

Endoscopic necrosectomy under fluoroscopic guidance during transmural drainage of walled-off pancreatic necrosis (WOPN)

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A – Study Design
B – Data Collection
C – Statistical Analysis
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ABSTRACT:

Introduction: The endoscopic treatment of walled-off pancreatic necrosis (WOPN) as well as other minimally invasive methods have been evolving since last years.

Aim: The aim of this study is evaluation of efficiency and safety of endoscopic necrosectomy under fluoroscopy done during the transmural drainage in patients with symptomatic WOPN. **M**

Material and methods: The retrospective analysis 114 consecutive patients with symptomatic WOPN were treated endoscopically in our medical center between 2011 and 2016.

Results: Endoscopic necrosectomy was performed under fluoroscopic guidance during transmural drainage in 24/114 (21.05%) patients. The mean amount of endoscopic procedures in each patient was 8.88 (3–27). The active drainage was continued averagely for 40.1 (11–96) days. The average number of necrosectomy procedures during continued drainage was 6.54 (1–24) per patient. Additional percutaneous drainage was applied in just two patients. The complications of endotherapy were present in 9/24 (37.5%) patients. The therapeutic success was reached in 23/24 (95.83%) patients. The mean time of observation was 35 [18–78] months. The recurrence of pancreatic fluid collection was stated in 4 patients during the observation time. The mean time between the end of endotherapy and recurrence of fluid collection was 19 [16–22] months. In three patients recurrent fluid collections were treated endoscopically and in one patient were treated surgically. Long-term success of endoscopic treatment of WOPN was reached in 22/24 (91.67%) patients.

Conclusions: Endoscopic necrosectomy under fluoroscopic guidance during transmural drainage is successful and safe method of minimally invasive treatment in selected patients with walled-off pancreatic necrosis.

KEYWORDS:

acute pancreatitis, endoscopic necrosectomy, walled-off pancreatic necrosis

ABBREVIATIONS

CECT – contrast-enhanced computed tomography

DDS – disconnected duct syndrome

ERP – endoscopic retrograde pancreatography

EUS – echoendosonographic

MPD – main pancreatic duct

WOPN – walled-off pancreatic necrosis

INTRODUCTION

Surgical treatment of pancreatic necrosis has for many years been the only method of treatment. The procedures of open necrosectomy have been related with high morbidity and mortality [1–4]. Nowadays, an efficient therapy is based on the complete removal of necrosis by application of a suitable drainage, which can be used with the support of minimally invasive techniques [5–14]. Depending on the access to necrotic collection and the applied technique, we distinguish endoscopic drainage, percutaneous drainage and surgical drainage with either retroperitoneal or transperitoneal approach [5–14]. Van Santvoort et al. proved in their randomized study that the exploitation of minimally invasive techniques in treatment of the consequences of acute necrotizing pancreatitis significantly

reduces the number of complications (including mortal complications) in comparison with the procedure of open necrosectomy [15].

Despite high efficiency of the above-mentioned techniques of walled-off pancreatic necrosis (WOPN) drainage, there are some limitations such as, among others a lower capability to remove poorly liquefied necrosis. Mechanical removal of necrotic tissues (necrosectomy) from the lumen of collection is a must in some patients with WOPN, in whom there is no improvement, despite the used drainage [5, 6, 7]. The performance of necrosectomy during pancreatic necrosis drainage considerably improves the efficiency of treatment [21, 22].

The endoscopic treatment of WOPN as well as other minimally invasive methods have been evolving in the recent years [5, 6, 7, 9, 11, 12, 16, 17, 18, 19, 20]. Endoscopic transmural drainage is now considered to be an efficient and common method of treatment of pancreatic necrosis [5, 6, 9, 11, 12, 16, 17, 18, 19, 20]. It is recommended to perform endoscopic necrosectomy, when the endoscopic drainage does not give the desired results [16, 17]. In 2015 we shared in Videosurgery the results of treatment of 8 patients, who had endoscopic necrosectomy done under fluoroscopic guidance during transmural drainage [17]. The mentioned technique [17] is an alternative to the endoscopic necro-

sectomy commonly described in the literature as endoscopic necrosectomy [5, 6]. Our method consists in the removal of necrotic tissues under fluoroscopy without the need to insert a fiberolescope to the necrotic cavity [17].

