A TAEWOONG MEDICAL NEWSLETTER
OCT 2016 / ISSUE 7

WE CONNECT YOUR LIFE

TAEWOONG NEWS

SCIENTIFIC ISSUE

A Look into Taewoong Medical Performances in 2016

We annually participate a lot of congresses, hands-on trainings and highly interactive events around the world. This year, we newly launched lumen apposing metal stent SPAXUS™ and organized a preclinical evaluation service to support R&D and provide histological analysis.

18th Dusseldorf International Endoscopy Symposium

(Dusseldorf, Germany) Feb 11-13

We had a second ELRA™ live demonstration following last year. Prof. Jacques Deviere was operator and patients had hilar cholangiocellular carcinoma with recurrent cholangitis due to the migration of the plastic stent. 18mm ELRA™ was inserted and ablate to R/L duct both. RFA procedure was successful and had received a lot of attention regarding RFA products after the live demonstration.

PPUM ENDOSCOPY 2016

(Kuala Lumpur, Malaysia) April 8-10

Taewoong Medical had three live demonstrations during PPUM. 2 cases of them were ELRA™ and 1case was Niti-S™ stent case. During the ELRA™ live demonstration, one of doctor asked that biliary duct ablation is really effective. Dr.N.Reddy said biliary ablation is effective to stent patency as well as life expectancy. A related paper said it will be published in the second half of this year.

SPAXUS™ Stent CE Approval

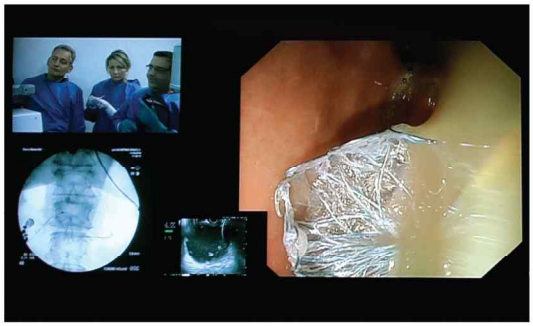
April

We have received CE mark approval for Lumen-apposing Metal Stent, SPAXUS™. After many years of research, based on feedback of the Interventional EUS field experts, a new approach has been developed for SPAXUS™. The design of SPAXUS™ is very user friendly that offers a more efficient and satisfying experience, also, it facilitates quick procedure of stent deployment without the need for any particular expertise in complicated delivery system.
The SPAXUS™ has been well applied to treat complex pancreaticobiliary diseases.

EUS & ENDO LIVE 2016

(Poland) April 28-29

GIOBOR™ and SPAXUS™ live procedures were conducted by Dr. Giovanni from France, and EUSRA™ performed by Dr. Senturk from Turkey. All the stent related procedures were successfully completed causing attendees during procedures using interactive questions and comments.



ENDO LIVE 2016

(Rome, Italy) May 11-13

SPAXUS™ stent live demonstration was conducted by Dr. Giovannini and Dr. Bruno for pancreatic fluid collection with necrosis. It was performed excellently using the blue marker on SPAXUS™ delivery system.

DDW 2016

(San Diego, USA) May 22-24

DDW is an important congress and we participate every year. It's one of the best opportunities for us to engage with customers. This year, we prepared a demonstration of SPAXUS™ stent, user friendly delivery system so that visitors could have hands-on experience of easy deployment.

2nd day of DDW congress, the valued customers and friends from all over the world were invited to SeaWorld, best attraction of San Diego. We prepared a special show with killer whales and dinner buffet beside the pool. All attendees seemed to return to the innocence of childhood during the show, and they had a great time even though some of them were dripping wet by whales.

GEEW 2016

(Brussels, Belgium) June 20-22

On the 2nd day of GEEW live demonstration, EUSRA™ was introduced using porcine model due to the patient's condition. Audiences have shown great interest in EUSRA™, especially they were impressed to make a large volume of ablation without tissue charring with the inner cooling system.

IDEN 2016

(Seoul, Korea) June 24-26

During IDEN congress period, we invited key opinion leaders and our partners to our factory to introduce our production process. Stent production tour was arranged to look all around the each production rooms, in addition, we had Endoscopic RFA hands-on experience.

"It was the first time to see how to make hand-made metal stent and impressive the many steps for producing the one stent." said one of the participants.

We have invited KOLs and partners to Korea twice an annual event on June and October during IDEN and SGI domestic congresses. To learn more about the invited program, please contact your local sales representative.

EUS-guided procedures are no longer the future of EUS but rather the present!

