

Evaluation of different methods of endoscopic papillectomy for adenomas of the major duodenal papilla

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OBJECTIVE – to assess the outcomes of endoscopic papillectomy (EP) using standard techniques, as well as to develop and implement novel surgical intervention approaches.

MATERIALS AND METHODS. Between 2021 and 2024, the Department of Interventional Endoscopy at the National Cancer Institute performed EP for adenoma of the major duodenal papilla (MDP) on 19 patients, 10 women (52.63 %) and 9 men (47.37 %), aged 24 to 78 years, with a mean age of 45.6 years. We observed clinical signs of biliary obstruction and cholangitis in the majority of cases (2 (63.15 %)).

RESULTS. 10 patients (52.63 %) with tumours <1.0 cm underwent the standard procedure of en-bloc loop resection (Group 1). To prevent intraoperative and postoperative complications, we developed and implemented a two-stage EP procedure in 6 (31.57 %) cases (Group 2). In 3 (15.78 %) patients with tumours ranging from 5.0 to 8.0 cm, the piecemeal approach was used to remove all fragments from the area of the neoplasm that reached into the intestinal lumen (Group 3). After a three-month follow-up, 2 patients (10.5 %) from Group 3 had a recurrence of an adenoma of the MDP. Both cases required loop diathermy excision for recurrent neoplasms and stent removal. Routine tests at 3 and 6 months revealed no evidence of disease progression.

CONCLUSIONS. The topographic and anatomical characteristics of the MDP area determine the complexity of surgical interventions for patients with neoplasms. The novel EP approach minimizes the risks associated with both early and late postoperative complications. The outcomes achieved by employing EP in the treatment of patients with MDP adenomas support its recommendation as the primary approach at specialized centers.

KEYWORDS

endoscopic papillectomy, adenoma of the major duodenal papilla, endosonography.

ARTICLE • Received 2025-10-29 • Received in revised form 2025-12-04

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Among obstructive neoplasms of the major papilla of the duodenum, carcinomas account for 37.7 %, adenomas for 19.6 %, and other benign tumours for 42.7 % [12]. Major duodenal papilla (MDP) adenomas may occur sporadically or be associated with ad-

enomatous polyposis syndromes (familial adenomatous polyposis and MUTYH-associated polyposis).

In the early stages of development, the disease is asymptomatic in 60.2–93.1 % of cases [5, 8, 10]. As the tumour size increases, complications arise due to

impaired outflow of secretions from the ductal systems of the liver and pancreas: mechanical jaundice (7.1–26%), cholangitis (0.3–1.6%), pain syndrome (6.9–21.6%), acute pancreatitis (1.9–6.3%). Malignancy occurs in 15 to 30% of cases [2]. In rare cases, the first clinical manifestation of the disease may be duodenal intussusception.

The morphological analysis of tissues collected after tumour biopsy plays an essential role in establishing the diagnosis [2]. False-negative findings are reported in 16.7–30.2% of observations, whereas false-positives are observed in 12.5–38% [3, 9]. Endoscopic papillectomy (EP) is thus regarded as a variant of excisional biopsy [6].

Endoscopic ultrasonography (EUS) of the hepatopancreatoduodenal organs improves the accuracy of identifying MDP neoplasms, especially in the early stages (size <1 cm). EUS has a sensitivity close to 100% in detecting tumour-like MDP lesions. It is important for treatment strategy selection, enabling the assessment of the depth of the pathological process in the layers of the duodenal wall and detection of possible signs of regional lymphadenopathy [4].

Currently, the only recognized treatment for this group of patients is surgical excision of the MDP. A number of techniques are used for this, including transduodenal papillectomy and pancreaticoduodenal resection by laparotomic or laparoscopic access. However, due to a high incidence of complications (19.7–23.8%) and mortality (10.2%), as well as disease recurrence in 26.1–30.4% of patients, minimally invasive endoscopic approaches to removing MDP neoplasms are increasingly preferred. Furthermore, the precision of performing endoscopic procedures with high-resolution equipment contributes to a reduction in the frequency of postoperative adenoma recurrences.

