MedNEXT
Journal of Medical an Health Sciences

ORIGINAL ARTICLE

DOI: 10.54448/mdnt22411

Echoendoscopy-guided drainage of pancreatic collections using self-expanding metallic prosthesis: a retrospective observational cross-sectional study

Luis Gustavo Santos Perissé[1]*, Claudia Elizabeth Martinez Franco[1], Rossano Kepler Alvim Fiorelli[1], Paulo Cézar Marques Perissé[1]

[1] UNIRIO - Universidade Federal do Estado do Rio de Janeiro / Federal University of the State of Rio de Janeiro, Rio de janeiro, Brazil.

*Corresponding author: Dr. Luis Gustavo Santos Perissé. UNIRIO - Universidade Federal do Estado do Rio de Janeiro / Federal University of the State of Rio de Janeiro, Rio de janeiro, Brazil.
E-mail: luisperisse@videoendo.com.br

DOI: https://doi.org/10.54448/mdnt22411

Received: Received: 08-28-2022; Revised: 10-29-2022; Accepted: 11-22-2022; Published: 11-25-2022; MedNEXT-id: e22411

Abstract

Background: Pancreatic fluid collections are local complications of acute pancreatitis. Advances in research and the development of new techniques to address local complications have allowed minimally invasive therapeutic options. Endoscopic ultrasound-guided drainage is currently the procedure of choice. **Objective:** To describe the results of the placement of a self-expanding metallic prosthesis for echoendoscopy-guided drainage of pancreatic collections in patients. **Methods:** This study followed a retrospective observational cross-sectional model (STROBE rules). The study was sent and approved by the Institutional Ethics Committee of the Federal University of the State of Rio de Janeiro, Brazil. For data analysis, descriptive statistical analysis (mean and standard deviation), non-parametric analysis (Kruskal-Wallis, with $p<0.05$ with a statistical difference in CI95%), and parametric analysis (One-Way Anova, with $p>0.05$ with a statistical difference in CI95%), and logistic regression analysis, with $p<0.05$ with statistical significance in CI95%. **Results:** Thirteen patients were referred for drainage of collections, and 4 patients were excluded. Of the 9 patients studied, there was a predominance of males (7:2) with a mean age of 54.5 years. Eight patients had walled-off necrosis (WON). The device used was the Hot AxiosTM self-expanding luminal apposition metallic prosthesis, which was inserted uneventfully in all patients. Complete resolution of the condition was found in 88.8% of cases. After logistic regression analysis between the categorical predictors (Gender and Age) versus the response predictors (Necrosectomy, Review Interval, and Stent Permanence), it was observed that certain Gender or Age can influence the response predictors. **Conclusion:** Drainage of pancreatic collections using minimally invasive techniques is a safe and effective procedure.

Keywords: Echoendoscopy; Pancreatic fluid collections; Pancreatic necrosis; Self-expanding metallic prosthesis.

Introduction

Acute pancreatitis continues to represent a major challenge to medical practice in terms of treatment and management of complications. Understanding the indications and timing for invasive treatment of these complications is critical to achieving good results. According to the revised Atlanta classification in 2012, acute pancreatitis can be subdivided into interstitial pancreatitis and necrotizing pancreatitis. Pancreatic collections are the most commonly encountered complications and a distinction is made between fluid-only collections versus those that arise from necrosis and contain a solid component [1].

Acute necrotizing pancreatitis can develop in up to 20% of cases and is associated with significant rates of early organ failure (38%), need for intervention (38%), and death (15%) [2]. Local complications are acute peripancreatic collection (<4 weeks) and pancreatic pseudocyst (>4 weeks), evolving from acute interstitial pancreatitis. Acute necrotic collection (<4 weeks) and walled-off necrosis (>4 weeks) evolve from acute necrotizing pancreatitis [1].

Advances in research and the development of new techniques to address local complications have allowed

minimally invasive therapeutic options [3]. Current options for symptomatic patients include surgical treatment, percutaneous drainage, and endoscopic treatment [4].

In the last decade, endoscopic transluminal drainage has become the procedure of choice, replacing surgical or percutaneous approaches [3]. The endoscopic ultrasound-guided procedure has traditionally been performed with the placement of plastic prostheses, with good results for pseudocysts, but worse outcomes for collections with solid fragments, such as pancreatic necrosis. Thus, internal drainage is preferable to external drainage due to better tolerability, lower morbidity rates, higher success rates, and fewer interventions needed [5].

Echo-guided drainage of pancreatic collections is a relatively new procedure. This study was carried out to describe the results of the placement of a self-expanding metallic prosthesis for echoendoscopy-guided drainage of pancreatic collections in patients referred to a hospital unit of a private network with health insurance coverage.

