



How to continue with sales successfully during the current crisis via remote manners of work?
We provide insight on optimizing virtual sales through Webinar's, product trainings, and etc, both during and after COVID-19.



# ONLINE TRAINING PLATFORM OPEN



#### www.taewoongotc.com

**The OTC site** is an online educational platform exclusively offered for registered members only. It is specifically designed to provide all users around the globe to obtain knowledge and apply the skills needed to become an expert in Taewoong Products.

On the OTC site, you can access a variety of contents including product tutorial videos, testimonial videos of Taewoong Product users (doctors), procedure videos, and past webinar videos.

OTC can be accessed at ANYTIME from ANYWHERE.







#### **STUDIO TAEWOONG**

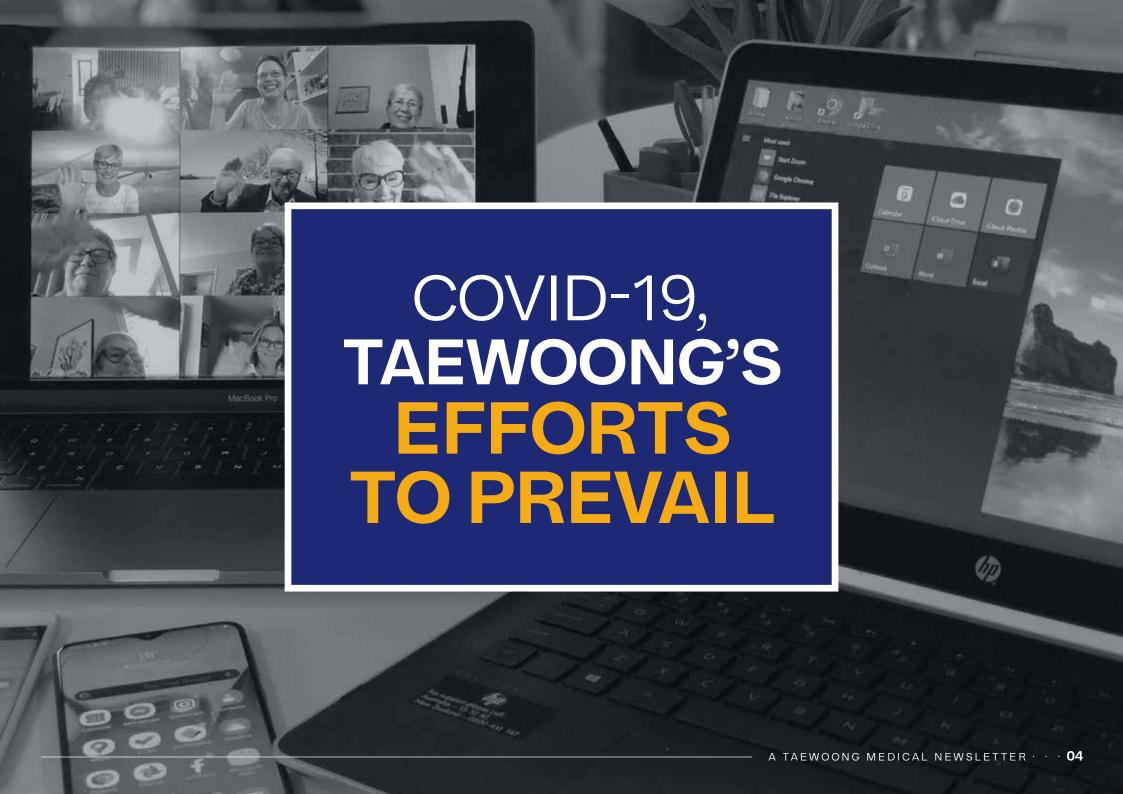
**STUDIO TAEWOONG** allows us to conduct professional webinar's, provide online real-time procedure support, create educational video contents, and produce necessary product related photographs and video sources.

We have now become able to use the specialized equipment's and programs available at the studio to provide high quality contents.

We request your continuous interest and support towards Taewoong Webinar's and other contents that are to be held in the future.







# **LOOK BACK AT TAEWOONG'S WEBINAR'S IN 2020 & UPCOMING WEBINAR'S IN 2021**

2020

#### 1st EUSRA™ Webinar

- June 17, 2020
- France, Marseille
- Prof. Marc Barthet

Prof. Marc Barthet led the Webinar through discussions and presentations focusing on RFA treatment of PNET and cystic neoplasms. Positive feedback from the participants were given in the circumstances of the COVID-19.





---0

Colonic stenting - Still a Challenge?

