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PARTIAL PAPILLOSPHINCTEROTOMY WITH BALLOON DILATATION IN THE TREATMENT OF CHOLEDOCHOLYTIASIS IN PATIENTS WITH PARAPAPILLARY DIVERTICULUM

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ABSTRACT: Results of treatment of 42 patients suffering from choledocholytiasis and parapapillary diverticle are compared, by which for treatment limited papillosfincterotomy supplemented with endoscopic balloon dilatation is performed with results of treatment of 56 patients with similar pathology, by which traditional endoscopic papillosfincterotomy was performed. Limited papillosphincterotomy with endoscopic balloon dilatation resulted in complete lithoextraction in 92.9% of cases as compared to 92.8% with endoscopic papillosphincterotomy only; an adequate drainage of extrahepatic bile ducts was achieved in 100% and 96.4%, respectively ($p > 0.05$). With endoscopic papillosphincterotomy, full removal of all concretions with a diameter of less than one centimeter was achieved without mechanical lithotripsy; for concretions from 1 to 1.5 cm in size the mechanical lithotripsy was necessary in 45.5% of cases. Limited papillosphincterotomy with endoscopic balloon dilatation allowed lithoextraction of concretions with a diameter of up to 1.5 cm without mechanical lithotripsy in all patients. The mechanical lithotripsy for concretions with a diameter above 1.5 cm was necessary in 60% of cases for both methods. In the treatment arm, two (4.8%) cases with complications were observed, while in the control arm there were 13 (23.2%) cases ($p = 0.012$). Acute pancreatitis was the only postoperative complication for which significant difference was observed ($p = 0.043$). In addition, after endoscopic papillosphincterotomy the incidence of bleeding from the suture line was 3.6% and the incidence of perforation of diverticula was 3.6%; this required an open surgery. The above mentioned demonstrates the advantages of limited papillosphincterotomy with endoscopic balloon dilatation over endoscopic papillosphincterotomy to resolve choledocholytiasis in the presence of parapapillary diverticulum.

Keywords: choledocholytiasis; obstructive jaundice; duodenal diverticulum; endoscopic retrograde cholangiopancreatography; endoscopic papillosphincterotomy; endoscopic balloon dilatation; mechanical lithoextraction.

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ОГРАНИЧЕННАЯ ПАПИЛЛОСФИНКТЕРОТОМИЯ, ДОПОЛНЕННАЯ БАЛЛОННОЙ ДИЛАТАЦИЕЙ, В ЛЕЧЕНИИ ХОЛЕДОХОЛИТИАЗА У БОЛЬНЫХ, СТРАДАЮЩИХ ПАРАПАПИЛЛЯРНЫМ ДИВЕРТИКУЛОМ

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Резюме. Сравниваются результаты лечения 42 больных, страдающих холедохолитиазом и парапапиллярным дивертикулом, которым для лечения выполнена ограниченная папиллосфинктеротомия, дополненная эндоскопической баллонной дилатацией, с результатами лечения 56 больных с аналогичной патологией, которым была произведена традиционная эндоскопическая папиллосфинктеротомия. Выполнение ограниченной папиллосфинктеротомии, дополненной эндоскопической баллонной дилатацией, и только эндоскопической папиллосфинктеротомии привело к полной литоэкстракции в 92,9 и 92,8% случаев соответственно и к адекватному дренированию внепеченочных желчных протоков в 100 и 96,4% наблюдений ($p > 0,05$) Выполнение только эндоскопической папиллосфинктеротомии позволило удалить все конкременты диаметром менее одного сантиметра без механической литотрипсии, а потребность в ее выполнении при размерах конкрементов от 1 до 1,5 см составила 45,5%. Ограниченная папиллосфинктеротомия, дополненная эндоскопической баллонной дилатацией, позволила произвести литоэкстракцию конкрементов диаметром до 1,5 см всем больным без механической литотрипсии. Потребность в механической литотрипсии при диаметре конкремента более 1,5 см составила 60% в обоих случаях. В основной группе имелись два (4,8%) осложнения, в то время как в контрольной их было 13 (23,2%) случаев ($p = 0,012$). Достоверные различия в послеоперационных осложнениях наблюдались только при остром панкреатите ($p = 0,043$). Кроме того, после выполнения эндоскопической папиллосфинктеротомии в 3,6% случаев обнаруживалось кровотечение из папиллотомного разреза и в 3,6% случаев — перфорация дивертикула, что потребовало выполнения открытого оперативного вмешательства. Вышеизложенное свидетельствует о преимуществах применения ограниченной папиллосфинктеротомии, дополненной эндоскопической баллонной дилатацией, перед эндоскопической папиллосфинктеротомией для разрешения холедохолитиаза при наличии парапапиллярного дивертикула.

