of surgical treatment of primary choledocholithiasis is laparoscopic cholecystectomy, intraoperative fibrocholedochoscopy, choledochotomy, choledocholithotomy, external drainage of the common bile duct with T-tube drainage.
6. Intraoperative fibrocholedochoscopy is the most informative method of diagnosing choledocholithiasis and its complications. The diagnostic value of choledochoscopy performed through the cystic duct stump is 89.8%. The diagnostic value of choledochoscopy through the choledochotomy opening is 100%.
7. Intraoperative fibrocholedochoscopy allows for the detection of intrahepatic lithiasis, and makes it possible to specifically remove calculi located in the segment and lobar ducts of the liver.
8. An effective and sufficient method of surgical treatment of secondary choledocholithiasis is intraoperative fibrocholedochoscopy, choledochotomy, choledocholithotomy, and external drainage of the common bile duct with T-tube drainage.

Recommendations

In the future, the application of the proposed complex-combined method of prevention, detection, correct diagnosis and effective treatment of choledocholithiasis using biophysical and biotechnological means can objectify and accelerate the determination of this pathological condition, and an in-depth study of these results can become the basis for successful surgical treatment of specialized patients.

Scientific Ethics Declaration

* The authors declare that the scientific ethical and legal responsibility of this article published in EPSTEM journal belongs to the authors.

Conflict of Interest

* The authors declare that they have no conflicts of interest.

Funding

* No funds have been received.

Acknowledgements or Notes

* This article was presented as an oral presentation at the International Conference on Research in Engineering, Technology and Science (www.icrets.net) held in Batumi/Georgia on July 09-12, 2026.

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To cite this article:

Sulyma, V., Polulyah-Chornovol, I., Verholaz, I. & Chornovol, O. (2026). Biomedical engineering and biomedical technologies for effective prevention, detection and elimination of choledocholithiasis. *The Eurasia Proceedings of Science, Technology, Engineering and Mathematics (EPSTEM)*, 41, 49-55.