#### **EUS Stenting 1st Webinar**

- July 15, 2020
- France, Marseille
- Prof. Marc Barthet

Prof. Marc Giovannini shared his experience of the Giobor, Spaxus, and HOT Spaxus stents by presentations of live cases.

2 online platforms of Youtube and Cisco Webex were used to reach out to many participants.

#### **RFA Webinar**

- October 15, 2020
- France, Marseille
- Prof. Giovannini, Dr. Dancour Alain, Dr. Dov Wengrower

RFA for Pancreatic Solid Tumor & biliopancreatic diseases was the main focus for the webinar held and led by Dr. Dancour and Prof. Marc Giovannini. Pre-recorded cases and productive discussions were held while requests for further Webinars in the future were given.



#### **Colon Webinar**

- October 28, 2020
- South Korea, Seoul
- Prof. Yoshihisa Saida, Prof. Dong-Hoon Yang, Prof. Supakij Khomvilai, Prof. Yorinobu Sumida

Dr. Yoshihisa Saida, Dr. Dong-hoon Yang, Dr. Supakij Khomvilai, and Dr. Yorinobu Sumida gave a presentation on Colonic Stenting which was on the platform ZOOM. The smooth transition from each presentation as well as a healthy discussion led to the successful webinar.

\*In addition, there were 2 PULSTA Webinar's and 1 unofficial Webinar.





#### **Lectures for EUS-guided** RFA, EUSRA

- January 7, 2021
- CET 13:00
- Dongwan Seo (Korea), Stephen Pereira (UK), Pradermchai Kongkam (Thailand), Nirav Thosani (USA)



#### How to manage the leak or fistula after Endoscopic bariatric surgery?

- January 28, 2021
- CET 18:00
- Devinder Bansi (UK). Stephane Koch (France), Hany Shehab (Egypt)

#### **Biliary interventions: Current treatment of Benign** biliary and postoperative anastomotic strictures

- January 19, 2021
- CST 05:00, CET 12:00. AET 22:00. KST/JST 20:00
- Dr. Arthur Kaffes (Australia), Dr. Dong-ki Lee (Korea), Dr. Tatsuya Sato (Japan),
- Dr. Deepak Joshi (UK),
- Dr. José G. de la Mora-Levy (Mexico)



Taewoong Medical plans to continue such activities in 2021, and we will introduce detailed plans later in the Taewoong Medical Online Channel.

## HOT SPAXUS

### Electrocautery-Enabled Tip of Catheter

The HOT SPAXUS™ delivery system is extremely intuitive. It is based on the SPAXUS™ delivery system, as we have applied an electrocautery tip and plug to make the EUS-Guided Drainage procedure Simpler, Easier and Safer.

Stent itself comes in 8, 10, 16mm in diameter, and 2cm in length.

The profile of the delivery system is 10Fr and the usable length is 180cm. For the procedure, an echoendoscope with a 3.7mm working channel or larger and 0.035" or 0.025" guidewire are needed.









### Combination of endoscopic-ultrasound guided choledochoduodenostomy and gastrojejunostomy resolving combined distal biliary and duodenal obstruction [Endoscopy. 2020 Nov 19. doi: 10.1055/a-1294-9399.]

A 68-year-old man presented with abdominal pain, jaundice, and weight lost for 1 month. Abdominal computed tomography revealed a periampullary mass measuring  $3.5 \times 3.5 \times 3.2$  cm with dilated bile duct.

An endoscopic retrograde cholangiopancreatography (ERCP) procedure was not possible owing to a large friable ampullary mass causing supra-ampullary duodenal obstruction.

An endoscopic ultrasound-guided choledocho-duodenostomy (EUS-CDS) was consequently performed with a linear echoendoscope (GF-UCT180; Olympus, Aizu, Japan). A dilated distal common bile duct (CBD) from an ampullary was shown. A 19-gauge endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) needle (EchotipUltra; Cook Medical Ltd., Limerick, Ireland) with an angled 0.025-inch guide-wire (Visiglide 2, Olympus) was used for puncturing. A 6-Fr cystotome (Endo-Flex, Voerde, Germany) and a 4-mm balloon dilatation catheter (Hurricane RX; Boston Scientific, Cork, Ireland) were used for dilation. An 8 × 12-mm lumen apposing metal stent (LAMS) (Niti-S Spaxus: Taewoong Medical Co., Ilsan, Korea) was successfully placed transduodenally into the distal CBD (▶ Fig. 4). Subsequently, an EUS-guided gastrojejunostomy was performed. A 10-Fr nasobiliary catheter (Flexima; Boston Scientific, Marlborough, Massachusetts, USA) was placed into the jejunum to flush a mix of diluted contrast, saline, and methylene blue into the lumen of the jejunum in order to distend the small bowel loop. A 16 × 20-mm LAMS with an electrocautery delivery system (Niti-S Spaxus; Taewoong Medical Co.) was successfully placed transgastrically into the lumen of the jejunum (▶Fig. 5). The patient resumed diet with a decline of bilirubin level at 48 hours after the procedure without adverse events. This case reported the feasibility of a combination of EUS-guided choledochoduodenostomy and EUS-guided gastrojejunostomy to resolve a problem of bile duct and duodenal obstruction type II. Previously, most literature used a combination of EUS-guided biliary drainage and duodenal stents with a technical and clinical success rate of 71.4 % to 100 % and 94.1 % to 100 %, respectively.