Methods

Study Design

This study followed a retrospective observational cross-sectional model, following the rules of clinical research of the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology), available at: https://www.strobe-statement.org/. This study was carried out through the analysis of medical records identified from the personal database of the specialist responsible for the procedures (L.G.S.P), also with the participation of the author of this project (C.E.M.F).

Ethical Approval

The study was sent and approved by the Institutional Ethics Committee of the Federal University of the State of Rio de Janeiro, Brazil, under number 5.324.654. A waiver was granted in the application of the Free and Informed Consent Term as it was a study of analysis of data from medical records.

Settings

This work was carried out in the Federal University of the State of Rio de Janeiro, Brazil, in a hospital unit of a private health network from January 2018 to December 2020.

Participants

Patients undergoing endoscopic ultrasound-guided drainage of pancreatic collections. This procedure is performed infrequently in hospitals due to the high cost of materials.

Patient Eligibility – Inclusion and Exclusion Criteria

The medical records of patients over 18 years of age with a diagnosis or documented history of acute pancreatitis who presented as a complication pancreatic pseudocyst or walled-off necrosis (WON - encapsulated pancreatic necrosis) pancreatic collections identified by computed tomography, magnetic resonance imaging, or endoscopic ultrasound were included.

Patients whose medical records could not be consulted, patients with contraindications for endoscopic drainage (Billroth II reconstruction, gastric bypass, previous surgery for diseases related to the pancreas), pancreatic necrosis not accessible via the endoscopic route, and patients undergoing other types of drainage were excluded or with spontaneous resolution.

Data Collect

The analyzed data comprise the period from January 2018 to December 2020. An electronic form was created based on the review of the scientific literature, where data related to patients were entered. The name of each patient was coded with numbers (from 1 to 9).

Professional Team

The procedures were performed by the same team consisting of a doctor specializing in general surgery and diagnostic, therapeutic, and advanced endoscopy, a doctor specializing in gastroenterology and diagnostic, therapeutic, and advanced endoscopy, and a doctor specializing in general surgery and digestive endoscopy, undergoing training in advanced endoscopy, two anesthesiologists, and a surgical instrument.

Technical Procedures and Equipments

Drainage of Pancreatic Collections

Each of the procedures was performed in the operating room under general anesthesia and continuous monitoring, after signing the informed consent form. To visualize the collection by endoscopic ultrasonography and its respective drainage, a sectorial echoendoscope (EG-580 UT, Fujinon® Tokyo, Japan) was used (**Figure 1**). The metallic prosthesis used in all patients was the Hot AXIOS™ (Boston scientific corp., USA) (**Figure 2**). This prosthesis has been available in Brazil since 2017, and its size is 15mm in diameter and 10mm in length.

After the identification of the lesion, evaluation of its characteristics, and the feasibility of drainage, the puncture was performed using the electrocautery that is attached to the device for releasing the prosthesis. Therefore, as the catheter progressed, the distal flange was released under endoscopic guidance. The proximal

portion was then released, already in the gastric wall, under endoscopic or endoscopic guidance.

Endoscopic Necrosectomy

The individual characteristics of each case were evaluated for programming according to the need or not for necrosectomy. Depending on the case, necrosectomy was performed in the second session (corresponding to the first review after endoscopic drainage). A single-channel endoscope (EG-530 Fujinon® Tokyo, Japan) was used to perform the necrosectomy (**Figure 3**). The procedure was adapted to each case, depending on the size and adhesion of debris, requiring irrigation, debridement, and in some cases extraction of this debris using polypectomy loops.

Figure 1. Echoendoscopic images (A) and (B). Pancreatic collection with liquid component (A). Pancreatic collection with liquid and solid components (B). Endoscopic view after Hot AXIOS stent insertion (C).