The number of patients treated in our medical centre with the use of endoscopic necrosectomy under fluoroscopic guidance has increased since the moment of our publication in 2015 [17]. What is more, the time of observation of the patients has been extended. These circumstances have led us to revising the results from previous publication.

It was aimed to evaluate the efficiency and safety of endoscopic necrosectomy under fluoroscopy during the transmural drainage in patients with symptomatic WOPN.

METHODS AND CLINICAL MATERIAL

114 patients (81 males, 33 females, mean age 51.7 years [21–85]) with symptomatic WOPN were treated endoscopically in our medical centre between 2011–2016. The patients were qualified for treatment on the basis of a clinical picture and contrast-enhanced computed tomography (CECT) of the abdomen or the results of magnetic resonance of the abdomen. A detailed description of the endoscopic methods done in our medical centre was included in our previous publications [11, 12, 17, 19, 20]. Endoscopic procedures were handled with Pentax ED3490TK duodenoscopes and Pentax EG3870UTK echoendoscope. There was an attempt to perform transmural drainage in each patient. The place of necrogastrostomy or necroduodenostomy was stated under echoendosonographic (EUS) guidance. Enterostomy was executed with Giovannini's cystostome (Cystotome CST-10, Wilson-Cook). The fistulostomy was widened with a high-pressure balloon with a diameter of 8 mm or 20 mm (Boston Scientific). A 7 Fr or 8.5 Fr (Balton or Wilson-Cook) nasal drain as well as 7 Fr or 8.5 Fr "double pigtail" endoprotheses (ZSO-10-5, Wilson Cook or Mar Flow) were inserted through the previously widened fistula into the lumen of necrosis. The collection of WOPN was flushed through the nasal drain with a saline solution (60–200 ml) every 2 hours during the first 48 hours and every 4 hours on the subsequent days.

The necrosectomy was performed under fluoroscopic guidance during transmural drainage with the use of a Dormia basket. The criteria of qualification for endoscopic necrosectomy are as follows: a lack of clinical improvement, despite the applied drainage, infection of necrotic collection and a large amount of necrotic tissues in the fluoroscopic and echoendoscopic images. Endoscopic necrosectomy was started with the removal of the nasal drain. Thereafter, the Dormia basket (FG-V422PR, Olympus) was guided through the fistula into the necrotic area near the transmural stent. Necrotic tissues were removed with the Dormia basket through the transmural fistula under fluoroscopy. This action was repeated several times during each necrosectomy. A nasal drain was placed again transmurally after the end of the procedure.

The efficiency of endoscopic treatment was evaluated every 7 days basing on the clinical condition and conventional ultrasonography of the abdomen. A complete regression of WOPN (diameter <40 mm) was stated on the basis of the abdominal CECT. Therapeutic success was defined as complete regression of WOPN and

a lack of symptoms related with WOPN. The active drainage was stopped in the moment of achieving therapeutic success. Long-term success was defined as a lack of symptoms and a size of collection <40 mm during the observation.

All the statistical calculations were performed with the use of the data analysis software StatSoft Inc. (2011) STATISTICA version 10.0 (licensed for the Medical University of Gdansk). Quantitative variables were characterized by arithmetic means, minimal and maximal values (range), whereas qualitative data were presented by means of numbers and percentage.