Endoscopic papillectomy has lower rates of postoperative complications (4.2–7.4%), mortality (0.8–1.1%), and recurrence (14.7–18.2%) [10, 13]. To reduce the risk of recurrence, a combination of EP and tissue ablation therapy is used, which involves multipolar, laser, and argon plasma coagulation of the tumour bed, which is controlled endoscopically in the Narrow-band imaging (NBI) mode [7].

OBJECTIVE – to assess the outcomes of endoscopic papillectomy using standard techniques, as well as to develop and implement novel surgical intervention approaches.

Materials and methods

Between 2021 and 2024, the Department of Interventional Endoscopy at the National Cancer Institute performed EP for the MDP adenoma on 19 patients,

10 women (52.63%) and 9 men (47.37%), aged 24 to 78 years, with a mean age of 45.6 years. Biliary obstruction and cholangitis were the reasons for the examination in the majority of cases (2 (63.15%)): pain in the epigastric region after eating–5 (26.31%), intermittent hyperbilirubinemia without pain syndrome–6 (31.57%), periodic fever–3 (15.78%), and weight loss–6 (31.57%). In the remaining 7 patients (36.84%), the condition was asymptomatic and was discovered accidentally during screening exams and testing for concomitant disorders.

The diagnostic regimen for the patients encompassed duodenoscopy with biopsy, abdominal ultrasound, computed tomography of the abdominal cavity and retroperitoneal space, magnetic resonance cholangiopancreatography as indicated, endoscopic ultrasound of the hepatoduodenal region, complete blood count, biochemical blood analysis, coagulogram, urinalysis, and electrocardiogram.

The origin of the MDP neoplasm, its size, mobility, spread to surrounding tissues, and the existence of fluctuating symptoms in the intramural section of the common bile duct (CBD) were assessed endoscopically. We employed instrumental examination and palpation for this objective. Furthermore, we used the NBI mode as an adjunct diagnostic instrument during the endoscopic evaluation. The observed alterations in the pit pattern, as per Kudo and Tsuruta, align with II–IIIL–IIIS classifications. In the study, a tumour biopsy was conducted, the outcome of which served as a primary criterion for patient selection for endoscopic therapy (patients with malignant neoplasms were excluded from the research).

Ultrasound examination indicated biliary hypertension in all patients, dilation of the main pancreatic duct (MPD) in 5 (26.31%), gallbladder stones in 3 (15.78%), bile duct stones in 1 (5.26%), and a foreign body («retained» CBD drainage) in 1 (5.26%).

The evaluation of computed tomography is deemed essential for determining the existence of regional and distant metastases in MDP neoplasms, which also served as a criterion for eliminating patients from the research cohort.

MRCP was conducted in 6 individuals (31.57%), revealing endoscopic evidence of damage to the intramural segment of the CBD. In 2 cases (10.52%), the spread of tumour tissues to the distant regions of the CBD was verified.

The application of EUS, alongside the measurement of adenoma size, facilitated the assessment of tumour penetration into the duodenum wall and its extension into the CBD lumen. Out of the 4 cases (21.05%) of tumour invasion into the duodenal wall, 2 cases (10.52%) were confined to the submucosal layer (third echo layer), whereas 1 case

(5.26 %) extended to the muscular layer of the intestine (fourth echo layer). Notwithstanding this, the patients were presented with the option of endoscopic surgery due to the existence of significant concomitant disease and elevated anesthetic risks. In 2 cases (10.52 %), the MRCP results regarding the spread of tumour growths into the lumen of the distal CBD were confirmed by EUS.

Upon admission, persistent hyperbilirubinemia was noted in 5 patients (26.31 %), with a period ranging from 5 to 17 days and bilirubinemia levels between 170.7 and 349.5 $\mu\text{mol/l}$. The initial phase of their therapy was biliary decompression. Suprapapillary choledochoduodenostomy was conducted in all cases. In 3 (15.78 %) patients, it was supplemented by bile duct stenting, and in 1 (5.26 %), it involved the removal of a «retained» drainage and choledocholithoextraction.