Ключевые слова: холедохолитиаз; механическая желтуха; дивертикул двенадцатиперстной кишки; ретроградная холангиопанкреатография; эндоскопическая папиллосфинктеротомия; эндоскопическая баллонная дилатация; механическая литоэкстракция.

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BACKGROUND

Despite advancements in treatment methods and endoscopic equipment, choledocholithiasis (CL) still complicates the course of biliary lithiasis in 8%–35% of patients and remains an urgent problem [1, 2]. Currently, transpapillary methods are the most common in the resolution of CL, since they are accompanied by minimal surgical trauma and mortality, in only 0.3%–1.6% of [3, 4]. Due to changes in the anatomical and topographical landmarks of the common bile duct (CBD) mouth, the parapapillary diverticulum (PPD) complicates its cannulation, endoscopic papillosphincterotomy (EPST) and lithoextraction (LE), which reduces significantly the efficiency of transpapillary methods [5, 6]. The incidence of PPD in the general population is 13.5%–32.8% [6, 7], and in the elderly and those of senile age, it is 50%–83% [5, 8, 9]. The risk of duodenal perforation during EPST in the presence of PPD is often a barrier to the performance of a full-fledged papillosphincterotomy as it results in additional trauma during LE, a large number of complications, and often forces the procedure to be stopped [10]. Limited EPST, supplemented by endoscopic balloon papillodilation (EBPD), creates better conditions for LE [2, 11, 12]. However, the efficiency of its use in the presence of CL and PPD has not been sufficiently studied.

The study aimed to improve the results of treatment of patients with PPD and CL by using limited EPST supplemented with EBPD.

MATERIALS AND METHODS

The work was based on the results of treatment of 98 patients with CL and PPD between 2017 and 2019 at the Department of Naval Surgery of the S.M. Kirov Military Medical Academy, in the Municipal Aleksandrovskaya Hospital and in the City Clinical Hospital No. 31. The main group (MG) consisted of 42 CL patients with PPD, who underwent limited EPST supplemented with EBPD for treatment. The control group (CG) comprised of the results of treatment of 56 patients with a similar pathology through traditional EPST. All patients underwent endoscopic retrograde cholangiopancreatography (ERCPG) for diagnostic purposes.

Women were predominant in both groups, namely 30 (71.4%) and 33 (58.9%) patients, respectively. There was majority of elderly and senile patients, namely 37 (90.4%) patients in the MG and 45 (80.3%) patients in the CG. The MG had 1 (2.4%) patient of middle age and 10 (17.9%) patients of the same age in the CG. There were two (4.8%) young patients in the MG and one (1.8%) young patient in the CG. The youngest patient who underwent limited EPST with EBPD was 39 years old, while the oldest was 90 years old.

The severity of obstructive jaundice (OJ) was determined according to the classification proposed by E.I. Galperin [13]. In both groups, patients with mild OJ predominated (69.1% and 51.8%, respectively). Jaundice of moderate severity in patients was noted in 19% and 23.2% of patients in the MG and the CG, respectively. Severe OJ was registered in four (7.1%) patients in the CG. In the MG, there were no patients with severe OJ. There were 5 (11.9%) patients with normal bilirubin levels in the MG and 10 (17.9%) such patients in the CG. In all these patients, jaundice was noted in the disease history.

During the period of analysis, primary limited EPST supplemented with EBPD was performed in 36 (85.7%) patients, and repeated intervention was performed in 6 (14.3%) patients. According to primary indications in CG patients, EPST was performed in 49 (87.5%) cases and in 7 (12.5%) patients repeatedly. The indications for re-intervention in the MG were residual choledocholithiasis after primary EPST in four (9.5%) patients, and complications during primary ERCPG were registered in two (4.8%) cases. In the CG, the indications for repeated EPST were recurrent choledocholithiasis in three (5.4%) patients, residual choledocholithiasis in two (3.5%) patients, and a complication of primary ERCPG was noted in one (1.8%) patient. In another instance, EPST was performed for choledocholithiasis and benign stricture of the terminal part of the CBD in one (1.8%) patient.