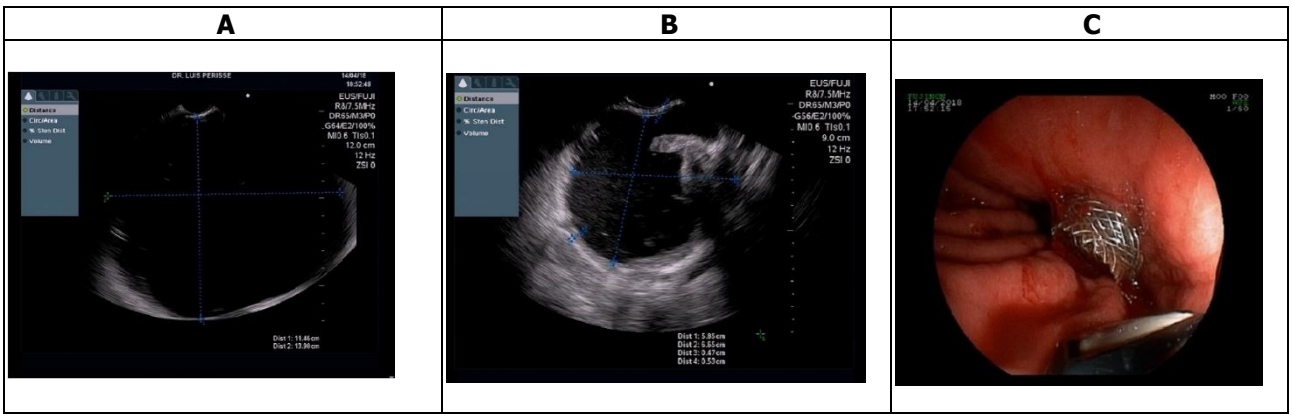


Figure 2. Presence of two concurrent collections. Pancreas head collection (A). Pancreas tail collection (B). Insertion and release of the Hot Axios stent under endoscopic view (C).

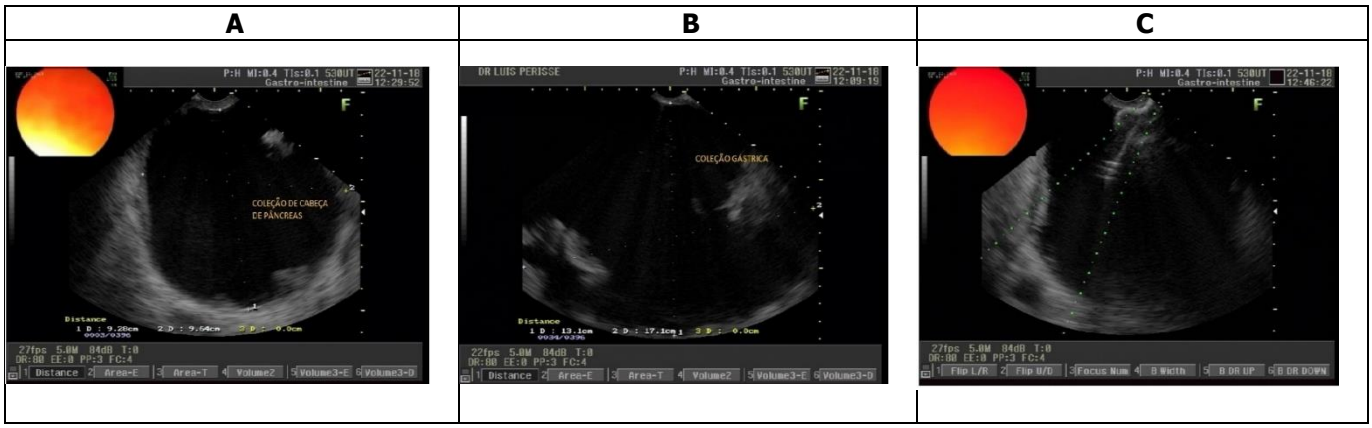
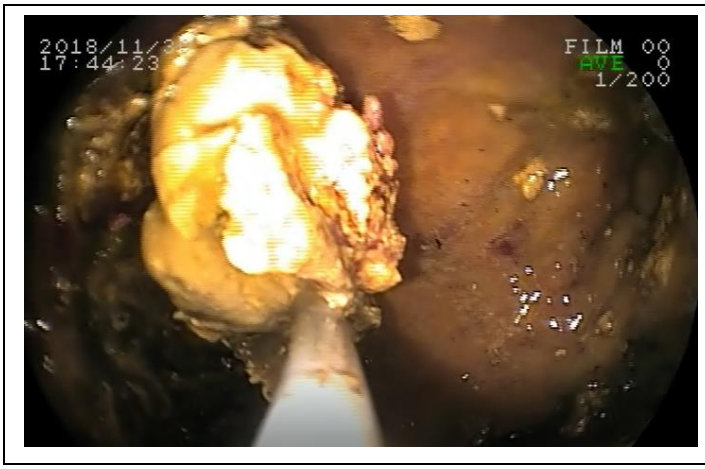


Figure 3. Direct endoscopic necrosectomy using a polypectomy loop.



Additional Interventions

Endoscopic retrograde cholangiopancreatography (ERCP) was necessary in some cases. For this, a duodenoscope (ED-530 Fujinon® Tokyo, Japan) and fluoroscopy were used. Lithotripsy and passage of biliary and pancreatic prostheses were necessary for some situations.