The size of the MDP adenoma did not restrict the application of EP but was critical in determining the surgical approach: en-bloc or piecemeal technique.

For the execution of EP, the following instruments were used: Olympus TJF-190 duodenoscope, Evis Exera CLV-190 video processor, Extron 7 X-ray C-arm, ESG-300 electro-surgical unit, 23 G injection endoscopic needles, polypectomy loops measuring 10 to 34 mm in diameter, endoscopic I-knife, guides with a diameter of 0.35 mm, lateral papillotomes, plastic stents of 7 and 8.5 Fr, coagrasper, alligator forceps, hot biopsy forceps, a net for foreign body retrieval, Dormia basket, and 11 and 16 mm rotary hemostatic clips.

The procedure was conducted in the operating room under endotracheal anesthesia with the patient in a prone position. If required, the patient was repositioned to the left side throughout the surgery. CO_2 was used as the gas for insufflation.

During en-bloc loop resection of the MDP adenoma, hydro-lifting of the duodenal mucosa around the papilla was previously performed in accordance with established and original papillectomy procedures.

The two-stage papillectomy technique we developed involves, in the initial stage, the dissection of the duodenal mucosa using a needle papillotomy at a distance of 3–5 mm from the major papilla (within healthy tissues), followed by the exfoliation of the submucosal layer tissues down to its tubular structures (the CBD and pancreatic duct) (Fig. 1). The second stage involves the transection of the ducts using a diathermic endoloop. The use of a diathermic loop during the final stage of the procedure facilitated the coagulation of the wound surface to the necessary degree. This ensured the reliability of hemostasis while simultaneously reducing the duration of endoloop usage, thereby minimizing electrothermal damage to adjacent tissues, particularly the pancreatic head, which subsequently decreased the risk of postoperative pancreatitis [1].

For the same objective, in cases of substantial tumour sizes (>2.0 cm), the piecemeal approach was employed for the portion of the neoplasm that protruded most into the intestinal lumen. The residual tissue that originated from the intestinal wall was excised using one of the aforementioned techniques.

After the removal of the macro-preparation and the establishment of hemostasis, we evaluated the possibility and feasibility of stenting the ductal systems. Plastic stents with diameters of 8.5 and 10 Fr were used for the draining of the CBD, while those with diameters of 5 and 7 Fr were employed for the MPD. In case of significant gaping in the CBD incision and free bile flow due to the CBD dilation caused by long-term biliary hypertension, drainage was not conducted. If 3–4 attempts at catheterization of the MPD were unsuccessful, stenting was deemed inadvisable to prevent unnecessary damage to the pancreas.

An inspection of the postoperative wound was conducted prior to the removal of the endoscope. Upon identification of defects in the duodenal wall extending to the muscular layer, closure was executed using hemostatic clips. In such instances (often involving big tumour sizes), the procedure concluded with the placement of a probe for enteral nutrition and a decompression nasogastric tube positioned beyond the duodenal-jejunal junction.

Postoperative pharmacological care comprised the administration of proton pump inhibitors, antispasmodics, analgesics, anti-inflammatory agents, antimicrobial medications, and, when appropriate, somatostatin analogues.

Dynamic monitoring encompassed controlled duodenoscopy and the removal of biliary and pancreatic stents after three months.

Results

The endoscopic surgical approach was selected based on the size of the MDP adenoma, the extent of duodenal wall, and the distal CBD involvement in the pathological process. Due to the complex topographic and anatomical relationships of organs and ductal structures in the parapapillary region, hydro-lifting of the MDP and adjacent intestinal mucosa was employed in all cases during EP to enhance intervention accuracy and mitigate associated risks.