Cholecystectomy (CE) was performed in 21.4% of cases in MG patients and in 30.4% of patients in the CG prior to admission to the hospital. All cases of major duodenal papilla (MDP) to the diverticulum, were classified according to J. Boix et al. [14] and were subdivided into intradiverticular location of the MDP, location at the border of the PPD and outside the PPD. The intradiverticular location was noted in 18 (42.9%) MG patients and in 19 (33.9%) CG patients; that at the border of the diverticulum was reported in 13 (30.9%) cases and 28 (50%) patients, in the MG and the CG respectively, while that outside the diverticulum was reported in 11 (26.2%) and 9 (16.1%) patients (Table 1).

The most common size of the diverticulum in both groups was 1 to 2.5 cm in greatest dimension. There were 26 (61.9%) such patients in the MG, including 18 (42.8%) patients with predominantly intradiverticular location of the MDP and at the PPD border. The intradiverticular location was predominantly of the MDP in 36 (66%) patients in the CG, and at the border of the diverticulum in 32 (57.1%) patients ($p > 0.05$). The difficulty of cannulating the CBD was assessed by J. Boix et al. [14].

Transpapillary interventions were performed using a Pentax ED-3490TK duodenoscope connected to a Pentax EPK-1000 video processor (Japan). The procedure was performed using a mobile interventional X-ray system C-arm by Philips Veradius Neo (Netherlands) or X-ray complex Siemens by Sireskop CX (Germany) of the electrosurgical unit ERBE VIO 200 S (Germany) and Olympus ESG-100 (Japan). EPST was performed with standard and needle type papillotomes from MTW Endoskopie and Endo-Flex (Germany). We used

Table 1. Distribution of patients depending on the location of major duodenal papilla and dimensions of parapapillary diverticulum (PPD)

Таблица 1. Распределение больных по отношению к расположению большого сосочка двенадцатиперстной кишки и размерам парапапиллярного дивертикула (ПДД)

Location of MDP	Diverticulum size, cm (%)					
	Main group			Control group		
	0–1	1–2.5	2.5 and more	0–1	1–2.5	2.5 and more
Intradiverticular	2 (4.8)	12 (28.6)	4 (9.5)	– (–)	13 (23.2)	6 (10.7)
At the boundary with PPD	3 (7.1)	6 (14.2)	4 (9.5)	6 (10.7)	19 (33.9)	3 (5.4)
Outside the PPD	1 (2.4)	8 (19)	2 (4.8)	3 (5.4)	5 (8.9)	1 (1.8)
Total amount:	6 (14.3)	26 (61.9)	10 (23.8)	9 (16.1)	36 (66)	10 (17.9)
Total:	42 (100)			56 (100)		

Stripe-Guide nitinol wires from Endo-Flex (Germany) 4500 mm long and 0.9 mm in diameter with a soft distal end and Hydra Jagwire hydrophilic wires from Boston Scientific (USA) 4500 mm long and 0.9 mm in diameter with a straight distal end. For LE, we used three-lumen balloons from Endo-Flex, each with a diameter of 1.9 mm and a length of 2000 mm, and used with a conductor with a diameter of 0.9 mm. The diameter of the inflated balloon was 14 mm. In addition, four-string nitinol baskets from MTW Endoskopie (Germany) 20 × 30 and 25 × 40 mm, PTFE stents from Endo-Flex and Boston Scientific with a diameter of 7, 8, and 10 Fr (2.3, 2.7, and 3.3 mm, respectively) were used to remove stones. Mechanical lithotripsy (ML) was performed using an Endo-Flex lithotripter with diamond-shaped four- and six-string lithotripsy baskets 2.6 mm in diameter, 4000 mm long, 50 mm high, and a guide-wire channel. The procedure was performed using an armed surgical aspirator 7a-23B (China) and a carbon dioxide insufflator from Olympus (Japan). The contrast agents for ERCPG were from Urographin (Germany) and Omnipak (Ireland), which were diluted 1:1 with saline.

