EUS-guided drainage of the pancreatic duct for the treatment of postoperative stenosis of pancreatico-digestive anastomosis or pancreatic duct stenosis complicating chronic pancreatitis: Experience at a tertiary care center

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ABSTRACT

Background and Objectives: For the treatment of pancreatic duct stenosis due to chronic pancreatitis (CP) or postoperative (PO) stenosis, endoscopic procedures are usually the first choice. In cases of failure of the recommended treatment by ERCP, anastomosis between the Wirsung duct and the stomach or duodenum can be performed under EUS guidance. The objective of this retrospective study was to compare the outcomes of pancreatico-gastric or pancreaticoduodenal anastomosis under EUS for PO stenosis versus CP stenosis. Subjects and Methods: This was a retrospective, single-center, consecutive case study of patients who underwent EUS-guided Wirsungo-gastric/bulbar anastomosis. Results: Forty-three patients were included. Twenty-one patients underwent treatment for PO stenosis, and 22 patients underwent treatment for CP stenosis. The technical success rate was 95.3% (41/43), with 100% in cases of PO stenosis and 90.9% in cases of CP stenosis. The clinical success rate was 72.5% (29/40): 75% (15/20) in cases of PO stenosis and 70% (14/20) in cases of CP stenosis. The overall morbidity rate was 34.9% (15/43). The main complication was postprocedural pain, occurring in 20.9% (9/443) of patients. The rate of stent migration or obstruction was 27.9% (12/43). There was no difference in patient outcomes or morbidity according to the etiology of the stenosis. The median follow-up duration in this study was 14 months. Conclusions: EUS-guided Wirsungo-gastric/duodenal anastomosis is a feasible, minimally invasive, safe, and relatively effective procedure. The rates of technical success, clinical success, and complications were not different between patients with PO and CP stenosis. However, the follow-up period was too short to assess recurrent symptoms in these patients.

Key words: chronic pancreatitis, drainage, EUS, pancreatic, postsurgery, stent

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INTRODUCTION

Stenosis of the main pancreatic duct can be associated with various pathologies, both benign and malignant (chronic pancreatitis [CP], recurrent acute pancreatitis, postoperative [PO] complications, trauma, pseudocysts, and tumor progression). Patients most often complain of persistent or recurrent pain, symptoms of exocrine pancreatic insufficiency, and recurrent acute pancreatitis. The pathophysiology of this pain is complex and is partly related to increased ductal pressure secondary to stenosis.

After elimination of the malignant pathology, the symptoms are treated through medical, endoscopic, and surgical strategies. Endoscopic management (drainage of the pancreatic duct), in which a pancreatic stent is inserted by ERCP, is the first-line intervention (excluding pancreatic lithiasis) for symptomatic pancreatic duct stenosis. Long-term pain regression was reported in 67.5% of 536 patients (95% confidence interval [CI]: 51.5%–80.2%) in a meta-analysis of 9 studies.
However, due to surgically altered anatomy or technical failure, up to 10% of patients do not benefit from ERCP drainage. Pancreaticojunval or pancreatico-gastric anastomotic stenosis after pancreatic surgery can occur in 25%–65% of cases. Although most cases are asymptomatic, patients can experience pain or signs of exocrine pancreatic insufficiency. Management with stent placement is difficult in many cases due to ERCP failure or the potential for high morbidity rates in cases requiring additional surgery.

At expert centers, EUS-guided drainage of the pancreatic duct through the gastric or duodenal wall is an alternative to surgery for cases of papillary drainage failure. This technique has been described in retrospective, mono- and multicenter series, with the largest multicenter series including 94 patients. In these different studies, the technical success rate ranged from 58% to 100%, with an early complication rate of 0%–37% and stent-related complication rate (stent migration or occlusion) of 0%–55%. Clinical improvement was observed in 57%–100% of cases. The duration of follow-up ranged from a few weeks to 55 months. No intervention-related deaths were reported.

In comparison, surgery is effective, with success rates of 65%–85%, although adverse event rates can be as high as 30%, and mortality rates as high as 2% have been reported in some series.