In 10 patients (52.63 %) with tumour diameters of <1.0 cm, the standard technique of en-bloc loop resection (Group 1) was employed (Fig. 2, 3) [10]. Larger tumour sizes result in a substantial volume of mucosal and submucosal layers being found in the excised loop, which significantly increases both the wound surface area and depth, hence adding to the risk of intestinal perforation upon exposure of the



Figure 1. **Dissection of the MDP mucosa with a needle papillotome around the MP (the initial stage of papillectomy)**



Figure 2. **MDP adenoma with a diameter of 0.9 cm**



Figure 3. **Condition after en-bloc loop resection of the MDP neoplasm**

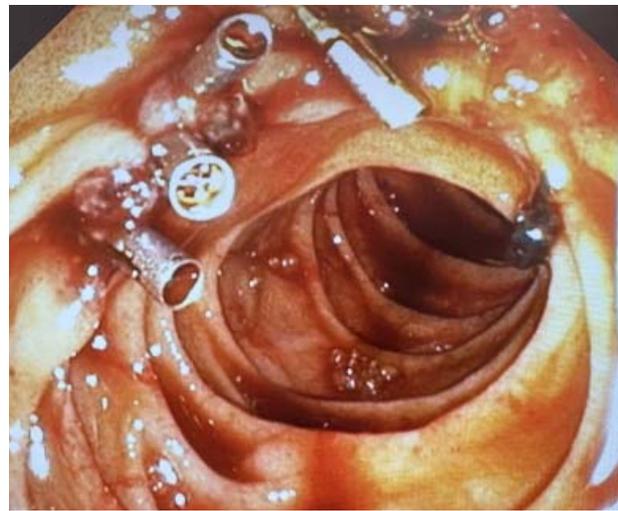


Figure 4. **Postoperative defect of the duodenum sutured using hemostatic clips**

muscle layer. This phenomenon is more frequently observed at the lower corner of the postoperative wound. To prevent intraoperative and postoperative complications, we designed and implemented a two-stage EP approach in 6 (31.57 %) cases (Group 2). The rationale for employing this approach was the detection of a tumour size between 1.0 and 2.0 cm.

Due to prolonged electrothermal exposure to pancreatic tissue, en-bloc loop resection with neoplasms larger than 2.0 cm increases the risk of duodenal perforation and acute pancreatitis. The piecemeal technique was used on the portion of the tumour that spread the most into the intestinal lumen in 3 patients (15.78 %) with tumour sizes ranging from 5.0 to 8.0 cm, necessitating the complete removal of all fragments (Group 3). The ability to observe the entire volume of tissues within the loop is limited by this approach. The intestinal wall layers adjacent to

the tumour are excised uncontrollably during the first stages of the procedure. In 3 (15.78 %) cases where there was a risk of intraoperative and/or delayed intestinal perforation, the resulting defects required suturing with hemostatic clips (Fig. 4). Using the method we developed, the residual tumour component that directly protruded from the intestinal wall was successfully removed in 2 (10.5 %) cases. When the tumour penetrated the intestinal muscle layer, the loop resection was not visually radical in one case (5.3 %). Therefore, spray coagulation (power 32 W, third mode) was used to diathermoablate the residual tumour tissue in the wound.

In 2 patients (10.5 %) from Group 3, previous investigations (MRCP) diagnosed the spread of tumour tissues to the distal portion of the CBD. After removing the primary neoplastic mass from the duodenum, we observed the protrusion of tumour

growths from the CBD lumen into the intestinal lumen. We conducted the excision using a diathermic loop and a coagrasper.

In Group 1, stenting of the MPD was not conducted, as small asymptomatic neoplasms did not result in ductal hypertension or dilation; nevertheless, stenting of the CBD was executed in 2 cases (10.5%). One patient (5.3%) who underwent the original procedure received stenting in both ductal systems, whereas two patients (10.5%) had stenting just in the CBD. Following EP by the piecemeal technique, stenting of both ductal systems was carried out in 2 patients (10.5%), while stenting of the CBD was conducted in 1 patient (5.3%).