Statistical Analysis

For data analysis, the database was built in a Microsoft Excel spreadsheet, which was exported to the Minitab 18® statistical program (version 18. Minitab. LLC. State College. Pennsylvania, USA). The variables were presented in the form of a percentage, average, and standard deviation. Depending on the Gaussian distribution (Normality test), the comparisons of the variables were performed using the Kruskal-Wallis Test, with $p<0.05$ with a statistical difference in the CI95%, and One-Way ANOVA with $p>0.05$ with a statistical difference in the CI95% between the variables of the present study in CI95%. Also, Logistic Regression analysis with Odds Ratio (OR) was carried out to analyze to know if the categorical predictors "Gender" and "Age" influenced the response predictors "Necrosectomy, Review Interval, and Stent Permanence", considering $p<0.05$ with significant statistical influence, in the CI95%.

Results

Thirteen (13) patients were referred for evaluation of collection drainage guided by echoendoscopy. Four (4) patients were excluded: two of them due to incomplete data in the follow-up records, one of them due to spontaneous resolution of the condition, and one of them due to a collection not related to acute pancreatitis. Of the 9 (nine) patients included in this study, 7 (seven) were male and 2 (two) were female, aged between 35 and 69 years, with an average of 54.5 years.

All patients studied developed acute pancreatitis of biliary etiology. Regarding the type of collection, only one patient had a pancreatic pseudocyst and seven developed WON (walled-of-necrosis). Most had a single collection, but one of the patients developed two collections. The approximate size of the collections covered a range between 5.15x3.22cm and 15x10cm.

After the installation of the prosthesis, endoscopic revisions were performed at an interval of 7 to 15 days. Among the additional interventions described, 5 (five) patients underwent endoscopic retrograde cholangiopancreatography (ERCP) for stone removal and positioning of biliary and pancreatic prostheses. Endoscopic necrosectomy sessions were required in 7 of 9 patients.

The prosthesis was removed at an interval of 3 to 5 weeks, after visualization of granulation tissue and evident healing process. Adverse events related to the procedure have been described. Patient number 3 presented prosthesis migration two weeks after its placement. In this same patient, Wirsung's duct stenosis was observed and it was necessary to place a plastic prosthesis in the duct. This patient presented a recurrence of the lesion and new endoscopic drainage associated with percutaneous drainage was indicated.

During the second endoscopic review of patient number 8, the splenic artery was visualized, with no signs of bleeding, and CT angiography was indicated to assess vessel involvement. No additional interventions related to this patient were required. After 15 days after the resolution of this case and the removal of the prosthesis, the formation of a new collection was observed.

The resolution of the condition after the insertion and consequent removal of the prosthesis, decided by the visualization of granulation tissue and absence of collection and necrotic residues through echoendoscopy, was observed in 8 of the 9 patients, corresponding to 88.8% of the cases that received the treatment and were included in this study (**Figure 4**).

Figure 4. Debris and granulation tissue within the collection (A). Visualization of the splenic artery during necrosectomy (B).