The reason for the high variability of morbidity is unclear. It is unclear in these series whether patient outcomes and morbidity depended on the etiology of the stenosis (CP or PO stenosis). Patients with CP or PO stenosis are not the same, and the stiffness of the pancreas is probably not the same in these patients. Thus, the goal was to compare the
outcomes of patients who underwent EUS-guided pancreatico-gastric/duodenal anastomosis, according to the etiology of the stenosis: PO or CP stenosis. We also evaluated whether the placement of a second stent in the created fistula 1 month later could prevent stent migration/obstruction during follow-up.

**SUBJECTS AND METHODS**

**Patients**

This was a retrospective, single-center, consecutive case study of patients who underwent EUS-guided Wirsungo-gastric/duodenal anastomosis at the Paoli Calmettes in Marseille between December 2004 and October 2019.

A search of the institution’s database was performed using ConSoRe. ConSoRe is a Big Data health software developed by Unicancer. ConSoRe uses artificial intelligence to process millions of documents from various data sources.

This software makes it possible to query with the keywords “gastric pancreaticoanastomosis,” “duodenal pancreaticoanastomosis,” bulbo-pancreatic, Wirsungo-gastric, Wirsungo-bulbar, and related spellings in the reports. These keywords were associated with the use of the coding “pancreatic duct stenting.” A total of 600 patients were identified with the coding, and 47 patients were identified with the keywords. From these patients, data were extracted by a physician of the unit not involved in the procedure.

Patient data were then retrieved from the center's patient management software Hospital Manager®.

The characteristics collected were age, sex, tobacco and alcohol consumption, etiology of main pancreatic duct (MPD) stenosis (CP/PO stenosis), pain, analgesic consumption, body mass index, length of hospitalization, and the occurrence of early or late stent-related complications.

The indication for CP was pain refractory to analgesic treatment, with dilatation of the pancreatic duct and prior failure of ERCP.

The Ethics Committee of the Paoli Calmette Institute approved this retrospective study (PANCREATOSTOMIE-IPC 2020-001).

The procedures were performed by the center’s endoscopists, all of whom are experts in therapeutic EUS and biliopancreatic catheterization.

**Procedure**

The procedures were performed with patients under general anesthesia in the supine position with orotracheal intubation using Pentax EG38UTK or 38J10UT therapeutic EUS and radioscopic control.

EUS-guided puncture of the Wirsung duct was performed by the transgastric or transduodenal route using a 19G Cook EchoTip Ultra puncture needle. Then, pancreatography was performed after the injection of contrast agent through the needle. Through the needle, a guidewire (Jagwire, 0.035”, Boston Scientific®) was placed into the pancreatic duct. In cases where the guidewire went through the papilla or through a site of surgical anastomosis and in cases of pancreatico-gastric anastomosis, a “rendezvous” technique was performed. After the guidewire was in place, a gastric or duodenal pancreatico-gastric fistula was created using a 6-Fr cystostome (Endo-Flex Company, Voerde, Germany®), followed by dilation of the fistula with a 4-mm dilatation balloon (Hurricane Balloon Dilation Catheter, 4 mm × 4 cm, Boston Scientific®). A straight Cotton-Leung plastic stent (Cook Medical®), usually 7 cm/7 Fr, was then placed through the guidewire [Figures 2-3]. Then, a false rendezvous technique was performed. The stent was placed through the papilla and through the stomach with an anterograde technique using the same method we have previously described. The difference was that the stent was placed through the papilla to theoretically facilitate subsequent endoscopy, which would be performed through the papilla. In order to avoid stent migration or obstruction, patients were scheduled for the placement of a second identical stent in parallel to the first stent using a duodenoscope 1 month after this procedure (Pentax scope® ED3410T).