#### Pradermchai Kongkam

Gastrointestinal Endoscopy Excellence Center, Department of Medicine, Faculty of Medicine, Chulalongkorn University and King Chulalongkorn Memorial Hospital, Thai Red Cross Society, Bangkok, Thailand

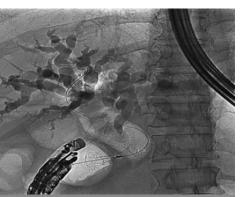


Fig 4. An 8 × 12-mm lumen-apposing metal stent (LAMS) was successfully placed transduodenally into the distal common bile duct.



Fig 5. A  $16 \times 20$ -mm lumen-apposing metal stent (LAMS) was successfully placed transgastrically into the lumen of the jejunum.



### A cholecystoduodenostomy with a new type of lumen-apposing metal stent

[Dig Liver Dis. 2020 Sep 1;S1590-8658(20)30402-3.]

A 67-year-old severe obese woman was admitted to our emergency room for upper right quadrant pain associated with fever (39.5°C). Biochemical evaluation showed 32 109/L WBC. Renal function was impaired. A significant increase of the cholestasis and cytolysis enzymes was also observed. An abdominal ultrasound showed an hydropic gallbladder with cholelithiasis and thickened walls

A diagnosis of multi-organ failure (MOF) was done and, after multidisciplinary discussion, we decided to drain the gallbladder by endoscopic ultrasonographic (EUS).

With a linear echoendoscope (GF-UCT180, Olympus, Hamburg-Germany) we performed a cholecystoduodenostomy (CDS) with a new fully-covered bi-flange shape lumen apposing metal stent (LAMS) with an electrocautetery tip (Hot-Spaxus 20×10 mm; Taewoong Medical Co, Ltd, Govang-si, Korea) (Figs. 1 and 2).

The procedure was carried out without X-ray in intensive care unit (ICU). The release of the proximal flange of the stent was performed inside the channel of the scope and no adverse events were experienced (video).

To our knowledge, this is the first report of an Hot-Spaxus placement.

#### **Benedetto Mangiavillano**

Gastrointestinal Endoscopy Unit, Humanitas Mater Domini Castellanza, VA, Italy



Fig 1. EUS appearance of the Hot-Spaxus distal flange deployed inside the gallbladder.

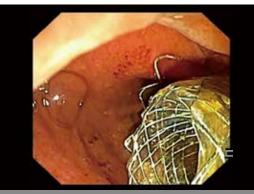
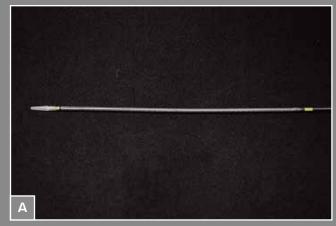


Fig 2. Hot-Spaxus proxymal flange deployed inside the duodenal lumen.

# Long-term outcomes of a long, partially covered metal stent for EUS-guided hepaticogastrostomy in patients with malignant biliary obstruction (with video)

by Yousuke Nakai et al. [Gastrointest Endosc. 2020 Sep;92(3):623-631.e1.]





A long, partially covered metal stent (LP-CMS; modified Giobor stent [Taewoong Medical, Seoul, Korea]). **A,** An 8.5F delivery system of the LP-CMS. **B,** Fully deployed LP-CMS with 1-cm uncovered portion in the hepatic end.

#### **BACKGROUND AND AIMS**

We previously reported safety and effectiveness of EUS-guided hepaticogastrostomy (EUS-HGS) using a long, partially covered metal stent (LP-CMS) for malignant biliary obstruction (MBO). In this study, we aimed to evaluate long-term outcomes of EUS-HGS in an expanded cohort.

#### **METHODS**

One hundred ten patients undergoing EUS-HGS using an LP-CMS in 2 centers were retrospectively studied. Technical and functional success, adverse events, recurrent biliary obstruction (RBO), and reinterventions were evaluated.

