

# CONNECT

Q3  
2021



TAEWOONG MEDICAL  
NEWSLETTER

## TaeWoong MEDICAL | ONLINE TRAINING CENTER

The goal of Taewoong OTC is to provide from basic information to expert's knowhow about Taewoong Products anytime, anywhere with simple access.



VIRTUAL  
**AP  
DW**  
2021

# ASIAN PACIFIC DIGESTIVE WEEK

*Vision of Excellence In Digestive Disorders & Sciences*

19 - 22 AUGUST 2021 | VIRTUAL APDW 2021

5TH  
**Online**  
Live Endoscopy  
Course of IECED &  
PTCE 2021

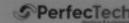
## SPONSORSHIP



TaeWoong  
MEDICAL



Medtronic



FUJIFILM



EUSRA

ELRA

TaeWoong  
NITI-S™

EUS-ENDO  
INTERNATIONAL  
LIVE COURSE

100% VIRTUAL

16-17  
SEPTEMBER

2021

COURSE DIRECTOR  
Dr. Marc Giovannini  
www.eus-endo.org

HISTORI PACU-CALMETTES  
Gustavo Marín

# WEBINAR REVIEW

Pradermchai Kongkam MD

Dra. Raquel Del Valle  
Ecuador

E-LIBANO LIVE  
Frontiers of interventional Endoscopy

E-LIBANO LIVE  
Frontiers of interventional Endoscopy

E-LIBANO LIVE  
Frontiers of interventional Endoscopy

SAMA  
LAB



**APDW 2021** [August 19-22]

Taewoong products including HOT SPAXUS™ were introduced during the lecture and two EUSRA™ treatments were introduced as Live cases.



**LIVE CASE 1.**

Advanced EUS-guided management of a large unresectable MD-IPMN  
By Pradermchai Kongkam, Thailand



**LIVE CASE 2.**  
EUS-RFA in PNET  
By Sundeeep Lakhtakia

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**5<sup>th</sup> Online Live Endoscopy Course of IECED & PTCE 2021** [August 21-22]

Taewoong participated as a sponsor, Dr. Raquel Del Valle and the course director Dr. Carlos Robles proceeded with the EUSRA™ live case for a patient with pancreatic adenocarcinoma.





### E-LIBANO LIVE 2021 [September 3-4]

Taewoong participated as a sponsor and our local distributor had a both exhibition during the conference while the programs were virtually shared.

A EUSRA™ live case on cystic ablation by Dr. Zaher Houmani & Mohamad Elnady was introduced.



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### EUS-ENDO 2021 [September 16-17]

EUS-ENDO 2021, which Taewoong has been with for a long time, has been successfully completed. Live cases of GIOBOR™ and EUSRA™ were performed. We wish a successful event next year too!

### UPCOMING EVENT



### New Technology and Treatments with Biliary RFA

- Learn about incorporating biliary RFA safely and effectively into your practice and treatment protocol
- Case presentations featuring a variety of indications and uses with ELRA



**Emmanuel Coronel, MD**  
Asst. Professor of Medicine  
Assoc. Clinical Medical Director  
Endoscopy Center  
Chief Quality and Safety Officer  
The University of Texas  
MD Anderson Cancer Center



**Nageshwar Reddy, MD**  
Chairman  
Asian Institute of  
Gastroenterology and AIG  
Hospitals, Hyderabad, India  
Past President of World  
Endoscopy Organization



**New Technology and Treatments with Biliary RFA** [Thursday, October 7, 2021 at 8:30 pm]



# ACTIVITIES

## PARTNERS

# HOT SPAXUS™ TRAINING IN SPAIN



Taewoong is continuously attempting to provide sufficient educational opportunities so that all customers of HOT SPAXUS™ can perform it safely. Taewoong also develops training tools and various programs suitable for it.

The Spanish distributor conducted a successful training session with the recently created hands-on tool. We plan to continuously develop educational tools and platforms based on that experience.

For the successful launch of HOT SPAXUS™ in Spain, STendoscopia organized a domestic study. They prepared and provided well-designed training programs for HOT SPAXUS™ for a fast but safe study process. The plan for the domestic study was in 3 different locations in Spain (25~30 hospitals join for 1 study) Training Program and Implantation plan.