**Statistical analysis**

The data were collected using Microsoft Excel software. Descriptive statistics are expressed as the mean with the minimum and maximum values. For quantitative data, the median and mean were calculated, and percentages and frequencies were calculated for qualitative data. The statistical tests were carried out with SAS Enterprise Guide v7.15 software. Pearson’s Chi-squared test, or Fisher’s test when necessary, was used to compare the
nominal qualitative data. The Wilcoxon test was used for the comparison of ordinal qualitative data. Student’s t-test was conducted to compare quantitative data. A significance level of \( P < 0.05 \) was used to compare the similarity between the two groups as well as differences in intervention outcomes.

The primary evaluation criterion was defined as the clinical success rate. Patients with an unknown clinical success status were excluded from the outcome analysis. Missing data in terms of the secondary evaluation criteria were not imputed.

**Definitions**

Technical success was defined by the placement of a stent through a pancreatico-duodenal/gastric fistula created under EUS guidance.

Clinical success was assessed after the first stent was placed at the time of the follow-up visit, most often at 1 month, and was defined as the reduction or disappearance of pain. Clinical success was only evaluated in patients in whom technical success was achieved. The reduction or disappearance of pain was noted during PO follow-up visits performed by the operator.

Follow-up visits were left to the discretion of the endoscopist. A follow-up visit was scheduled at 1 month after the first procedure and then every 3 months during the 1st year. The follow-up period began on the date of the procedure and stopped 1 month later in the case of clinical failure, at the last visit, or at the time of relapse (for PO stenosis due to malignant disease) or death.

Mortality was defined as death within 1 month after the endoscopic procedure.

Morbidity was defined as complications occurring within 1 month after the procedure. Morbidity was assessed using the Clavien–Dindo score.\(^{[23]}\)

Late complications related to stents were defined as obstruction or migration after 1 month.

**RESULTS**

**Patients**

A total of 43 patients were included. The patient characteristics are described in Table 1. Twenty-one patients (48.8%) had PO pancreatic duct stenosis, 14 had malignant disease, and 7 had benign disease. Twenty-two patients (51.1%) had CP stenosis after ERCP failure.

In cases of PO stenosis, 14 patients had surgical pancreaticojejunal anastomosis, 4 patients had surgical pancreatico-gastric anastomosis, and 3 patients had pancreaticoduodenal anastomosis (2 patients underwent surgical ampullectomy, and 1 underwent endoscopic radiofrequency ablation).

The mean diameter of the pancreatic duct was 11.15 mm, and the highest values could be explained by the presence of fluid collection complicating rupture of the Wirsung duct in four patients.

The median follow-up duration was 14 months; it was 24 months among patients with PO pancreatic duct stenosis and 10 months among patients with CP stenosis. The minimum follow-up duration was 1 month, and the maximum was 168 months. A comparison of the results is presented in Table 2.

**Technical success**

Technical success was achieved in 95.3% (41/43) of patients overall, ranging from 100% (21/21) of patients with PO stenosis to 90.9% (20/22) of patients with CP stenosis.

Pancreaticoduodenal anastomosis was performed in five patients with CP, and pancreatico-gastric anastomosis was performed in the other patients.

A rendezvous technique allowing surgical pancreatico-gastric anastomosis catheterization was performed in 2 patients.

The average length of hospitalization after the procedure was 2 days (minimum, 1 day; maximum, 19 days).

Two cases of technical failure were reported (2/43, 4.7%); one was related to bleeding during puncture, and the other was related to stent insertion failure.

**Clinical success**

Clinical success was achieved in 72.5% of patients overall (29/40), ranging from 75% (15/20) in patients with PO stenosis to 70% (14/20) in patients with CP stenosis.
For postsurgical anastomosis, recurrence of the initial disease was noted in six patients.

One patient was lost to follow-up (CP stenosis); this case was regarded as a technical success and was not included in the assessment of clinical success.

The initial attempt to perform anastomosis failed in one patient, despite clinical success in performing anastomosis during a second procedure.

A decrease in analgesic use was reported in only 31.3% (10/32) of patients, but the data were incomplete and not available for nine patients.

Only seven (7/40, 17.5%) patients underwent the placement of a second stent in a second procedure: two patients (10%, 2/20) in the PO stenosis group and five patients (25% 5/20) in the PC group.