#### **RESULTS**

The cause of MBO was pancreatic cancer in 50%, and the location of MBO was distal in 68%. The stent length was 8 cm in 2%, 10 cm in 84%, and 12 cm in 15%, with a median intragastric stent length of 54 mm. Technical and functional success rates were 100% and 94%, respectively. The adverse event rate was 25% (mild 15%, moderate 7%, severe 3%), but about one-half of adverse events were mild transient fever and abdominal pain. RBO developed in 33%, with a median cumulative time to RBO of 6.3 months. The major cause of RBO was hyperplasia at an uncovered portion. The presence of prior biliary drainage and short intragastric stent length were significantly associated with RBO. Reintervention for RBO was successfully achieved through the EUS-HGS route in 92%. The remaining reintervention procedures were 1 EUS-HGS and 2 percutaneous transhepatic biliary drainage all in cases with hilar MBO.

#### **CONCLUSIONS**

EUS-HGS using an LP-CMS for unresectable MBO was safe and effective. RBO was not uncommon, but reintervention through the EUS-HGS route was technically possible in most cases. (Gastrointest Endosc 2020;92:623-31.)

Clinical outcomes of EUS-guided hepaticogastrostomy			
Outcomes	Value		
Technical success	110 (100)		
Clinical success	103 (94)		
Adverse events, grade	27 (25), mild 17, moderate 8, severe 2		
Transient fever	10 (9), mild 10		
Abdominal pain	4 (4), mild 4		
Peritonitis	4 (4), mild 2, moderate 2		
Cholangitis	3 (3), moderate 2, mild 1		
Pseudoaneurysm	1 (1), severe 1		
Abscess	2 (2), moderate 1, severe 1		
Bleeding	1 (1), moderate 1		
Hemobilia	1 (1), moderate 1		
Cholecystitis	1 (1), moderate 1		
RBO	36 (33)		
Hyperplasia	25 (23)		
Sludge	7 (6)		
Newly developed biliary stricture	2 (2)		
Hemobilia	1 (1)		
Nonocclusive cholangitis	1 (1)		
Time to RBO in cases with RBO, months	3.2 (2.0-5.9)		

In our analysis, the presence of prior biliary drainage was significantly associated with RBO because of hyperplasia. In cases with the presence of biliary drainage, the bile duct showed reactive changes as previously shown in the intraductal ultrasound findings.23 We speculate that the pre-existing reactive inflammation can promote hyperplastic change by the stent and lead to RBO at an uncovered portion. Some patients with prior biliary drainage underwent conversion to EUS-HGS because of recurrent cholangitis24; chronic inflammation in the biliary system is inevitable. A fully CMS can prevent RBO because of hyperplasia but at the cost of an increased risk of stent dislocation and side branch obstruction. In a previous study of an original Giobor stent,25 which is a half-covered metal stent, HGS stent occlusion was observed in 5 of 37 patients (14%), although the cause of stent occlusion was not clearly described. Whether the length of the uncovered portion can affect stent occlusion or not needs to be further investigated. A study26 showed promising results of a dedicated plastic stent for EUS-HGS, but an ideal stent for EUS-HGS has not been established thus far.

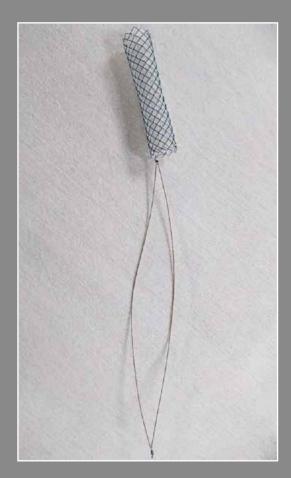
Values are n (%) or median (interquartile range). RBO, Recurrent biliary obstruction.

Clinical outcomes by prior biliary drainage and stent diameter						
	Prior biliary drainage			Stent diameter		
	Yes (n=64)	No (n=46)	P value	10mm (n=71)	8mm (n=39)	P value
RBO	29 (45)	7 (15)	<.01	22 (31)	14 (36)	.67
Hyperplasia	21 (33)	4 (9)		16 (23)	9 (23)	
Sludge	5 (8)	2 (4)		5 (7)	2 (5)	
Time to RBO in cases with RBO, months	3.1 (1.8-5.9)	3.5 (2.7-5.8)	.45	3.3 (2.0-5.9)	3.0 (1.6-6.1)	.62
Adverse events	18 (28)	9 (20)	.37	16 (23)	11 (28)	.64
Mild	9 (14)	8 (17)		9 (13)	8 (21)	
Moderate	8 (13)	0		5 (7)	3 (8)	
Severe	1 (2)	1(2)		2 (3)	0	

Values are n (%) or median (interquartile range). RBO, Recurrent biliary obstruction.