## ANIMAL LAB

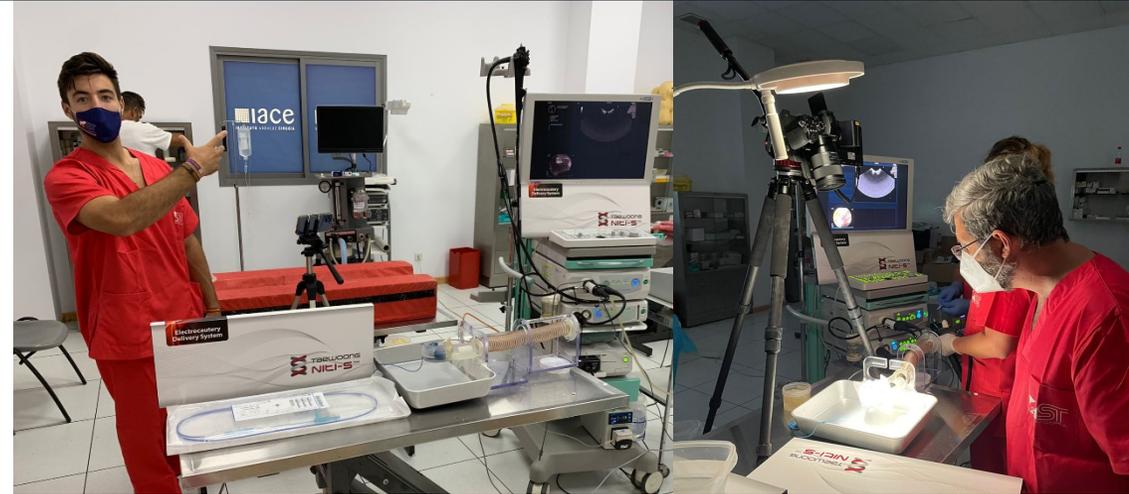
Step 1 - HOT SPAXUS™ dummy  
Step 2 - Live pig