Indeed, nine (9/41, 22.0%) patients experienced a stent-related complication in the interval before the second intervention. A second stent was not indicated in cases of clinical failure (12/41, 29.3%) or in patients who underwent treatment with a rendezvous technique (2/41, 4.9%) or fluid drainage (4/41, 9.8%). Three patients (3/41, 7.3%) did not receive a second stent, as there were insufficient data to justify this procedure. In four (4/41, 9.8%) patients, placement of the second stent failed. Placement of the second stent failed because of the stiffness of the pancreas and the difficulties of inserting a second stent in parallel despite previous dilation.

Adverse events
The adverse events are described in Table 3.

Mortality
No cases of mortality were reported.

Morbidity
The early complication rate was 34.9% (15/43), ranging from 38.1% (8/21) for patients with PO stenosis to 31.8% (7/22) for patients with CP stenosis.

A grade I complication according to the Clavien–Dindo classification was noted in 28% of patients (i.e. 12 among 22 complications). Most were related to postprocedural pain, occurring in 20.9% (9/43) of the patients (28% [6/21] had PO stenosis, and 13.6% [3/22] had stenosis related to CP). The pain

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**Table 1. Baseline characteristics of the postsurgery and chronic pancreatitis groups**

|                     | Postsurgery | Chronic Pancreatitis | All patients | P    |
|---------------------|-------------|----------------------|--------------|------|
| n                   | 21          | 22                   | 43           |      |
| Age (years), mean±SD| 64.3±10.88  | 55.2±10.87           | 59.6±11.79   | 0.0056|
| Sex                 |             |                      |              |      |
| Male                | 33.33% (7/21)| 95.5% (21/22)       | 65.12% (28/43)| <0.001|
| Female              | 66.67% (14/21)| 4.5% (1/22)         | 34.88% (15/43)|    |
| BMI (kg/m²), mean±SD| 22.81±4.1   | 20.51±2.85          | 21.6±4.94    | 0.0761|
| Smoking             | 42.86% (9/21)| 68.18% (15/22)      | 55.81% (24/43)| 0.2357|
| Alcohol             | 14.29% (3/21)| 63.64% (14/22)      | 39.33% (17/43)| 0.019 |
| Analgesic level 1   | 47.62% (10/21)| 40.91% (9/22)      | 44.19% (19/43)| 0.6578|
| Analgesic level 2   | 19.05% (4/21)| 27.27% (6/22)      | 23.26% (10/43)| 0.5234|
| Analgesic level 3   | 19.05% (4/21)| 36.36% (8/22)      | 27.91% (12/43)| 0.2057|
| Analgesic level 1+3 | 4.76% (1/21)| 13.64% (3/22)      | 9.30% (4/43)  | 0.3166|
| NSAIDs              | 14.92% (3/21)| 0% (0/22)           | 6.98% (3/43)  | 0.0660|
| Wirsung diameter (mm), mean±SD| 7.47±2.95 | 14.83±11.26        | 11.15±12.38  | 0.0317|

WHO analgesic ladder: Level 1: Nonopiod analgesics such as acetaminophen with or without adjuvants; Level 2: Weak opioids (hydrocodone, codeine, and tramadol); Level 3: Potent opioids (morphine, methadone, fentanyl, oxycodeone, buprenorphine, tapentadol, hydromorphone, and oxymorphone); NSAIDs: Nonsteroidal anti-inflammatory drugs; BMI: Body mass index; SD: Standard deviation; WHO: World Health Organization