A correlation was discovered between the size of the MDP adenoma and, as a result, the method of its endoscopic removal, as well as the volume of intraoperative measures that prevent complications (closure of incomplete intestinal wall defects with hemostatic clips and the installation of feeding and decompression probes). We did not apply decompression techniques for the stomach and duodenum in Group 1, as there were no intestinal wall defects that needed to be repaired. In Group 2, decompression of the stomach and duodenum was noted in 2 (10.5%) and 2 (10.5%) cases, respectively (33.3% of all patients in this group). All patients in Group 3 (tumour sizes >2.0 cm) had the marginal defects of the post-papiloscopic incision closed and both probes inserted.

The frequency of early postoperative complications in Group 1 was (Table): bleeding – 5.3% (stopped by conservative measures), pain syndrome that did not require the administration of narcotic analgesics – 15.8%, transient hyperamylasemia (up to 1100–1700 U/l for 2 days) – 10.5%. We detected no signs of acute postoperative pancreatitis. In Group 2, no clinically significant postoperative complications were registered. In Group 3, 1 (5.3%) case of bleeding that required the use of endoscopic hemostasis (clipping), 1 (5.3%) case of pain syndrome that required the administration of

narcotic analgesics, and 1 (5.3%) case of transient hyperamylasemia (up to 1300 U/l for 2 days) were observed in the postoperative period. No cases of duodenal perforation were registered.

All patients required basic postoperative care, including proton pump inhibitors, antispasmodics, analgesics, anti-inflammatories, and antibacterial medications. Somatostatin analogues were administered to 3 (15.8%) patients in Group 1, as well as all patients in Group 3.

During a three-month control trial, the MDP adenoma recurred in 2 (10.5%) patients from Group 3 with preoperatively confirmed tumour progression to the distal section of the gastrointestinal system (Fig. 5). In both patients, we used loop diathermy to remove the recurring neoplasms, as well as the biliary and pancreatic stents (Fig. 6). Tumour remains were recovered and removed using a polypectomy loop in 1 (5.3%) case during revision with a Fogarty balloon from the distal region of the CBD into the duodenal lumen. Both patients exhibited no evidence of disease progression during subsequent planned tests at 3 and 6 months (Fig. 7).

Discussion

The asymptomatic occurrence of MDP adenomas in the early stages of the disease accounts for the randomness and relative infrequency of their detection during screening assessments. Symptomatic MDP adenomas are mostly large, sometimes accompanied by complications or the involvement of surrounding organs and tissues in the disease process.

EUS is pivotal in determining the access and extent of surgical intervention for benign MDP neoplasms. This investigation facilitates the evaluation of the tumour's dimensions and the degree of its infiltration into the duodenal wall and the CBD [12].

Most experts agree that abdominal procedures are needed when an adenoma invades the muscular layer of the intestine and/or the distal parts of the

Table. **Early postoperative complications**

Complications	Grade*	Group 1	Group 2	Group 3
Pain syndrome that did not require the administration of analgesics	I	3 (15.8%)	0	0
Pain syndrome that required the administration of narcotic analgesics	II	0	0	1 (5.3%)
Bleeding that did not require hemotransfusion, endoscopic hemostasis, surgical intervention	I	1 (5.3%)	0	0
Bleeding that required endoscopic hemostasis	IIIa	0	0	1 (5.3%)
Transient hyperamylasemia	I	1 (5.3%)	0	1 (5.3%)

* Clavien-Dindo classification.



Figure 5. **Recurrent MDP adenoma 3 months after removal of the primary tumour by the piecemeal technique**



Figure 6. **Diathermy loop resection of recurrent MDP adenoma and simultaneous removal of both stents**



Figure 7. **Control duodenoscopy 3 months after removal of recurrent MDP adenoma. No signs of prol. morbi were detected**

CBD. However, EP may be possible if the adenoma is found on the intestinal mucosa and there is no evidence that it has spread to the CBD [2].

The original EP approach facilitated a reduction in postoperative bleeding incidence compared to conventional loop resection of the MDP, due to the sequential electrocoagulation of vessels adjacent to the neoplasm during tumour excision.