RESULTS

114 patients underwent the endoscopic drainage of symptomatic WOPN in our medical centre between 2011–2016. Endoscopic necrosectomy was performed under fluoroscopic guidance during transmural drainage in 24/114 (21.05%) patients (18 males, 6 females, mean age 50.67 years [33–81]) (Fig. 1 A.–H.). The etiology of acute necrotizing pancreatitis (ANP) was alcoholic in 18 patients and non-alcoholic in 6 patients (biliary-3, iatrogenic-1, idiopathic-2). The average time between the start of ANP till the beginning of endoscopic treatment was 9 [3–22] weeks. The indications for the beginning of endoscopic WOPN treatment in the study group included: gastrointestinal obstruction together with weight loss and abdominal pain (12/24 patients), clinical suspicion of infected WOPN (11/24 patients), jaundice (1/24 patient). In all 11 patients with a clinical suspicion of infected WOPN, an infection of the collection was confirmed by a culture of necrotic content. The average size of WOPN collection was 19.86 cm (10.6–33.0 cm). Mixed (pancreatic and peripancreatic) necrosis was discovered in 18 patients, central (pancreatic) necrosis was recognized in 4 patients, while only 2 patients suffered from peripheral (peripancreatic) necrosis.

Endoscopic necrosectomy was performed under fluoroscopic guidance during transmural drainage in 24/114 (21.05%) patients. The mean amount of endoscopic procedures in each patient was 8.88 (3–27). The active drainage was continued averagely for 40.1 (11–96) days. The average number of necrosectomy procedures during continued drainage was 6.54 (1–24) per patient. Transmural access was performed in all patients (transgastric – 19 patients and transduodenal – 5 patients). Additional percutaneous drainage was applied in just two patients.

The complications of endotherapy were present in 9/24 (37.5%) patients. The most common complication was bleeding from the upper gastrointestinal tract, which was found in 6 patients. All patients underwent conservative treatment (transfusions of packed red blood cells). Dislocation of transmural endoprotheses up to the lumen of WOPN collection during the insertion of nasal drains was observed in 2 patients. Both of them had the endoprotheses removed endoscopically with use of the Dormia basket. One patient underwent perforation of the gastrointestinal tract, which was treated conservatively. It had come to perforation during the fistulotomy.

Endoscopic retrograde pancreatography (ERP) was done in 22/24 (91.67%) patients. The leak of contrast outside main pancreatic duct (partial disruption of MPD) was recognized in 15/22 (68.18%) patients. The pancreatic stent was placed in all of them bridging