**Table 2. Comparison of the results between the postsurgery and chronic pancreatitis groups**

| Results                | Postsurgery | Chronic pancreatitis | All patients | P    |
|------------------------|-------------|----------------------|--------------|------|
| Technical success      | 100% (21/21)| 90.9% (20/22)        | 95.34% (41/43)| 0.2  |
| Clinical success       | 75% (15/20) | 70% (14/20)          | 72.5% (29/40)| 0.72 |
| Decrease in analgesics | 28% (5/18)  | 37.5% (5/14)         | 31% (10/32)  | 0.63 |
| Need for an additional procedure | 9.5% (2/21) | 13.63% (3/22) | 11.6% (5/43) | 0.77 |
| Celiac plexus neurolysis | 4.7% (1/21)| 4.5% (1/22)          | 4.6% (2/43)  |      |
| Surgery                | 4.7% (1/21) | 9% (2/22)            | 7% (3/43)    |      |
was rapidly resolved under level I or II analgesic use. Prolonged hospitalization was required for three of these patients, an additional day for two patients and 2 additional days for one patient. Two cases of acute pancreatitis were reported (2/43, 4.7%); additional procedures were not required, but a longer hospital stay was required (4 days for both patients).

One procedure had to be interrupted due to a hemorrhage at the time of puncture. There was no need for further hemostasis or blood transfusion.

A grade IIIb complication was noted in 7% (3/43) of patients. Early prosthesis migration occurred in two patients (2/43, 4.7%), one promptly after the procedure (within 3 days) and the other at 27 days, requiring new anastomosis. Postprocedural fluid collection (1/43, 2.3%) was reported, with indications for antibiotic therapy and endoscopic drainage. A prolonged hospitalization of 19 days was necessary.

Late (stent-related) complications

A stent-related adverse event after the 1st month following endoscopy occurred in 27.9% (12/43) of patients overall, ranging from 23.8% (5/21) in patients with PO stenosis to 31.8% (7/22) in patients with CP stenosis. These complications were related to migration in 14.0% (6/43) and stent obstruction in 14.0% (6/43). New canalization of the orifice following migration was possible only when the patient had been treated with a “rendezvous” technique. Four patients underwent another procedure for pancreatico-gastric anastomosis following stent migration, while one patient did not; this patient did not want to undergo another intervention. The six patients who experienced stent obstruction were able to benefit from a change in the prosthesis through the previously performed anastomosis.

The median time to stent migration or occlusion was 8 months, ranging from 10 months in patients with CP stenosis and 6.5 months in patients with PO stenosis.

**Stent migration and obstruction according to the number of stents**

Seven patients underwent the placement of a second straight stent in parallel to the first stent. Migration was noted in these patients, with a stent-related complication rate of 14.3% (1/7).

**DISCUSSION**

Increased ductal pressure is one of the major components of pain associated with CP. This pain is also found in cases of surgical pancreatico-digestive anastomatic stenosis, such as after Whipple surgery.

ERCP drainage, when possible, is an effective approach to resolve these symptoms in approximately 60% of cases.³
In the event of endoscopic drainage failure, surgical management can be offered as an effective solution but at the cost of a significant mortality rate.

Progress in therapeutic EUS in recent decades has made it possible to drain the main pancreatic duct under ultrasound control through the wall of the stomach or duodenum.

The technique was first described in 2002 by François et al.[9] Approximately 15 studies, all retrospective and mostly monocentric, have since been carried out on the subject.[8-19]

This approach allows access to the Wirsung duct in cases of prior ERCP drainage failure or duct inaccessibility due to a surgical history and therefore avoids the need for major surgery, which has a potentially higher morbidity rate and a mortality rate estimated at approximately 2%.[20-22]

In our study, the technical success rate was 95%, and the clinical success rate was 72.5%, which are comparable to those in the literature.

A 34.9% rate of early adverse events was observed, and a 27.9% rate of late adverse events related to stent malfunction was observed.

A major limitation of this study regarding its retrospective design is the evaluation of pain, which was done by the endoscopist during PO follow-up. The evaluation was not quantitative but only qualitative and based on the consideration of the endoscopist. In other words, one of the main limitations of our study is the subjective evaluation of pain by physicians without the use of a validated scale before and after the procedure.

The median follow-up duration in this study was 14 months, which is too short to evaluate recurrent symptoms in those patients with Wirsung stenosis related to anastomosis or CP, which are benign diseases. However, the follow-up period was truncated by the loss of a patient to follow-up. It affects the results and potentially decreases the clinical success rate. For PO pancreatoco-gastric anastomosis, it is likely that several clinical failures are due to recurrence of the disease and not to inefficiency of the anastomosis.