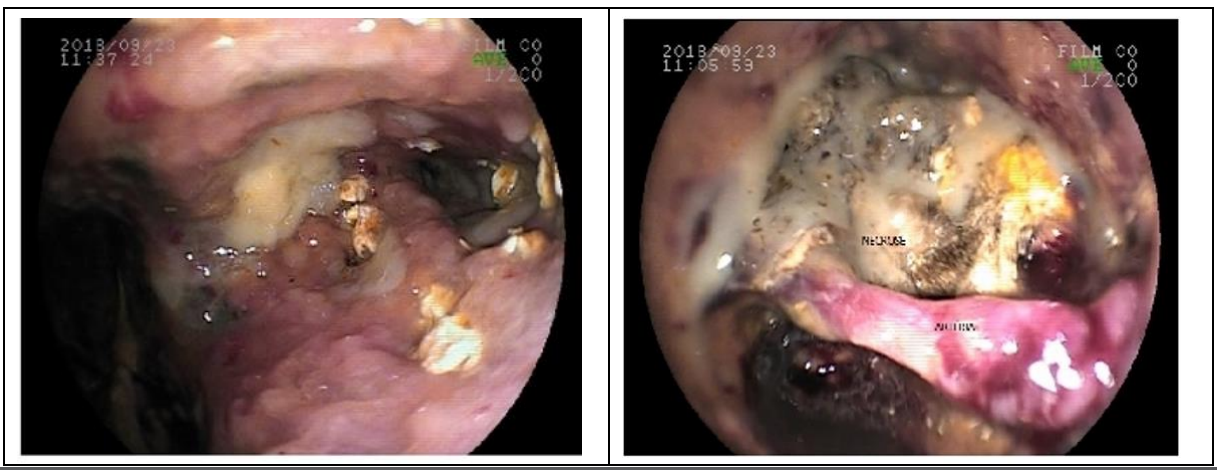


Table 1 shows the general characteristics of the patients, the number of necrosectomies, and the length of stent permanence. In all comparisons where the variables per column are in Table 1, there was a statistically significant difference, with p<0.005 for non-parametric variables (Gender and Review Interval) at CI95%, as well as p>0.005 for parametric variables (Age, Necrosectomy, and Stent Permanence) at CI95%.

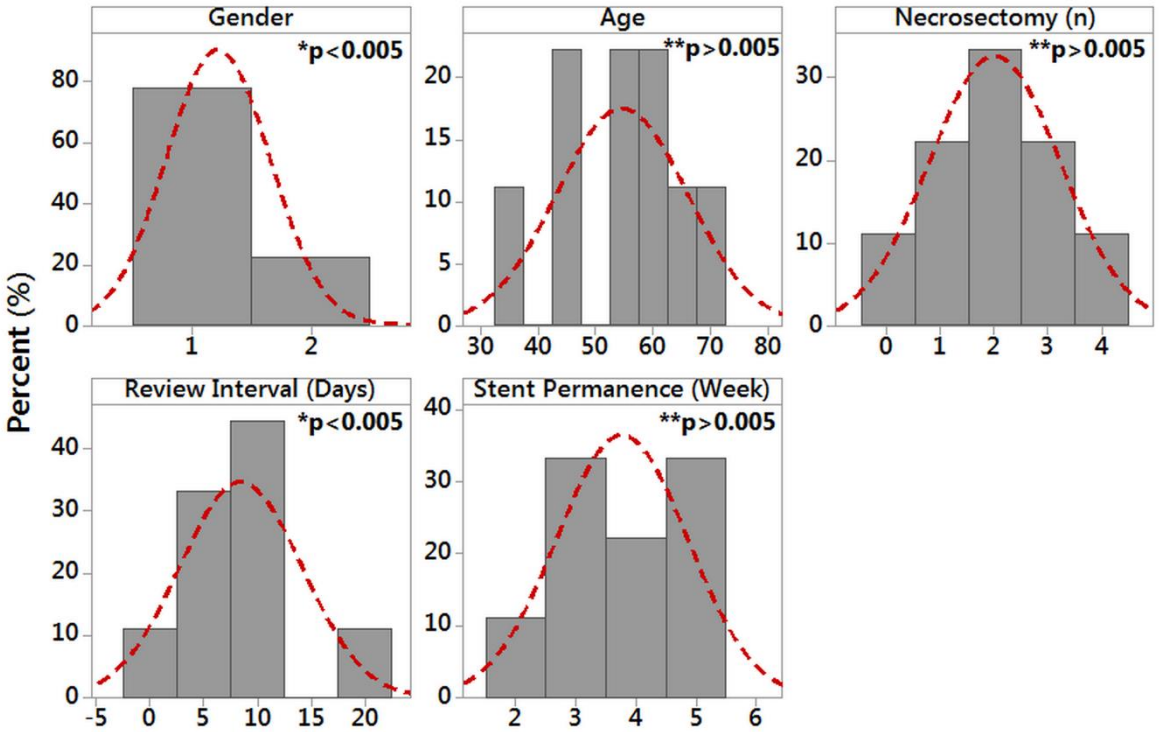
The histogram graphs presented in **Figure 5** show the distribution of values (x-axis) and the mean percentage (peak of the dashed red line) of the variables Gender, Age, Necrosectomy, Review Interval, and Stent Permanence.

Table 1. Patient characteristics, number of necrosectomies, and stent length of stay.

Patient	*Gender*	*Age*	*Collection type*	*Collection Size (cm)*	*Necrosectomy (n)*	*Review Interval (Days)*	*Stent Permanence (Weeks)*
1	1	53	Pseudocisto	14.57 x 11.57	0	0	4
2	1	35	WON***	7.68 x 5.67	3	8	3
3	1	62	WON	10 x 12	2	7.6	2
4	1	47	WON	9.28 x 9.64 + 13 x 17	4	7	5
5	2	61	WON	5.15 x 3.22	1	22	5
6	1	43	WON	7.18 x 4.17	1	10	3
7	2	66	WON	15 x 10	2	7.6	4
8	1	70	WON	10.7 x 8.35	3	7	5
9	1	55	WON	6.09 x 7.52	2	7.3	3
Mean (SD);p-value	1.22 (0.44); *p<0.005	54.67 (11.41); **p>0.005	ns	ns	2.00 (1.22); **p>0.005	8.50 (5.75); *p<0.005	3.78 (1.09); **p>0.005

Non-parametric analysis (reference: p<0.005 with statistical difference); ** Parametric analysis (reference: p>0.005 with statistical difference). * walled-off necrosis (WON).*

Figure 5. Histogram graphs show the distribution of values (x-axis) and the mean in percentage (peak of the dashed red line) of the highlighted variables.