## FIRST CASE

Mentored Implantation

## FROM SECOND CASE

Self-implantation

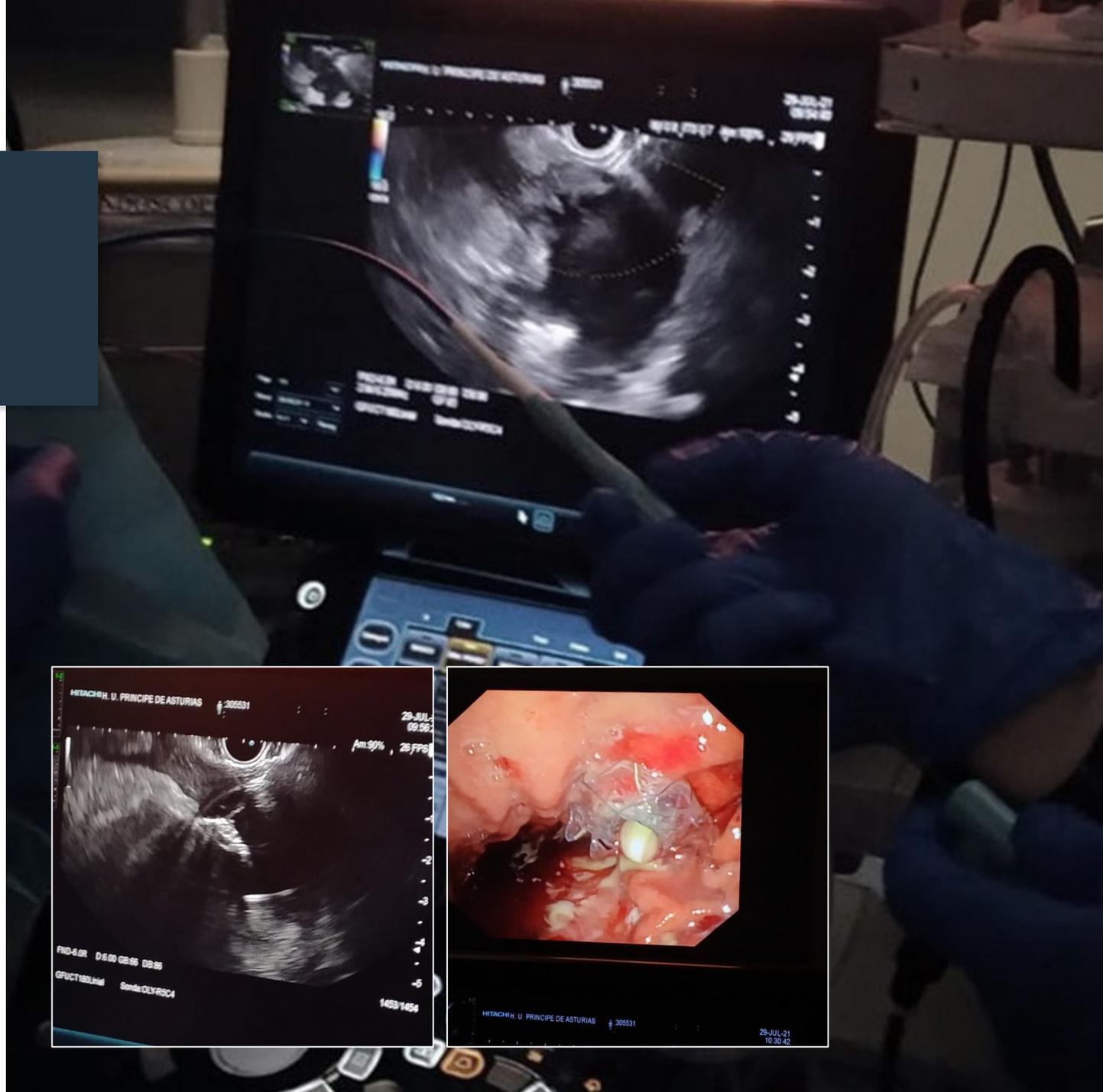


# SPANISH DEBUT OF THE **HOT SPAXUS™**

We congratulate Hospital Príncipe De Asturias of Alcalá de Henares for successfully implanting his first HOT SPAXUS™ of TaeWoong Medical.

A case of pancreatic pseudocyst drainage by HOT SPAXUS™ stent (self-expandable metallic stent with electrocautery system) guided by EUS approach and superbly commanded by Dr. Elvira Poves and her team.

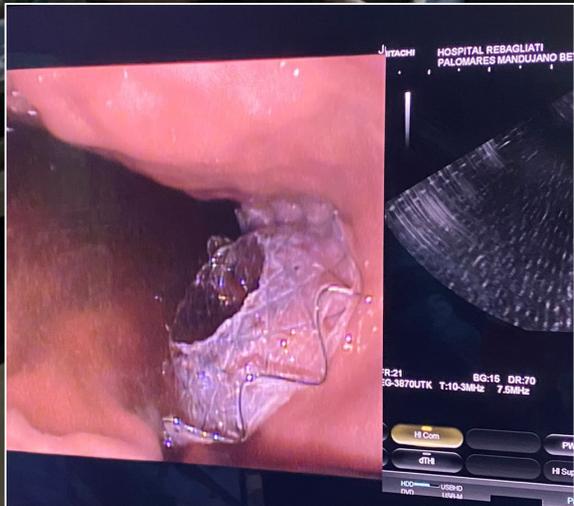
Congratulations to the whole team!



## CONGRATULATION FOR THE 1<sup>ST</sup> HOT SPAXUS™ CASE IN PERU!

Doctors from Hospital Nacional Enrique Rebagliati Martins, Peru : Alfonso Chacaltana, Edson Guzmán, Ramiro Díaz and Ronald Arcana performed an EUS guided pseudocyst drainage using HOT SPAXUS™ stent without any trouble.

Thanks for the great work!



# CONGRATULATION ON THE 1<sup>ST</sup> EUSRA™ PROCEDURE TO DR. SALOM MACAYA FEDERICO IN COSTA RICA!

A 32 years old patient was referred to our Hospital. She was diagnosed with unresectable pancreatic adenocarcinoma. An Endoscopic Ultrasound (EUS) for cancer staging and tissue acquisition was performed six months earlier. Chemotherapy was started at the time of diagnosis and the disease has remain stable since, with no evidence of progression. Different therapeutic approaches were discussed at multidisciplinary meetings. EUS guided Radiofrequency Ablation (EUS RFA) was requested.

No immediate adverse events were reported. This is the first EUS RFA treatment done at Hospital Mexico, San José, Costa Rica; with excellent technical success. Post therapeutic imaging evaluations is being awaited to evaluate clinical success.

A grayscale photograph of a hand holding a pen, poised to write on a document. The document has several lines of text, some of which are partially visible and appear to be form fields. A semi-transparent dark gray overlay covers the entire image, and the word 'ARTICLE' is written in large, white, bold, sans-serif capital letters across the center. Below it, 'NITI-S, RFA' is written in a smaller, white, sans-serif font.

# ARTICLE

NITI-S, RFA

# Safety and efficacy of a novel electrocautery-enhanced lumen-apposing metal stent in interventional EUS procedures

Benedetto Mangiavillano et al. [Gastrointest Endosc. 2021 Jul 30;S0016-5107(21)01544-3.]

[CLICK TO ORIGINAL ARTICLE](#)

## BACKGROUND AND AIMS

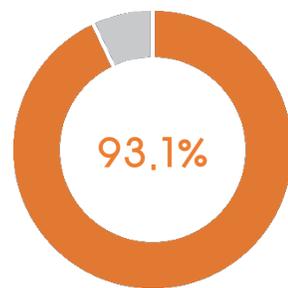
Electrocautery-tip lumen-apposing metal stents (EC-LAMSs) have extended the indications of therapeutic EUS. We aimed to retrospectively evaluate safety, technical and clinical success of a newly developed EC-LAMS for various EUS-guided procedures.