For EBPD, in addition to the standard tool kit for traditional EPST, balloons with controlled radial expansion with a diameter of 10, 11, and 12 mm (to create pressures of 3, 5, and 8 atm in the balloons); and diameters of 12, 13.5, and 15 mm (to create pressures of 3, 4.5, and 8 atm in the balloons) and a diameter of 5.5 cm in length from Boston Scientific were used. Limited EPST before EBPD was performed with the aim of crossing a part of the muscle fibers of the sphincter apparatus of the CBD and was performed at 1/3 or 1/2 of the length of the longitudinal fold, depending on its length, the MDP size, and its location in relation to PPD.

Statistical processing of the study results was performed using the STATA software.

RESULTS AND DISCUSSION

In 42 (100%) MG patients, CL and OJ were resolved by transpapillary methods. In 39 (92.9%) of them, complete LE was performed. Another three (7.1%) patients underwent CBD stenting due to partial removal of calculi, which was associated with difficulties during the surgery. One of these patients developed bleeding after limited EPST supplemented with EBRD, leading to need for endoscopic hemostasis and stent placement. In another patient, it was not possible to reinsert the Dormia basket since the patient developed edema in the EPST area after ML and partial LE from the CBD. In one more patient, it was impossible to perform a complete ML due to a large dense calculus. Open surgery was not performed in any PPD patient after limited EPST supplemented with EBPD for CL.

In the CG, resolution of CL and OJ using endoscopic methods was performed in 54 (96.4%) patients. There were no statistically significant differences between the MG and the CG. Complete LE was performed in 52 (92.8%) patients. Another two (3.5%) patients underwent CBD stenting due to incomplete ML and LE. LE after EPST was not performed in two (3.6%) patients due to perforation of the diverticulum wall in one patient with a papillotome, and with a conductor in another patient. Both cases required termination of the procedure, followed by laparotomy, CE, drainage of the CBD and retroperitoneal space. Both of these patients have recovered. There was also one perforation of the duodenum after repeated EPST and LE, which was detected on the day after the procedure. The initial EPST, performed the day before the repeated procedure, had been unsuccessful due to bleeding from the papillotomy zone, which was stopped endoscopically. The complication of perforation required an open surgical intervention, namely laparotomy, suturing of the perforation

of the PPD, CE, drainage of the CBD, sanitation and drainage of the abdominal cavity and retroperitoneal space. In this case, the patient also recovered.

It was not possible to perform cannulation in 3 (3%) patients out of 101 due to technical difficulties. To resolve CL and OJ, these patients underwent open surgery of CE, choledocholithotomy, and drainage of the CBD according to Kerr. Difficult catheterization of MDP was registered in 14 (33.3%) MG patients and in 24 (42.9%) CG patients ($p > 0.05$). No lethal outcomes were noted in the MG. In the CG, mortality rate was 3.6% (two patients died) but their deaths were not associated with the transpapillary surgery.

A significant difference was revealed between the number of complications after performing limited EPST supplemented with EBPD and only EPST for CL in PPD ($p = 0.012$). In the MG, only two (4.8%) complications were registered, while in the CG, there were 13 complications in 10 patients (Table 2). However, significant differences in postoperative complications were noted only in acute pancreatitis ($p = 0.043$). Bleeding in the main and control groups arose from the papillotomy incision. In the MG, one (2.4%) patient developed mild acute pancreatitis in the postoperative period due to difficult cannulation of the CBD. Stent installation in the Wirsung duct was required after repeated cannulations of the main pancreatic duct. After EPST, acute pancreatitis was recorded in 8 (14.3%) patients and in 3 (5.4%) of them, it was of moderate severity.

Single and multiple calculi in the CBD were almost equal in patients who underwent limited EPST supplemented with EBPD, and those that underwent only EPST (54.8%) and in 48.2% of cases, respectively ($p > 0.05$), these were multiple (Table 3).

Limited EPST supplemented with EBPD was performed in 16 (38.2%) patients with calculi less than one centimeter in size and in 40 (71.5%) CG patients ($p = 0.001$). With stone sizes from 1 to 1.5 cm, EPST supplemented with EBPD was performed in 16 (38%) patients, and EPST was performed in 11 (19.6%) patients ($p = 0.043$). For patients with calculi larger than 1.5 cm, partial EPST supplemented with EBPD was performed in 10 (23.8%) MG patients and in only 5 (8.9%) CG patients with traditional EPST ($p = 0.043$).