*Non-parametric analysis (reference: p<0.005 with statistical difference); **Parametric analysis (reference: p>0.005 with statistical difference).

After logistic regression analysis between categorical predictors (Gender and Age) versus response predictors (Necrosectomy, Review Interval, and Stent Permanence), **Tables 2** to **7** present the results of the influence of categorical predictors on response predictors.

Thus, the influence of the categorical predictor Gender vs. Necrosectomy (n) was significant in Logit 3: (1/2), with Odds Ratio (OR) = 2.00 (0.05-78.25) to the number of necrosectomy in males (**Table 2**).

The influence of the categorical predictor Gender vs. Review Interval (Days) was significant in Logit 1: (22.0/8.0), with Odds Ratio (OR) = 1.44 (0.0-58.55) concerning Review Interval (Days) in females, and Logit 3: (7.6/8.0), with Odds Ratio (OR) = 2.08 (0.08-47.56) concerning Review Interval (Days) in females (**Table 3**).

Table 2. Gender vs. Necrosectomy (n).

					Odds	95% CI	
Predictor	Coef	SE Coef	Z	p-value	Ratio	Lower	Upper
Logit 1: (4/2)							
Constant	20.6035	36131.2	0.00	1.000			
Gender	-21.2967	36131.2	-0.00	1.000	0.00	0.00	*
Logit 2: (3/2)							
Constant	21.2967	25548.6	0.00	0.999			
Gender	-21.2967	25548.6	-0.00	0.999	0.00	0.00	*
Logit 3: (1/2)							
Constant	-1.38629	2.82843	-0.49	0.624			
Gender	0.693147	1.87083	0.37	0.002	2.00	0.05	78.25
Logit 4: (0/2)							
Constant	20.6035	36131.2	0.00	1.000			
Gender	-21.2967	36131.2	-0.00	1.000	0.00	0.00	*

Table 3. Gender vs. Review Interval (Days).

						95% CI	
Predictor	Coef	SE Coef	Z	p-value	Odds Ratio	Lower	Upper
Logit 1: (22.0/ 8.0)							
Constant	-64.4700	93246.5	-0.00	0.999			
Gender (Female)	44.1158	89060.9	0.00	0.003	1.44	0.00	58.55
Logit 2: (10.0/ 8.0)							
Constant	-0.0000000	123915	-0.00	1.000			
Gender	0.0000000	123915	0.00	1.000	1.00	0.00	*
Logit 3: (7.6/ 8.0)							
Constant	-23.7616	87621.3	-0.00	1.000			
Gender (Female)	23.7616	87621.3	0.00	0.002	2.08	0.08	47.56
Logit 4: (7.3/ 8.0)							
Constant	-0.0000000	123915	-0.00	1.000			
Gender	0.0000000	123915	0.00	1.000	1.00	0.00	*
Logit 5: (7.0/ 8.0)							
Constant	0.693147	107314	0.00	1.000			
Gender	0.0000000	107314	0.00	1.000	1.00	0.00	*
Logit 6: (0.0/ 8.0)							
Constant	-0.0000000	123915	-0.00	1.000			
Gender	0.0000000	123915	0.00	1.000	1.00	0.00	*

The influence of the categorical predictor Gender vs. Stent Permanence (Weeks) showed a significant reduction in Logit 1: (5/4), Logit 2: (3/4), and Logit 3: (2/4), with Odds Ratio (OR) = 0.5 (0.01-19.56), Odds Ratio (OR) = 0.00 (0.0-*), and Odds Ratio (OR) = 0.00 (0.0-*), respectively, concerning Stent Permanence (Weeks) in both females and males (**Table 4**).

The influence of the categorical predictor Age vs. Necrosectomy (n) showed a significant reduction in Logit 1: (4/2), with Odds Ratio (OR) = 0.86 (0.66-1.12) compared to Necrosectomy (n) at age 47 years (**Table 5**).