## A prospective study of fully covered metal stents for different types of refractory benign biliary strictures

by Tatsuya Sato et al. [Clinical Trial Endoscopy. 2020 May;52(5):368-376.]



Photograph of a fully covered metal stent with a 10-cm lasso (Niti-S Kaffes; TaeWoong Medical, Gyeonggi-do, South Korea) and a central section diameter 2mm smaller than the diameter at the ends.

#### **BACKGROUND**

While endoscopic management of benign biliary strictures (BBSs) is the standard of care, long-term treatment remains the issue in refractory cases, especially for anastomotic strictures after living-do-nor liver transplantation (LDLT) and hepaticojejunostomy anastomotic strictures (HJAS). The aim of this prospective study was to evaluate the safety and effectiveness of a fully covered self-expandable metal stent (FCSEMS) for patients with refractory BBSs.

#### **METHODS**

Patients with BBSs that were unamenable to endoscopic plastic stent placement with a treatment period of more than 6 months were eligible. An FCSEMS was placed endoscopically and removed after 90 days. In patients with surgically altered anatomy, an FCSEMS was placed using a double-balloon endoscope. The primary outcome was stricture resolution at FCSEMS removal. The secondary outcomes included stricture recurrence and adverse events.

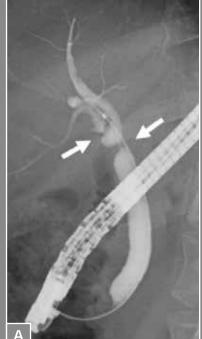
#### **RESULTS**

A total of 30 patients were enrolled: the causes of their BBSs were anastomotic stricture after LDLT in 13, HJAS in 12, post-cholecystectomy in two, chronic pancreatitis in two, and post-hepatectomy in one. The technical success rate of FCSEMS placement was 100 % and all FCSEMSs were successfully removed. The rate of stricture resolution at FCSEMS removal was 96.6 % (91.7 % in the post-LDLT group and 100 % in the HJAS group). Stricture recurrence occurred in three HJAS patients (10.7 %) during a median follow-up period of 15.6 months. Adverse events were observed in 12.1 %: five cholangitis, one pancreatitis, and one perforation. Conclusion Temporary placement of an FCSEMS was a feasible and effective treatment option for refractory BBSs, especially for post-LDLT strictures and HJAS.

### Outcomes of a fully coveredmetal stent (FCSEMS) placement for refractory benign biliary strictures in 29 patients.

Outcomes	Patients
Successful FCSEMS placement, n (%)	29 (100%)
Procedure time, median (IQR), minutes	46 (35-64)
Number of FCSEMSs, n (%)	
1	25 (86.2%)
2	4 (13.8%)
Concomitant plastic stent placement, n (%)	23 (79.3%)
Indwelling time, median (IQR), days	91 (65-98)
Successful FCSEMS removal, n (%)	27/27 (100%)
Stricture resolution at FCSEMS removal, n (%) [90% confidence interval]	28 (96.6%) [84.7%-99.8%]
Follow-up after FCSEMS removal, median (IQR), months	21.5 (13.5-24.0)
Stricture recurrence, n (%)	3/28 (10.7%)
Time to recurrence, median (IQR), months	19.5 (12.8-20.9)
Type of benign biliary stricture with recurrence	
Hepaticojejunostomy anastomotic stricture	3
Adverse events, n (%)	7/58 (12.1 %)
Cholangitis	5 (mild 2; moderate 3)
Pancreatitis	1 (moderate)
Perforation <sup>1</sup>	1 (moderate)
Stent dysfunction, n (%)	2/29 (6.9%)
Stent occlusion <sup>2</sup>	1 4
Asymptomatic migration <sup>3</sup>	1 A

IQR, interquartile range.







Cholangiographic images showing: **A** two biliary anastomotic strictures after living-donor liver transplantation (LDLT) with a right graft (arrows); **B** two fully covered metal stents placed across the anastomotic strictures in the "side-by-side" manner; **C** (with balloon occlusion) resolution of the two anastomotic strictures (arrows).

<sup>&</sup>lt;sup>1</sup>Pneumoperitoneum was diagnosed on computed tomography the day after the procedure in a patient with surgically altered anatomy who underwent double-balloon endoscope-assisted endoscopic retrograde pancreatography.

<sup>&</sup>lt;sup>2</sup> Stent occlusion occurred due to biliary sludge.