A key point of success is the duration drainage. In the case of ERCP in CP patients, 1 year is recommended. In the case of EUS drainage, the timing of stent removal is a very relevant question because of the difficulties of drainage. This question cannot be answered by this study, which is another limitation.

Placement of a second stent in parallel with the first stent, which is not always easy, could reduce the risk of migration or obstruction, as the majority of cases of stent migration or obstruction occur when only one stent is in place. This procedure was intended to be performed in the unit because the rate of obstruction is lower when two stents are placed in cases of pseudocyst drainage. Similarly, the policy of the unit was to place two stents when possible to avoid migration or obstruction. This difference was not significant in our study, as a limited number of patients benefited from the placement of two stents. Further trials on the subject will be necessary. Making the placement of a second stent more systematic could reduce the risk of migration and obstruction.

At our center, we use only plastic stents. A study was carried out by Oh et al.[16] with the placement of entirely covered metal stents. This study did not report superiority over plastic prostheses in terms of migration, with higher rates of adverse effects, especially pain, observed in the immediate period after stent placement. The development of metal stents that can be directly integrated into the cystostome could, however, facilitate their placement.

Another study compared EUS with access using an enteroscope for Wirsungo-gastric anastomosis performed after surgical modification of the anatomy, particularly after the Whipple procedure. Technical success was achieved in 92.5% of procedures in the EUS group compared to 20% of procedures in the enteroscopy group (odds ratio: 49.3; P < 0.001). Clinical success (per patient) was achieved in 87.5% of procedures in the EUS group versus 23.1% in the enteroscopy group (OR: 23.3; P < 0.001).[18]

Due to the better stability of the endoscope in the duodenum, anastomosis between the bulb and Wirsung duct should be preferred over anastomosis with the stomach. However, it is not feasible in cases of surgical modification of the anatomy or in cases of stenosis located in the isthmus or body of the pancreas. The two cases of stent placement failure reported in our study occurred during attempts at pancreatoco-gastric anastomosis.
Another limitation due to the retrospective design is the lack of data regarding technical failure. These procedures are technically difficult due to the small and fragile target (the Wirsung duct), the fibrous and hard texture of the pancreas due to CP or chronic obstruction, and the large number of steps with dilatation, as well as the need to work within a needle and the risk of peeling off the guidewire and intraperitoneal looping in an unstable environment (the stomach). Patients who experienced clinical failure were managed by the referent physician of the patient. Some of them could continue analgesic use, and some of them could be managed by surgery. Our follow-up for these patients stopped at 1 month after the procedure because of the design of the study.

Performing these procedures therefore requires significant expertise in interventional EUS and may explain the technical failure rate of approximately 10% in the literature as well as the rate of early complications of up to 35%, with the rate of significant serious undesirable side effects reaching up to 10%.

The indications for performing this procedure are limited to selected patients. In the literature, an average of two patients per year per center are candidates. At our center, 2.8 new patients per year benefited from this procedure. This explains the absence of comparative studies, especially surgical and prospective studies. Our study is no exception.

CONCLUSIONS

To avoid the need for surgical drainage, EUS-guided Wirsungo-gastric/duodenal anastomosis is feasible, minimally invasive, safe, and effective, but it is a technically difficult procedure that should be reserved for selected with Wirsung duct dilatation after ERCP failure or in whom ERCP is impossible. There was no significant difference in our results of gastric/duodenal anastomosis versus Wirsung anastomosis between those procedures performed due to CP or PO stenosis. The placement of a second straight plastic stent in parallel with the first stent may reduce migration; however, it is rarely feasible, which decreases its potential impact. Comparative studies with a larger number of patients and a prospective, multicentric, randomized design are necessary to confirm these conclusions. It is recommended that these procedures be performed at tertiary centers by experts in therapeutic EUS.

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Conflicts of interest

Marc Giovananni is a Founding Editor-in-Chief of the journal. The article was subject to the journal's standard procedures, with peer review handled independently of this editor and his research groups.

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