## METHODS

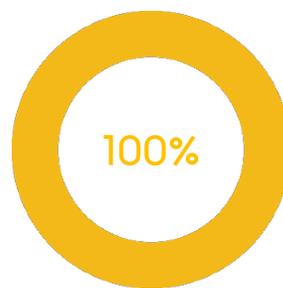
We included and retrospectively analyzed consecutive patients at 8 tertiary care referral centers who had undergone EUS interventional procedures using the Hot-Spaxus (Taewoong Medical Co, Gimpo, Korea) between October 2018 and February 2021.

## RESULTS

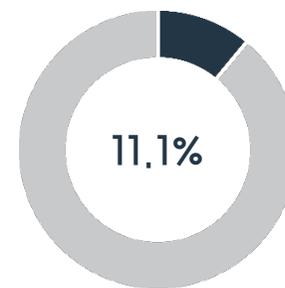
Fifty-eight patients (M/F: 36/22; mean age:  $63.5 \pm 14.9$  years) were retrieved, 29 of whom had undergone pancreatic fluid collection drainage (50%), 22 (37.9%) biliary drainage for malignant distal obstruction, 3 (5.1%) gallbladder drainage for acute cholecystitis, 3 gastroentero anastomoses, and one pelvic collection (1.7%) drainage. Technical success was achieved in 54 out of the 58 (93.1%) patients, and in all of them clinical success was achieved. Adverse events occurred in 6 patients (11.1%): 2 early (3.7%), 1 late (1.8%), and 3 long term (5.6%). The outcomes were similar to those observed in a control group of patients treated with the Hot-Axios (Boston Scientific, Marlborough, Mass, USA), the other available EC-LAMS.



● Technical success



● Clinical success



● Adverse events occurred

## CONCLUSIONS

Our study showed that the novel EC-LAMS has high technical and clinical success rates for various interventional EUS indications. Future multicenter prospective studies will better clarify the role of this new EC-LAMS for different indications.



# A novel electrocautery-enhanced delivery system for one-step endoscopic ultrasound-guided drainage of the gallbladder and bile duct using a lumen-apposing metal stent: a feasibility study

Hae Won Yoo et al. [Endoscopy. 2021 Sep;53(9):922-926.]

[CLICK TO ORIGINAL ARTICLE](#)

## BACKGROUND

The use of a lumen-apposing metal stent (LAMS) capable of one-step endoscopic ultrasound-guided transmural drainage (EUS-TD) can increase the effectiveness of the procedure. We evaluated the newly developed electrocautery-enhanced (EC) delivery system with a LAMS for one-step EUS-guided gallbladder drainage (EUS-GBD) or choledochoduodenostomy (EUS-CDS).

## METHODS

In the animal experiment, an EC-LAMS was advanced into the gallbladder without prior tract dilation in four pigs. A conventional LAMS was inserted in another four pigs as a control group. After the animal experiment, 17 patients underwent EUS-TD using the EC-LAMS (EUS-GBD in 10 patients, EUS-CDS in 7). The primary outcome was the technical success rate.

## RESULTS

In the animal study, the mean procedure time was significantly shorter in the EC-LAMS group than in the conventional LAMS group. In the human study, the overall technical success rate was 94.1 %, with one EUS-GBD failure. The clinical success rate was 100 %. The overall adverse event rate was 17.6%.

## CONCLUSIONS

One-step EUS-GBD or EUS-CDS using the novel EC-LAMS is a feasible approach that achieves a high success rate and maintains safety.



Transduodenal endoscopic ultrasound-guided gallbladder drainage using a lumen-apposing metal stent with the newly developed electrocautery-enhanced delivery system.

Online content viewable at: <https://doi.org/10.1055/a-1301-1526>



## Adverse events of endoscopic ultrasound-guided biliary drainage procedures using the novel lumen-apposing metal stent with electrocautery-enhanced delivery system.

	Type of procedure		Total (n=17)
	EUS-CDS (n=7)	EUS-GBD (n=10)	
Intraprocedural adverse events, n (%)	0	0	0/17 (0)
Early adverse events, n (%)	0	1	1/17 (5.9)
Follow-up periods, median (range), days	-	-	120 (60 – 210)
Late adverse events, n (%)			
Stent occlusion, n (%)	1	0	1 (5.9)
Stent migration, n (%)	0	1	1 (5.9)
Re-intervention, n (%)	1	1	2 (11.8)
Overall adverse events	1	2	3 (17.6)

EUS-CDS, endoscopic ultrasound-guided choledochoduodenostomy; EUSGBD, EUS-guided gallbladder drainage.