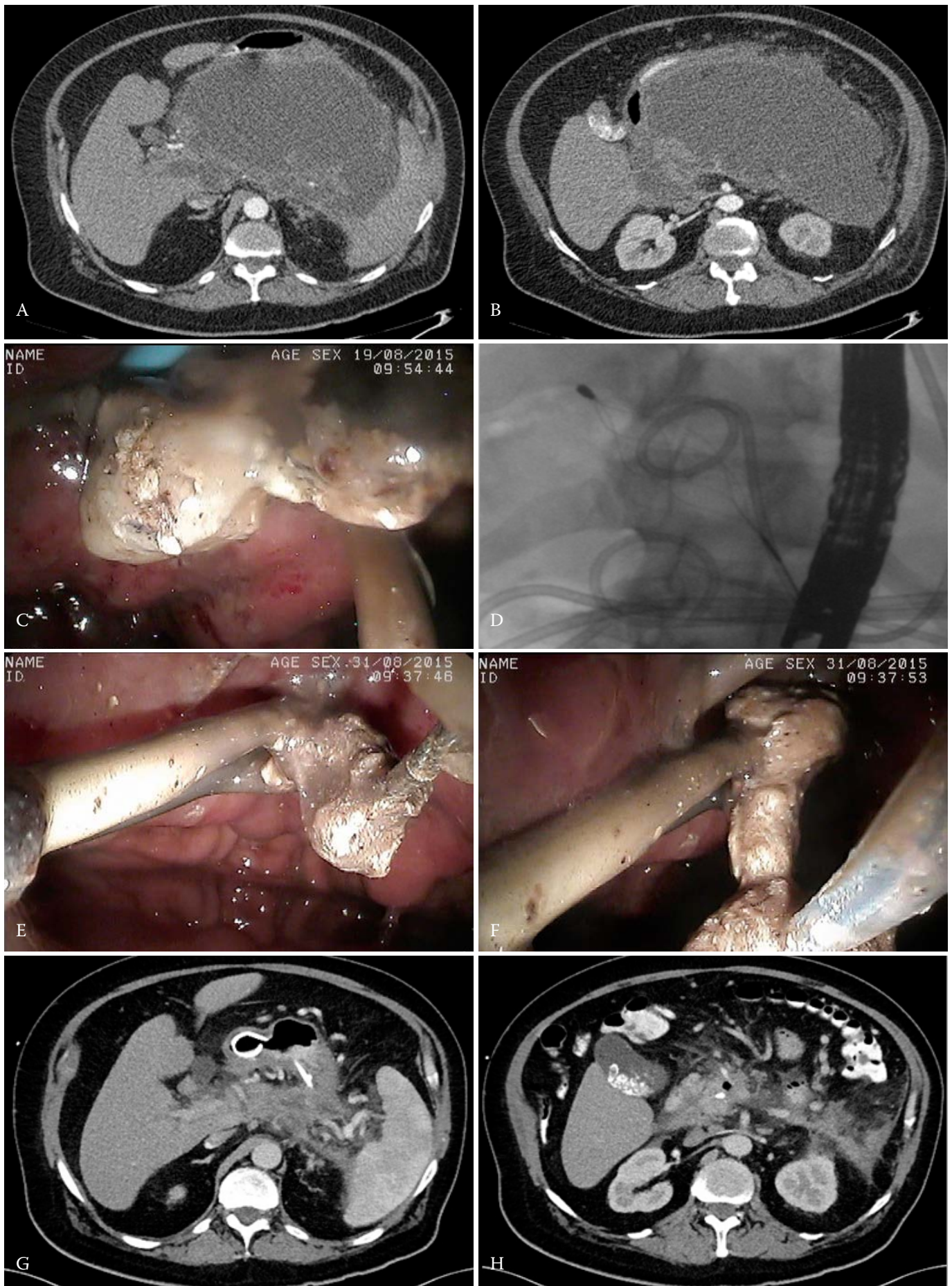


Fig. 1A–H. A patient with walled-off pancreatic necrosis visible in contrast-enhanced computed tomography of the abdomen (A, B). Endoscopic necrosectomy under fluoroscopic guidance was performed during transmural drainage (C, D). Numerous fragments of necrotic tissues were removed from the necrotic cavity during endoscopic necrosectomy (E, F). Abdominal contrast-enhanced computed tomography performed after the end of endoscopic treatment revealed complete regression of WOPN (G, H).

the place of duct disruption. The fragment of MPD without a leak of contrast outside was stated during ERP in 5/22 (22.73%) patients. A normal pancreatogram was discovered in 2/22 (9.09%) patients. Disconnected duct syndrome (DDS) was found out in 5/24 (20.83%) patients in imaging examinations. During the next endoscopic procedure (ERP) performed after 3–6 months in all 15 patients with partial disruption, the pancreatography revealed a normal MPD without a leak of contrast outside (successful endoscopic treatment of pancreatic duct disruption).

Therapeutic success of endotherapy WOPN was reached in 23/24 (95.83%) patients. One patient with DDS in the course of WOPN did not complete endoscopic treatment. This patient required surgical drainage due to sepsis. The mean time of observation was 35 [18–78] months. The recurrence of pancreatic fluid collection was stated in 4 patients with DDS during the observation time. The mean time between the end of endotherapy and the recurrence of fluid collection was 19 [16–22] months. In three patient's recurrent fluid collections were treated endoscopically and in one patient they were treated surgically. Long-term success of endoscopic treatment of WOPN was reached in 22/24 (91.67%) patients.

DISCUSSION

Herein we presented the technique of endoscopic necrosectomy, which is an alternative to the one described in current literature. The success rate of endoscopic necrosectomy under fluoroscopy was 95.83%, the complication rate was 37.5%. Long-term success was gained in 91.67% patients with a quite long average time of observation of 35 [18–78] months.