The influence of the categorical predictor Age vs. Review Interval (Days) was significant in Logit 1: (22.0/8.0), with Odds Ratio (OR) = 4.37 (1.66-6.32) concerning Review Interval (Days) at age 61, with a longer review interval (22 days) (**Table 6**).

Also, the influence of the categorical predictor Age vs. Stent Permanence (Weeks) showed a significant reduction in Logit 2:(3/4), with Odds Ratio (OR) = 0.82 (0.61-1.10) compared to Stent Permanence (Weeks) at ages 35 years (**Table 7**).

Table 4. Gender vs. Stent Permanence (Weeks).

Predictor	Coef	SE Coef	Z	p-value	Odds Ratio	95% CI Lower	95% CI Upper
Logit 1: (5/4)							
Constant	1.38629	2.82843	0.49	0.624			
Gender	-0.693147	1.87083	-0.37	0.004	0.50	0.01	19.56
Logit 2: (3/4)							
Constant	23.0884	20860.4	0.00	0.999			
Gender	-21.9898	20860.4	-0.00	0.002	0.00	0.00	*
Logit 3: (2/4)							
Constant	21.9898	36131.2	0.00	1.000			
Gender	-21.9898	36131.2	-0.00	0.002	0.00	0.00	*

Table 5. Age vs. Necrosectomy (n).

Predictor	Coef	SE Coef	Z	p-value	Odds Ratio	95% CI Lower	95% CI Upper
Logit 1: (4/2)							
Constant	6.89975	7.13588	0.97	0.334			
Age (47 years)	-0.146682	0.133808	-1.10	0.0045	0.86	0.66	1.12
Logit 2: (3/2)							
Constant	5.04101	6.09383	0.83	0.408			
Age	-0.0953535	0.105396	-0.90	0.366	0.91	0.74	1.12
Logit 3: (1/2)							
Constant	5.28134	6.09608	0.87	0.386			
Age	-0.0999532	0.105813	-0.94	0.345	0.90	0.74	1.11
Logit 4: (0/2)							
Constant	4.10360	7.12101	0.58	0.564			
Age	-0.0907231	0.125236	-0.72	0.469	0.91	0.71	1.17

Table 6. Age vs. Review Interval (Days).

Predictor	Coef	SE Coef	Z	p-value	Odds Ratio	95% CI Lower	95% CI Upper
Logit 1: (22.0/ 8.0)							
Constant	-566.173	58931.1	-0.01	0.992			
Age (61 years)	13.1082	1368.11	0.01	0.001	4.37	1.66	6.32
Logit 2: (10.0/ 8.0)							
Constant	-176.255	35832.0	-0.00	0.996			
Age	4.51613	902.513	0.01	0.996	1.48	0.00	3.32
Logit 3: (7.6/ 8.0)							
Constant	-570.619	58931.1	-0.01	0.992			
Age	13.1903	1368.11	0.01	0.992	1.72	0.00	2.32
Logit 4: (7.3/ 8.0)							
Constant	-558.390	58931.1	-0.01	0.992			
Age	12.9740	1368.11	0.01	0.992	1.69	0.00	3.12
Logit 5: (7.0/ 8.0)							
Constant	-562.113	58931.1	-0.01	0.992			
Age	13.0519	1368.11	0.01	0.992	1.65	0.00	3.22
Logit 6: (0.0/ 8.0)							
Constant	-555.603	58931.1	-0.01	0.992			
Age	12.9224	1368.11	0.01	0.992	1.94	0.00	3.52

Table 7. Age vs. Stent Permanence (Weeks).

Predictor	Coef	SE Coef	Z	p-value	Odds Ratio	95% CI Lower	95% CI Upper
Logit 1: (5/4)							
Constant	0.565071	6.95320	0.08	0.935			
Age	-0.0026862	0.115978	-0.02	0.982	1.00	0.79	1.25
Logit 2: (3/4)							
Constant	10.8464	8.03988	1.35	0.177			
Age (35 years)	-0.200792	0.150354	-1.34	0.004	0.82	0.61	1.10
Logit 3: (2/4)							
Constant	-3.47162	10.5863	-0.33	0.743			
Age	0.0456968	0.171530	0.27	0.790	1.05	0.75	1.47

Discussion

In 2013, a new fully coated metal prosthesis was approved by the FDA for draining pancreatic collections (Axios: Boston Scientific, Boston, MA) [7]. The Hot AXIOS stent is designed to provide anchorage to non-adherent surfaces of luminal structures. The release mechanism with an electrocautery-associated system allows puncture and release of the stent in a single step, reducing the number of accessories to be changed and, consequently, potentially reducing the frequency of complications [6]. This study aimed to describe the results of the placement of this prosthesis in patients referred to a hospital unit of a private health network in the city of Rio de Janeiro, Brazil.