Limited EPST supplemented with EBPD enabled performance of LE of calculi of sizes up to 1.5 cm in diameter in all patients. Only EPST was used to remove all calculi with a diameter of less than one centimeter in patients with CL and PPD; the need for lithotripsy was 45.5% (5 of 11 patients) with calculus sizes from 1 to 1.5 cm, which was statistically different from the MG of patients ($p = 0.003$). In the remaining 55.5% of the cases (6 patients), calculi with a diameter of 1 to 1.5 cm were removed fragmentarily due to their friability. Consequently, the need for ML in patients with CL and PPD, who underwent EPST only, was 14.3%, as in the MG of patients.

Complete ML and LE in MG patients with calculi larger than 1.5 cm was performed in 40% of the cases (in 4 out of 10 patients). In another three (30%) patients, larger calculi were removed using the Dormia basket due to calculus friability. Three more (30%) patients required CBD stenting due to incomplete LE after ML. Therefore, the need for ML

Table 2. Types of complications after papilla surgery

Таблица 2. Виды осложнений после выполнения сосочковых операций

Parameter	Main group		Control group		*p*
	n	%	*n*	%	
Bleeding:	1	–	2	3.6	> 0.05
– endoscopic hemostasis	1	2.4	2	3.6	> 0.05
– surgery	–	–	–	–	–
Acute pancreatitis:	1	2.4	8	14.3	= 0.043
– mild	1	2.4	5	8.9	> 0.05
– moderate	–	–	3	5.4	> 0.05
Cholangitis	–	–	–	–	–
Perforation:	–	–	3	5.4	> 0.05
– with apparatus	–	–	–	–	–
– with papillotome	–	–	2	3.6	> 0.05
– with guidewire	–	–	1	1.8	> 0.05
Total	2	4.8	13	23.2	= 0.012

Table 3. Distribution of patients by number and size of concretions in choledoch, abs. (%)
Таблица 3. Распределение больных по количеству и размеру конкрементов в холедохе, абс. (%)

Indicator	Number of calculi							
	Calculus size, cm							
	Main group				Control group			
	0–1	1–1.5	more than 1.5	total	0–1	1–1.5	more than 1.5	total
Single calculus	10 (23.9)	8 (19)	5 (11.9)	23 (54.8)	17 (30.4)	6 (10.7)	4 (7.1)	27 (48.2)
Multiple calculi	6 (14.3)	8 (19)	5 (11.9)	19 (45.2)	23 (41.1)	5 (8.9)	1 (1.8)	29 (51.8)
Total	16* (38.2)	16* (38)	10* (23.8)	42 (100)	40* (71.5)	11* (19.6)	5* (8.9)	56 (100)

Note: * — intergroup differences, $p < 0.05$.

after limited EPST supplemented with EBPD, with calculi larger than 1.5 cm, was 70%. With a calculus diameter of more than 1.5 cm, the need for ML after performing only EPST was 60% (3 out of 5 patients). One of the patients underwent complete LE, and in two more cases, stenting of the CBD was performed due to incomplete removal of calculi.

Thus, PPD in CL patients results in complicated catheterization in a significant number of patients. More frequently, the development of acute pancreatitis after EPST is associated with insufficient dissection in some cases of MDP due to the risk of perforation of the diverticulum wall and the traumatic nature of manipulation during LE. For the same reason, EPST in CL is performed more often in patients with small calculi, especially in cases of PPD. Dense calculi with a diameter of more than 1 cm during EPST require more frequent use of ML for LE compared with the use of limited EPST supplemented with EBPD.

CONCLUSIONS

1. The implementation of limited EPST, supplemented with EBPD and isolated EPST led to complete lithoextraction in 92.9% and 92.8% of cases, respectively, and to adequate drainage of the extrahepatic bile ducts in 100% and 96.4% of cases, respectively, which indicates the efficiency of these interventions in resolving CL in PPD.

2. EPST is most effective in single and multiple CL in patients with small calculi. Partial EPST supplemented with EBPD is also effective in major CL.

3. The use of limited EPST supplemented with EBPD is accompanied by a significantly lower number of postoperative complications compared with the use of EPST only.

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