# Efficacy of a Novel Large-cell Niti-S stent with a Slim Delivery System for Hilar Biliary Obstruction: A Preliminary Study

Mitsuru Sugimoto et al. [Research Square, BMC series 2021.]

[CLICK TO ORIGINAL ARTICLE](#)

## BACKGROUND

The large-cell Niti-S stent is useful for multiple stenting in malignant hilar biliary obstruction (MHBO) patients. Recently, a novel uncovered self-expandable metallic stent (USEMS) (a large-cell Niti-S slim-delivery stent) was developed. In this study, we aimed to evaluate the efficacy of this slim-delivery USEMS in MHBO patients.

## METHODS

Outcomes related to USEMS placement, clinical course, and patency period were evaluated in MHBO patients who received multiple USEMSs.

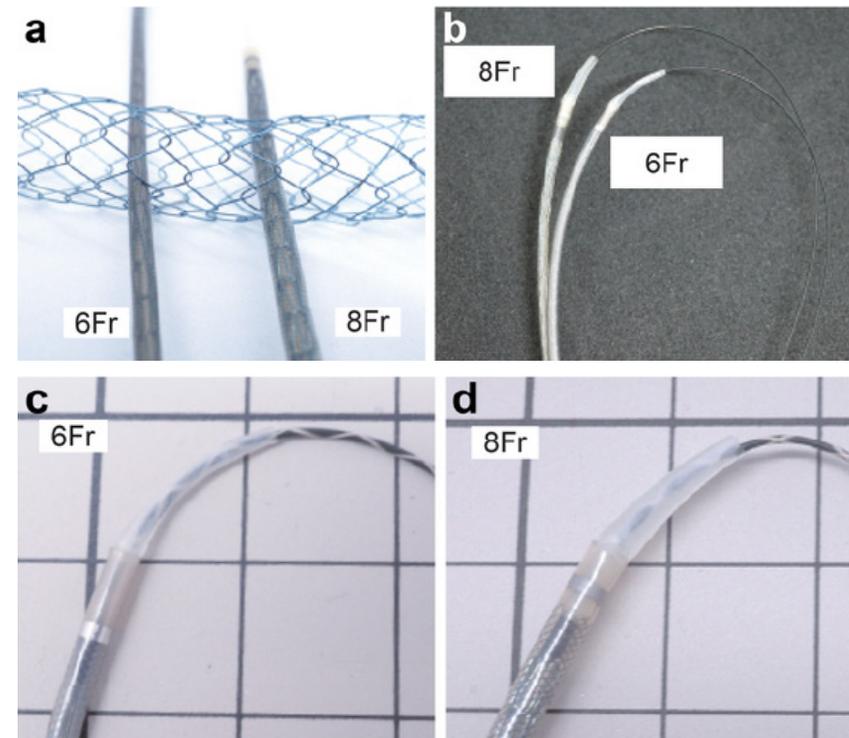


## RESULTS

Fourteen MHBO patients underwent the placement of multiple USEMSs, including using the novel slim-delivery stent. Three patients had a past history of Billroth-II reconstruction. The number of USEMSs placed in each patient was 2-6. Three procedures were reinterventions. The new slim delivery system was used to place the first stent in three patients and an additional stent in the remaining patients. The technical and clinical success rates were both 100%. According to Kaplan-Meier analysis, the cumulative patency rate 50 days after USEMS placement was 87.5%.

## CONCLUSIONS

Placing multiple USEMSs in patients with a past history of abdominal surgery or in reintervention is difficult. The novel USEMS might overcome these difficulties and be the first choice for MHBO patients.



The large-cell Niti-S slim-delivery stent (6 Fr) and the conventional large-cell Niti-S stent (8 Fr). (a) The new slim-delivery Niti-S stent is thinner than the conventional large-cell Niti-S stent. (b) The new slim-delivery Niti-S stent has better trackability for a guidewire than the conventional large-cell Niti-S stent. (c, d) The 6 Fr delivery system has a smaller step between the delivery system and 0.025 guidewire than the 8 Fr delivery system.

# Comparison of Long-term Outcomes of Colonic Stenting as a “Bridge to Surgery” and Emergency Surgery in Patients With Left-Sided Malignant Colonic Obstruction

Supakij Khomvilai et al. [Ann Coloproctol. 2021 Jul 29.]

[CLICK TO ORIGINAL ARTICLE](#)

## PURPOSE

Long-term oncologic outcomes of colonic stenting as a “bridge to surgery” in patients with left-sided malignant colonic obstruction (LMCO) are unclear. This study was performed to compare long-term outcomes of self-expandable metal stent (SEMS) insertion as a bridge to surgery and emergency surgery in patients with acute LMCO.