Our study indicates that in operated patients of Group 3, with neoplasms exceeding 2.0 cm, early postoperative complications were more prevalent than in patients from Group 1 and Group 2

(neoplasm size < 2.0 cm). This is ascribed to an increased extent of tissue damage and prolonged exposure to high temperatures during electrocoagulation affecting adjacent tissues and organs, including the pancreas. To mitigate these adverse traumatic consequences during the excision of large adenomas, we recommend using the piecemeal approach.

We concur with certain authors that stenting of the MPD does not significantly influence the occurrence of acute pancreatitis in the postoperative phase. This problem arose in just 1 case (5.26%), when the stent was placed in the MPD following tumour excision with the piecemeal approach. The traumatic nature of tumour excision, due to its dimensions and spread, in this case probably contributed to the development of acute pancreatitis.

In our study, the recurrence rate of MDP adenomas after EP was 10.5%, necessitating further endoscopic excision of the tumour at scheduled follow-up examinations of patients.

The limited traumatic impact of EP and the reduced incidence of postoperative complications enable us to regard the suggested procedure as a priority for the excision of MDP adenomas [2, 8].

Conclusions

The topographic and anatomical characteristics of the MDP area determine the complexity of surgical interventions for patients with neoplasms. The novel EP approach minimizes the risks associated with both early and late postoperative complications. The outcomes achieved by employing EP in the treatment of patients with MDP adenomas support its recommendation as the primary approach at specialized centers.

DECLARATION OF INTERESTS

The authors declare the absence of a conflict of interest and their own financial interest in the preparation of the manuscript.

Funding. External sources of funding and support were not used. No fees or other compensation were paid.

AUTHORS CONTRIBUTIONS

All authors made an equal contribution to this work.

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Оцінка різних методів ендоскопічної папілектомії при аденомах великого дуоденального сосочка

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Мета — оцінити результати виконання ендоскопічної папілектомії з використанням відомих методик, розробити та впровадити оригінальні технології оперативних втручань.

Матеріали та методи. З 2021 до 2024 р. у відділі інтервенційної ендоскопії ДНП «Національний інститут раку» ендоскопічну папілектомію з приводу аденоми великого дуоденального сосочка (ВДС) проведено 19 пацієнтам (10 (52,63%) жінок та 9 (47,47%) чоловіків) віком від 24 до 78 років (середній вік — 45,6 року). У більшості випадків (2 (63,15%)) мали місце клінічні вияви біліарної обструкції та холангіту.

Результати. У 10 (52,63%) хворих при розмірах новоутворення <1,0 см використовували загальноприйнятну методику петлевої резекції єдиним блоком (перша група). Для запобігання виникненню інтраопераційних та післяопераційних ускладнень нами розроблений та в 6 (31,57%) випадках застосований двохетапний метод ендоскопічної папілектомії (друга група). У 3 (15,78%) пацієнтів із розміром пухлини від 5,0 до 8,0 см використано методику фрагментації частини новоутворення, що найбільш виступає в просвіт кишки, з обов'язковим видаленням усіх фрагментів (третья група). Рецидив аденоми ВДС при контрольному дослідженні через 3 міс виявлено в 2 (10,5%) пацієнтів третьої групи. В обох випадках виконано петлеву діатермоексцизію рецидивних новоутворень і видалення стентів. При планових обстеженнях через 3 та 6 міс ознак продовження захворювання в обох випадках не зареєстровано.

Висновки. Топографо-анатомічні особливості ділянки ВДС зумовлюють складність хірургічного лікування пацієнтів з його новоутвореннями. Розроблена оригінальна методика ендоскопічної папілектомії дає змогу знизити ризики виникнення ранніх та пізніх післяопераційних ускладнень. Отримані результати застосування ендоскопічної папілектомії в лікуванні пацієнтів з аденомами ВДС дають змогу пропонувати даний метод як основний в експертних центрах.

Ключові слова: ендоскопічна папілектомія, аденома великого дуоденального сосочка, ендосонографія.

FOR CITATION

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