<sup>&</sup>lt;sup>3</sup> A stricture was resolved in a patient with asymptomatic migration of an FCSEMS.

## Newly developed self-expandable Niti-S MD colonic metal stent for malignant colonic obstruction

by Yuki Miyasako et al. [World J Gastrointest Surg. 2020 Apr 27;12(4):138-148.]

Conventional D type (22mm in diameter)



New developed MD type (22mm in diameter)



The newly developed Niti-S MD type stent (22 mm in diameter). The newly developed stent, "Niti-S MD type," has a diameter of 22 mm, that can be introduced into a 9-Fr delivery system while maintaining the Niti-S D type structure.

#### BACKGROUND

Colonic stents are increasingly used to treat acute malignant colonic obstructions. The WallFlex and Niti-S D type stents are the commonly used self-expandable metallic stents available in Japan since 2012. WallFlex stent has a risk of stentrelated perforation because of its axial force, while the Niti-S D type stent has a risk of obstructive colitis because of its weaker radial force. Niti-S MD type stents not only overcome these limitations but also permit delivery through highly flexible-tipped smaller-caliber colonoscopes.

#### AIM

To compare the efficacy and safety of the newly developed Niti-S MD type colonic stents.

#### **METHODS**

This single-center retrospective observational study included 110 patients with endoscopic self-expandable metallic stents placed between November 2011 and December 2018: WallFlex (Group W, n = 37), Niti-S D type (Group N, n = 53), and Niti-S MD type (Group MD, n = 20). The primary outcome was clinical success, defined as a resolution of obstructive colonic symptoms, confirmed by clinical and radiological assessment within 48 h. The secondary outcome was technical success, defined as accurate stent placement with adequate stricture coverage on the first attempt without complications.

#### **RESULTS**

The technical success rate was 100% in Groups W, N, and MD, and the overall clinical success rate was 89.2% (33/37), 96.2% (51/53), and 100% (20/20) in Groups W, N, and MD, respectively. Early adverse events included pain (3/37, 8.1%), poor expansion (1/37, 2.7%), and fever (1/37, 2.6%) in Group W and perforation due to obstructive colitis (2/53, 3.8%) in Group N (likely due to poor expansion). Late adverse events (after 7 d) included stent-related perforations (4/36, 11.1%) and stent occlusion (1/36, 2.8%) in Group W and stent occlusion (2/51, 3.9%) in Group N. The stent-related perforation rate in Group W was significantly higher than that in Group N (P < 0.05). No adverse event was observed in Group MD. CONCLUSION In our early and limited experience, the newly developed Niti-S MD type colonic stent was effective and safe for treating acute malignant colonic obstruction.

#### **CORE TIP**

We developed a new self-expandable metallic stent, the Niti-S MD colonic stent (with a diameter of 22 mm), that can be deployed using the 9-Fr delivery system. The stent not only increased the radial force while maintaining the stent structure and low axial force but also permitted delivery through highly flexible-tipped smaller-caliber colonoscope with a working channel of 3.2 mm. In this study, the technical and clinical success rate of the Niti-S MD type was 100%, and its perforation rate was 0%. It was safe and effective for treating acute malignant colonic obstruction.

#### 110 lesions (105 patients)

Nov. 2011 to Dec. 2018 BTS 61 / PAL 49

### Wall Flex (Group W)

Nov. 2011 to Sep. 2013 37 lesions (35 patients) BTS 19 / PAL 18

#### Niti-S (Group N)

Oct. 2013 to Dec. 2017 53 lesions (51 patients) BTS 32 / PAL 21

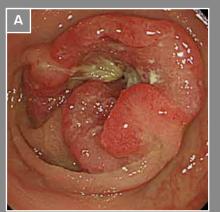
#### MD type (Group MD)

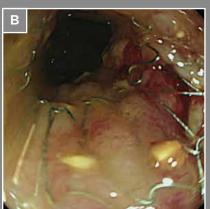
Jan. 2018 to Dec. 2018 20 lesions (19 patients) BTS 10 / PAL 10

**Flow chart of patient allocation.** Of the 105 patients (110 lesions) who were enrolled in the study, 35 patients (37 lesions) were treated with WallFlex stents (Group W), 51 patients (53 lesions) with Niti-S stents (Group N), and 19 patients (20 lesions) with the newly developed Niti-S MD type stent (Group MD). BTS: Bridge-to-surgery; PAL: Palliative.