## METHODS

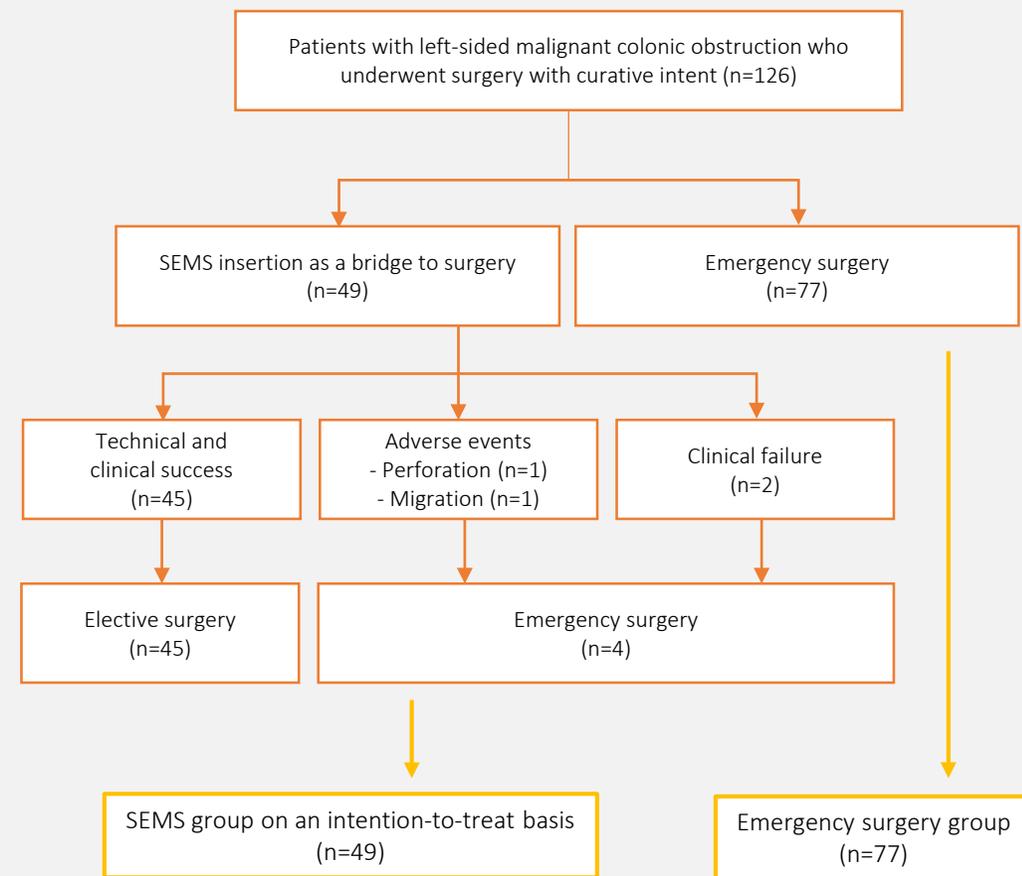
This retrospective cohort study included patients with acute LMCO who underwent SEMS insertion as a bridge to surgery or emergency surgery. The primary outcomes were 5-year disease-free survival (DFS), overall survival (OS), and recurrence rate. Survival outcomes were determined using the Kaplan-Meier method and compared using log-rank tests.

## RESULTS

There was a trend of worsening 5-year OS rate in the SEMS group compared with emergency surgery group (45% vs. 57%,  $P = 0.07$ ). In stage-wise subgroup analyses, a trend of deteriorating 5-year OS rate in the SEMS group with stage III (43% vs. 59%,  $P = 0.06$ ) was observed. The 5-year DFS and recurrence rate were not different between groups. The overall median follow-up time was 58 months. On multivariate analysis, age of  $\geq 65$  years and American Joint Committee on Cancer stage of  $\geq$  III, and synchronous metastasis were significant poor prognostic factors for OS (hazard ratio [HR], 1.709; 95% confidence interval [CI], 1.007–2.900;  $P = 0.05$ /HR, 1.988; 95% CI, 1.038–3.809;  $P = 0.04$ /HR, 2.146; 95% CI, 1.191–3.866;  $P = 0.01$ ; respectively).

## CONCLUSION

SEMS as a bridge to surgery may have adverse oncologic outcomes. Patients in the SEMS group had a trend of worsening 5-year OS rate without higher recurrence.



# EUS-guided radiofrequency ablation as an alternative to surgery for pancreatic neuroendocrine neoplasms: Who should we treat?

Alberto Larghi et al. [Endoscopic Ultrasound July-August 2019.]