In 2015 we published in *Videosurgery* the results of endotherapy of 8 patients with symptomatic WOPN, who had been treated with the use of endoscopic necrosectomy under fluoroscopic guidance [17]. The success rate there was 100% with a complication rate of 25% [17]. No recurrence of pancreatic fluid collection was noted during the six-month follow-up [17]. Nevertheless, it should be emphasized that both publications vary between themselves in a significant way, which complicates accurate comparison [17], especially that we did include the results concerning treatment of 8 patients from the previous paper in the current publication [17]. The current study was conducted basing on a three times larger group of patients comparing to the previous study, which in our humble opinion explains the 100% efficiency from the older publication [17]. The time of observation is also much longer in this paper (an average of 35 months), while it averagely lasted 6 months in the previous publication [17]. As we proved in this paper, the mean time between the end of endoscopic treatment and recurrence of collection is 19 months. It seems that this is why we reached a 100% long-term success rate earlier, without stating any recurrence of pancreatic fluid collections [17]. Furthermore, the average size of necrotic collections was lower (14.6 cm) in the previous study compared to the present paper (19.86 cm) [17]. The time from ANP till the endoscopic intervention was also longer – 14 weeks previously and 9 weeks now [17]. These two parameters – a lower size of necrotic collection as well as a longer time between ANP and the start of endotherapy (better liquidation of necrosis) play a great role in the distinctiveness between our publications, particularly in the efficiency of treatment, amount of endoscopic procedures and the length of active drainage [17].

The first description of endoscopic necrosectomy was presented by Seifert et al. in 2000 [21]. Since that moment we have been observing significant changes in the strategy of pancreatic necrosis treatment. Initially in most publications endoscopic necrosectomy used to be the basis of endotherapy, which was applied in all patients with WOPN [16, 22, 23, 24]. As per the currently accepted strategy of treatment of pancreatic necrosis (“step-up approach”) not all patients require necrosectomy [15, 25, 26, 27, 28]. The “step-up approach” recommends running active transmural drainage and necrosectomy is to be done as the next step only in case of its inefficiency [25, 26, 27, 28]. Active transmural drainage has been our basic strategy of endoscopic treatment since the moment of its implementation in our medical centre, while necrosectomy has been used in highly-selected patients [17]. 24/114 (21.05%) patients in our paper had the indications for endoscopic necrosectomy during the transmural drainage. Therapeutic success was reached in a fair majority of patients suffering from symptomatic WOPN, thanks to the application of active endoscopic drainage without necrosectomy.

In 2012 Bakker et al. proved in their randomized study that transmural necrosectomy results in a lower risk of multi-organ changes, systemic complications and a smaller number of deaths in the group of patients with infected pancreatic necrosis in comparison with the group of patients, who underwent surgical necrosectomy [29]. The same group of researchers compared two approach strategies in their publication in 2017 – the endoscopic “step-up approach” and the surgical “step-up approach” – in patients with pancreatic necrosis [27, 28]. In this paper van Brunschot et al. did not manage to confirm the differences in the risk of systemic complications – also the lethal ones – in patients with pancreatic necrosis, in whom endoscopic treatment (endoscopic “step-up approach”) was applied equating to the patients treated with the use of minimally invasive surgical techniques (surgical “step-up approach”) [27, 28]. The same study showed a smaller amount of pancreatic fistulas and a shorter time of hospitalization in patients treated with endotherapy (endoscopic “step-up approach”) [27, 28].

However, our study has some limitations, of which the main include a lack of randomization and a retrospective nature. Furthermore, our study group consisted of highly-selected patients originating from a single medical centre.

In conclusions, our study proved that endoscopic necrosectomy under fluoroscopic guidance during transmural drainage of walled-off pancreatic necrosis is an effective and safe method of minimally invasive treatment. The endoscopic “step-up approach” is an efficient strategy of treatment in patients with pancreatic necrosis. According to this strategy, endoscopic necrosectomy should be performed in selected patients with insufficient transmural drainage. Surgical treatment (optimal surgical “step-up approach”) remains the treatment of choice in case of inefficiency of endotherapy.

CONCLUSIONS

Endoscopic necrosectomy under fluoroscopic guidance during transmural drainage is a successful and safe method of minimally invasive treatment in selected patients with symptomatic walled-off pancreatic necrosis.

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