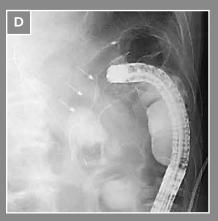
Early and late adverse events					
	Group W	Group N	Group MD	Total	
Early (≤ 7 d)					
Perforations	0/37 (0%)	2/53 (3.8%)1	0/20 (0%)	2/110 (1.8%)	
Bleeding	0/37 (0%)	0/53 (0%)	0/20 (0%)	0/110 (0%)	
Poor expansion	1/37 (2.7%)	0/53 (0%)	0/20 (0%)	1/110 (0.9%)	
Abdominal pain	3/37 (8.1%)	0/53 (0%)	0/20 (0%)	3/110 (2.7%)	
Stent occlusion	0/37 (0%)	0/53 (0%)	0/20 (0%)	0/110 (0%)	
Fever	1/37 (2.7%)	0/53 (0%)	0/20 (0%)	1/110 (0.9%)	
Late (> 7 d)					
Perforations	4/36 (11.1%) <sup>a2</sup>	0/51 (0%)ª	0/20 (0%)	4/107 (3.7%)	
Bleeding	0/36 (0%)	0/51 (0%)	0/20 (0%)	0/107 (0%)	
Stent migration	0/36 (0%)	0/51 (0%)	0/20 (0%)	0/107 (0%)	
Abdominal pain	0/36 (0%)	0/51 (0%)	0/20 (0%)	0/107 (0%)	
Stent occlusion	1/36 (2.8%)	2/51 (3.9%)	0/20 (0%)	3/107 (2.8%)	

<sup>&</sup>lt;sup>1</sup>Perforation occurred due to obstructive colitis in all two cases;











One of the bridge-to-surgery cases using the newly developed Niti-S MD type stent. A and C: The patient was an 83-year-old man with peritoneal type 2 advanced colorectal cancer (arrowhead) in the transverse colon; B and D: Using a smaller caliber colonoscope, we placed a 22 mm × 8 cm stent (arrow); E: Abdominal radiograph 2 d later shows firmly expanded stent successfully decompressing the acute obstruction. Tight stenosis is seen, and the enhanced expansible force of this stent enables successful decompression.

<sup>&</sup>lt;sup>2</sup>All four cases were stent-related perforation.

 $<sup>^{</sup>a}P < 0.05$ .

# Prospective Assessment of the efficacy and safety of a Newly Designed Endoscopic Ultrasound Guided Radiofrequency Ablation (EUS-RFA) Device for treating Pancreatic Neuroendocrine Tumors and Secondary Pancreatic Metastasis

by Tom Malikowski et al.

#### **BACKGROUND**

There is considerable need to find safe and effective locally ablative therapies for patients with particular pancreatic malignancies in an effort to forego the need for oncologic surgical resection. While pancreatic ductal adenocarcinoma cannot be cured by local therapy alone, other tumor types to include pancreatic neuroendocrine tumors (pNET) and secondary metastasis to the pancreas have the potential for cure and/or substantially prolonged survival with local therapy alone. To date, local chemical or physically ablative therapies rarely yield complete tumor ablation. The recent introduction of a new radiofrequency ablation (RFA) device offers an alternative option, but limited data are available. We examined the safety and efficacy of EUS-RFA, when used for pNETs and secondary metastasis to the pancreas.

#### **METHODS**

Using a prospectively maintained multi-center EUS database, we identified all patients who underwent EUS-RFA using the newly designed 19G EUSRA, STARmed, Taewoong, South Korea, and abstracted their clinical and EUS RFA data to determine the safety and efficacy. Non-functioning pNETs were considered fully ablated when pre-therapy enhancement was completely absent post-therapy. Functioning pNETs also required resolution of abnormal laboratory parameters and index symptoms to be considered fully ablated.

#### **RESULTS**

Ten patients underwent EUS RFA to treat 11 enhancing pancreatic lesions located within the head (n=6), neck (n=2), body (n=1), and tail (n=2) to treat non-functioning pNETs (n=5), insulinomas (n=3), and renal cell carcinoma pancreatic metastasis (n=2). The tumors measured 21 mm [6-64 mm] in long axis diameter and were solid (n=9) or mixed solid and cystic (n=2).