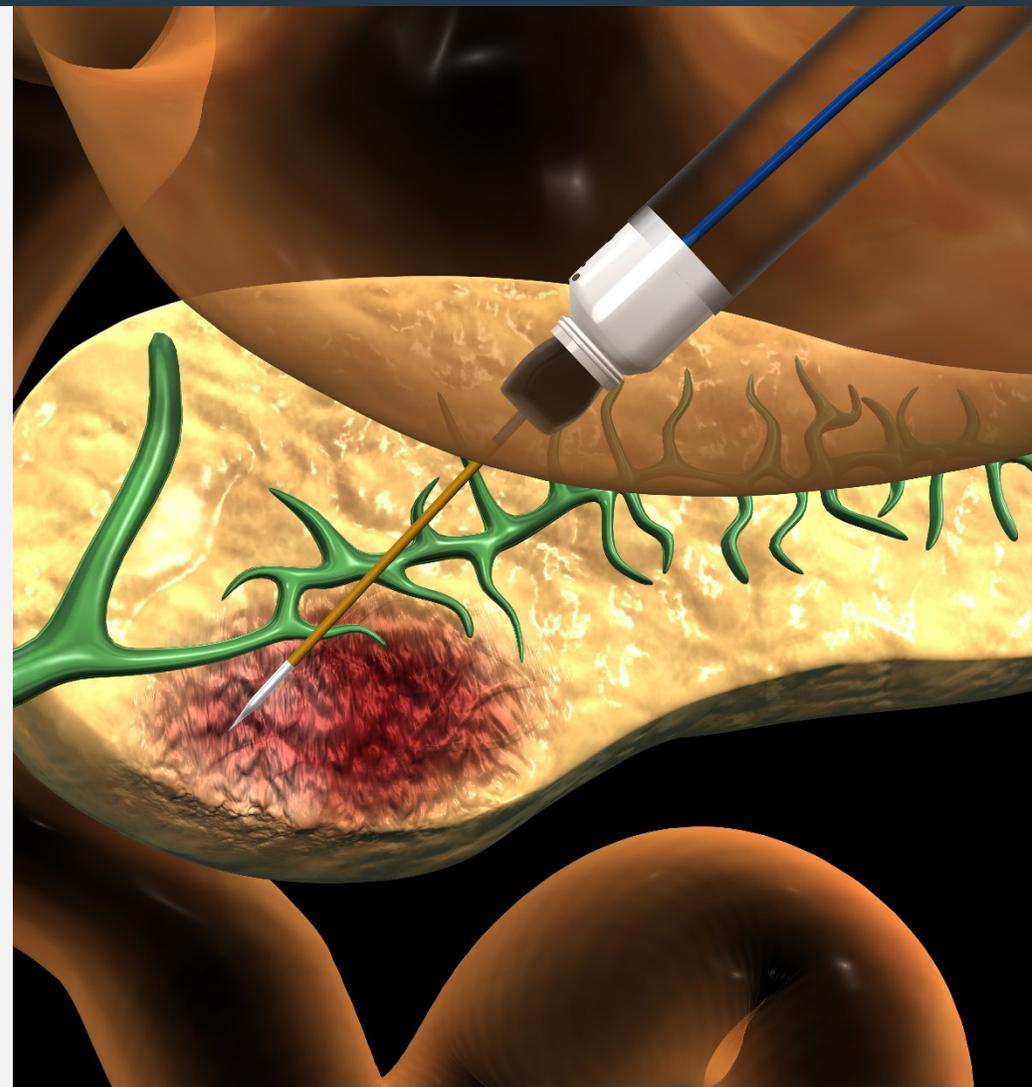
[CLICK TO ORIGINAL ARTICLE](#)

## ABSTRACT

Pancreatic neuroendocrine neoplasms (PanNENs) are rare tumors, but their incidental diagnosis has significantly increased due to the widespread use of imaging studies. Therefore, most PanNENs are now diagnosed when completely asymptomatic and in early stages. PanNENs are classified according to their grade (Ki-67 index) and can be functional (F-) or nonfunctional (NF-) depending on the presence or absence of a clinical, hormonal hypersecretion syndrome. The mainstay treatment of PanNENs is a surgery that is mostly curative but also associated with significant short- and long-term adverse events. Therefore, less invasive alternative locoregional treatment modalities are warranted. Recently, few case reports and two case series have described EUS-guided radiofrequency ablation (EUS-RFA) for the treatment of patients with both F-PanNENs and NF-PanNENs.