In this Brazilian case series, the success rate in draining pancreatic collections with the use of metallic luminal apposition prosthesis was 88.8%. Our work presented data similar to those presented in the meta-analysis performed by Renelus et. al., which involved 1708 patients and the cumulative technical success was 88%. Both works had results consistent with the literature showing a success rate between 75 and 95% [7].

In this series, the 9 selected patients underwent the procedure in a private health institution covered by the patient's health plan. It should be noted that Brazil is a country with social inequality and high-cost health treatments are restricted to a small portion of the population. In the case series published by a German group that gathered 9 patients, drainage of pancreatic collections was performed with the help of health insurance [8]. The work published by Chen et al. compares the cost-effectiveness of using metallic prostheses and plastic prostheses, concluding that metallic prostheses are more effective but more expensive [9].

In the present study, male patients were predominant (7:2), with a mean age of 54.5 years, in agreement with studies already published by Chandran et. al. and Tae Jun Song [10,11]. Furthermore, this study found that in all independent comparisons where the variables per column are found in Table 1, there was a statistically significant difference, with $p<0.005$ for each non-parametric variable (Gender and Review Interval) in the CI95%, as well as with $p >0.005$ for each parametric variable (Age, Necrosectomy, and Stent Permanence) in the 95% CI, showing that this cohort of participants presented heterogeneous clinical and demographic data. It was also found that the Odds Ratio (OR) was significantly higher concerning the number of necrosectomies in males, the Review Interval (Days) was significant in females, and Stent Permanence (Weeks) showed a significant reduction both in females as in the male. Regarding the categorical predictor "age", there was a significant reduction concerning Necrosectomy (n) at the age of 47 years, whereas the Review Interval (Days) was significant concerning the age of 61 years, with a longer review interval (22 days), and finally, a significant reduction was found concerning Stent Permanence (Weeks) at the age of 35 years.

In this sense, the drainage of pancreatic collections has undergone an evolutionary process over the years. Initially, drainage was performed by open surgery and, over time, was replaced by video laparoscopic and percutaneous surgery, to be later performed endoscopically using plastic prostheses of the double pigtail type. The metallic luminal apposition prosthesis was invented and patented by Binmoeller in 2004, being reported for the first time in animal studies in 2011. It is the first prosthesis specifically designed for transluminal drainage of pancreatic collections guided by echoendoscopy [12].

In both types of pancreatic collections, drainage was performed with a metallic luminal apposition prosthesis guided by echo endoscopy. In cases of WON, there was a need for debridement and removal of necrotic residues under endoscopic vision, a procedure known as a direct endoscopic necrosectomy. After stent insertion, an average of 2 interventions were required to perform a necrosectomy, with a maximum stent permanence time of 5 weeks. In the study carried out by Kilian Weigand, the need for necrosectomy was reported approximately 5.7 times [8].

As for etiology, a recently published Korean study described alcohol as the most frequent cause of pancreatitis [11]. In our study, all patients developed pancreatitis of biliary etiology. Among the expected adverse events, bleeding is the most commonly reported complication, with an incidence of 18% [2], but in our study, there were no complications during stent placement, such as migration or bleeding. Only one case of prosthesis migration occurred two weeks after insertion. During the second review endoscopy of patient 8, the splenic artery was visualized, intact, and without bleeding, which did not require additional intervention after being evaluated by the interventional radiology service.

Conclusion

Endoscopic retrograde cholangiopancreatography is an important component of assessing pancreatic duct integrity in addition to treating the cause. In our series, Endoscopic retrograde cholangiopancreatography was required in 5 of the 9 patients. From our experience, it became evident that Endoscopic retrograde cholangiopancreatography contributed to the

therapeutic success of the patients approached in this series. This study has limitations as it is a study of a small series of cases. The metallic prosthesis used is specific for drainage of this type of collection and a comparison with other techniques or with another type of prosthesis was not performed. Future studies with a larger cohort of patients should be performed to continue the evaluation and validation of the use of this material.

Acknowledgement
Not applicable.

Funding
Not applicable.

Ethics approval
The study was sent and approved by the Institutional Ethics Committee of the Federal University of the State of Rio de Janeiro, Brazil under number 5.324.654. A waiver was granted in the application of the Free and Informed Consent Term as it was a study of analysis of data from medical records.

Informed consent
Not applicable.

Data sharing statement
No additional data are available.

Conflict of interest
The authors declare no conflict of interest.

Similarity check
It was applied by Ithenticate@.

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