Lesions were treated for a maximum of 3 sessions utilizing 5-7-9 mm caliber probes, median power per application of 20W (10-30), and 3 treatment zones (1-6) per session with a RFA duration of 15 sec (4-30) per zone. (Table 1) The lesions were completely ablated (n=6) or showed initial sonographic response at time of EUS with follow-up pending cross sectional imaging to determine treatment efficacy (n=5). Of the 6 lesions with complete response, 1 previously failed an ethanol ablation and was fully ablated following one RFA treatment. Another patient experienced apparently unsuccessful RFA with subsequent full ablation following alcohol injection 1 month later. All patients were clinically re-evaluated within 7 and 30 days of therapy and 1 (14%) experienced peritonitis. No patients developed pancreatitis.an(10-30), and 3 treatment zones (1-6) per session with a RFA duration of 15 sec (4-30) per zone. (Table 1) The lesions were completely ablated (n=6) or showed initial sonographic response at time of EUS with follow-up pending cross sectional imaging to determine treatment efficacy (n=5). Of the 6 lesions with complete response, 1 previously failed an ethanol ablation and was fully ablated following one RFA treatment. Another patient experienced apparently unsuccessful RFA with subsequent full ablation following alcohol injection 1 month later. All patients were clinically re-evaluated within 7 and 30 days of therapy and 1 (14%) experienced peritonitis. No patients developed pancreatitis.

#### **CONCLUSION**

Our preliminary 19G EUSRA ablation experience highlights the capability of complete tumor ablation of pNETs and metastatic tumor to the pancreas, which may be an alternative to pancreatic resection in select patients. Further study is needed to verify and safety and long-term efficacy of EUS RFA, and its impact on prognosis, clinical care, and outcomes.

# Efficacy and safety of palliative endobiliary radiofrequency ablation using a novel temperature-controlled catheter for malignant biliary stricture: Za single-center prospective randomized phase II TRIAL

by Huapyong Kang et al. [Surg Endosc. 2020 Jun 2.]

Biliary SEMS placement and photodynamic therapy (PDT) have been widely used to treat obstructive jaundice in patients with MBS. SEMS placement has been recognized as a safe palliative option entailing fewer serious adverse events and less invasiveness. Nevertheless, placement of a SEMS alone may require repeating the procedure because of stent obstruction or migration. PDT requires expensive photosensitizers and equipment. Moreover, it is a time consuming procedure with certain risks of complications, including cholangitis, hemobilia, and photosensitivity (12.5–30%). Thus, patients who undergo PDT are required to avoid exposure to light for 2 weeks after treatment. On the contrary, EB-RFA allows earlier recovery of patients and is relatively less expensive than PDT. EB-RFA has another advantage that it can be easily performed by ERCP experts, because it is not very different from handling other devices over the guidewire.

In an early clinical study evaluating the safety of temperature-controlled EB-RFA, no serious complications were reported after RFA with settings of 75 °C, 10 W, and 120 s.ln our first randomized controlled study using temperature-controlled EB-RFA, SEMS placement after EB-RFA did not prolong survival or patency when compared with SEMS placement alone. Although the treatment efficacy in the RFA group was comparable to that reported in previous EB-RFA studies, it needs to be considered that the patients in our study had various sites of MBS.

A subgroup analysis of patients with MBS at the CBD showed a trend of a higher rate of 90-day stent patency in the RFA group.

This may indicate that the specific indications for EB-RFA should be defined. In a recent study in 18 patients who underwent temperature-controlled EB-RFA, the distal MBS group showed a longer median patency than the hilar MBS group (110 vs. 187 days).

In conclusion, we demonstrated that EB-RFA with a temperature-controlled catheter followed by SEMS placement can be a safe and feasible procedure with acceptable biliary patency for patients with inoperable MBS.

Comparison of outcomes					
	RFA group (n=24)	Non-RFA group (n=24)	Р		
Technical success	24 (100)	24 (100)	1.000		
Clinical success	21 (87.5)	20 (83.3)	1.000		
Stent diameter (mm)	10 (10-0)	10 (10-10)	0.301		
Stent length (cm)	7 (6-8)	7 (6-7)	0.806		
Via percutaneous transhepatic route	4 (16.7)	4 (16.7)	1.000		
Follow-up period (days)	135.0 (80.3-190.8)	119.5 (85.5-255.0)	0.621		
90-day stent patency	14 (58.3)	11 (45.8)	0.386		
Duration of stent patency, median (95% CI) (days)	132.0 (99.6-164.4)	116.0 (52.4-179.6)	0.440		
OS, median (95% CI) (days)	244.0 (117.8-370.0)	180.0 (27.8-332.2)	0.281		

All categorical variables are presented as n (%). All continuous variables are presented as median (interquartile range)

RFA radiofrequency ablation, OS overall survival, CI confidence interval



#### **HEAD OFFICE**

14, Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, Korea 10022

#### **SALES OFFICE**

Bldg.C 4F, 158 Haneulmaeul-ro, ilsandong-gu, Goyang-si, Gyeonggi-do, Korea 10355 **E:** contact@stent.net **T:** +82 31 904 6153 **F:** +82 31 904 6157