If for F-PanNENs EUS-RFA can very easily become the standard of care, for NF-PanNENs it is still controversial how to select patients for EUS-RFA. A balance between overtreatment (i.e., RFA/surgery in patients who will not progress) and undertreatment (locoregional treatments in patients with undetected metastases) needs to be found based on solid data. The decision should also take into account patients' comorbidity and risk of postoperative death, life expectancy, tumor location, risk of postoperative fistula and postoperative morbidity, and risk of long-term exocrine and/or endocrine insufficiency. To answer the important question on which a patient should be treated with EUS-RFA, properly designed studies to evaluate the efficacy of this treatment in large cohorts of patients with NF-PanNENs and to establish prognostic factors associated with treatment response are urgently needed.

**Key words:** EUS, individualized therapy, pancreatic neuroendocrine neoplasms, radiofrequency ablation.



# EUS-guided radiofrequency ablation as an alternative to surgery for pancreatic neuroendocrine neoplasms: Who should we treat?

Alberto Larghi et al. [Endoscopic Ultrasound July-August 2019.]

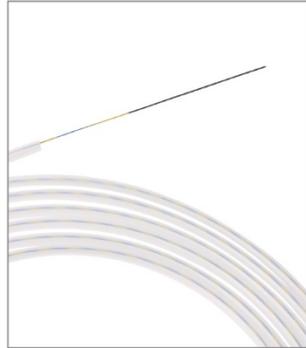
Characteristics of available studies on EUS-radiofrequency ablation for pancreatic neuroendocrine neoplasms

Author (year)	Number of Patients	F-PanNENs/ NF-PanNENs	NEN grade	Study type	Patients selection	RF device	Median follow-up (months)	Median tumor size (mm)	Outcome	Efficacy	Adverse events
Barthet et al., 2018 <sup>[33]</sup>	12 (14 NENs)	0/14	Grade 1	Prospective, multicenter	PanNEN <2 cm, unfit or refusing surgery	EUSRA RF electrode; STARmed, Koyang, Korea	12	13.1 (range 10-20)	Complete radiologic ablation	86% (12/14)	1 patient mild pancreatitis
Choi et al., 2018 <sup>[20]</sup>	8	1/7	NA	Prospective, Single center	PanNEN <3 cm, unfit for surgery or high surgical risk (ASA III or IV)	EUSRA RF electrode; STARmed, Koyang, Korea	13 (range 8-30)	20 (range 8-28)	Complete radiologic ablation	75% (6/8)	1 patient with abdominal pain; 1 with pancreatitis
Bas-Cutrina et al., 2017 <sup>[19]</sup>	1	1/0	NA	Case report	Unfit for surgery	Habib™ EUS-RFA catheter, Emcision Ltd., London	10	10	Complete radiological ablation. Symptoms resolution	100% (1/1)	0
Waung et al., 2016 <sup>[17]</sup>	1	1/0	NA	Case report	Failure of medical therapy, unfit for surgery	Habib™ EUS-RFA catheter, Emcision Ltd., London	10	18	Complete radiological ablation. Symptoms resolution	100% (1/1)	0
Pai et al., 2015 <sup>[15]</sup>	2	0/2	NA	Prospective, multicenter	NA	Habib™ EUS-RFA catheter, Emcision Ltd., London	3-6	27.5	Change in vascularity and central necrosis	100% (2/2)	0
Armellini et al., 2015 <sup>[16]</sup>	1	0/1	Grade 1	Case report	Refusing surgery	EUSRA RF Electrode; STARmed, Koyang, Korea	1	20	Complete radiologic ablation	100% (1/1)	0
Lakhtakia et al., 2015 <sup>[18]</sup>	3	3/0	NA	Case report	Unfit for surgery	EUSRA RF Electrode; STARmed, Koyang, Korea	12	17.7 (range 14-22)	Symptoms resolution	100% (1/1)	0

NA: Not available, PanNENs: Pancreatic neuroendocrine neoplasms, NEN: Neuroendocrine neoplasms, RFA: Radiofrequency ablation



Stone basket



Guidewire



Clip



Injector



Cystotome



ENBD Catheter



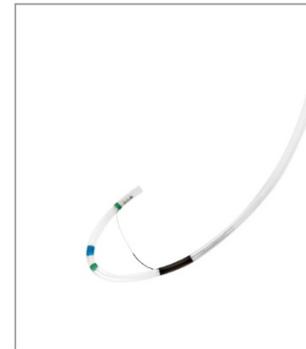
ERCP Catheter



ESD Knife



Hook



Sphincterotome



ClearCap



Polypectomy Snare

\*Device registration may vary depending on the product

For more information [click here!](#) ↑↑↑

For more information [click here!](#) ↓↓↓



ONLINE TRAINING CENTER



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HEPATICOGASTROSTOMY  
**GIOBOR** STENT  
FOR UNRESECTABLE  
MALIGNANT BILIARY OBSTRUCTION