AERAT 2016

Upcoming Program Schedule

Closed registration

EUS-guided RFA Master Class in Marseille, France: 29-30 November by Prof. Marc Barthet

Now enrolling

AERAT (Asan EUS-guided Radiofrequency Ablation Training) in Seoul, Korea: January, 2017 by Prof. Seo, Dong Wan

Nowadays EUS has emerged as an essential field in diagnostic and therapeutic endoscopy. Our EUS-guided RFA master course is not only to provide the opportunities to understand mechanism of EUS-guided RFA, but also to learn the essential technical tips for successful RFA applications through comprehensive lectures and hands-on courses including patient's case observation and animal test, phantom hands-on. We are convinced that our comprehensive and intensive 2 days course will guide all of attendees to EUS-guided RFA program practice as well as introduce our EUS-RFA novel device. We are completed twice of EUS-guided RFA master course successfully until now in Seoul, Korea and Marseille, France.

Let's share the program inside story together from now.

EUS-guided RFA Master Course Program is primarily focused on the following training courses and lectures. First program was held in Seoul, Korea Asan Medical Center directed by Prof. Seo, Dong Wan and second program was held in Marseille, France Nord Hospital directed by Prof. Marc Barthet. Both training program were consisted of EUS lectures by director and EUS-RFA case observation, and hands-on with phantom model and porcine model. EUS lectures are open to questions from the participant's review of case observation and hands-on training in a preliminary session.

This one-to-one interaction training program will hopefully build up links and long term relationships helpful for personal development and a greatest integration of future procedure.

Most of the participants hope that EUSRA™ can be applied to a variety of indication not only pancreas tumor but also, gradually predict increase these EUS treatment in the future.

Marseille Training

Taewoong Medical Research Center has newly-organized a preclinical team to provide preclinical evaluation service for medical devices

'Build a foundation for systematic research to support R&D and provide histological analysis.'

Angiography Room

MRI Safety Evaluation System

Laboratory of Mammalian Cell Biology

Laboratory of Manual Evaluation and Histology

Taewoong Medical has been continuously investing in product development since its foundation in 1999 and engaged in organic research cooperation with many research institutions at home and abroad, making efforts to diversify and improve the functionality of the product. This year in March, a preclinical team has been established in Taewoong Medical's Osong research center.

Preclinical Studies are executed to test a medical device in animals before conducting any clinical trials in the patient to verify biological safety and effectiveness of the medical device. Biocompatibility testing and risk assessment for marketing approval of medical devices necessarily entails accurate analysis of data from biological evaluation and animal testing. Therefore, the newly-organized preclinical team is attracting expectations to enhance the competitiveness of the product while improving the safety in medical procedures.

The new preclinical team provides expert research support services to various medical personnel and researchers, not to mention supporting Taewoong's own products in development. The team has already been entrusted with animal tissue with biomaterial implant from several universities and research institutions and has embarked on the histological analysis service.

For those researchers who require animal experiments will benefit from a laboratory animal center of Osong Medical device development center (Department of evaluation Bio Compatibility assessment team; www.kiobhealth.kr). A researcher-centered 'One-way system' embracing from the whole process of animal testing to histological analysis will be introduced in the near future. In addition, to aid the safe and correct use of commercial products, the domestic and international sales divisions are preparing to implement training programs using experimental animals targeted for medical specialists.

With the installation of the new preclinical team, Taewoong Medical can internally evaluate cell testing and animal testing from early stages of development to the point of completing a new product, which will enable Taewoong to introduce mature products to the market in a much shorter period of time. Also, offering targeted training programs to medical specialists and histological analysis service will enhance efficiency and research achievements of medical devices.

Preliminary report on a EUS guided pseudocyst drainage with a new lumen apposing metal stent (SPAXUS™); single center, 9 months experience

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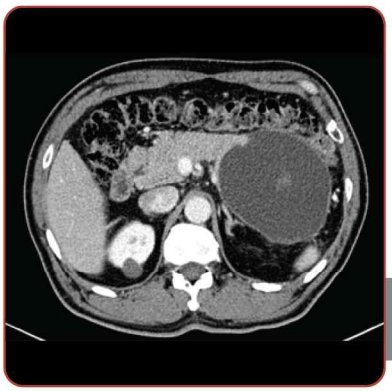
Background and Aims

Endoscopic ultrasound (EUS)-guided drainage has become a mainstay for treating peripancreatic fluid collection and fully covered metal stent provided more efficient drainage than plastic stent. Recently, wide-flanged fully covered metal stent is introduced in EUS-guided pseudocyst drainage and showed promising results. The aim of this study was to evaluate the feasibility and efficacy of EUS-guided pseudocyst drainage with a new lumen apposing metal stent (Niti-S™ SPAXUS™ Stent; Taewoong Medical, Seoul, Korea).



CT scan of huge pancreatic pseudocyst

Method

A prospective, single-arm, multicenter feasibility study of EUS-guide pseudocyst drainage with SPAXUS™ is now enrolling patients at 6 tertiary hospital in Korea. This preliminary report describes single center, 9 months experiences of the multicenter study. Between January and September 2016, a total of 11 patients were treated with EUS-guided pseudocyst drainage with SPAXUS™ in our institute. Baseline characteristics and outcomes including technical/clinical success rate, adverse event, and recurrence rate were evaluated.

Table 1. Baseline characteristics of patients

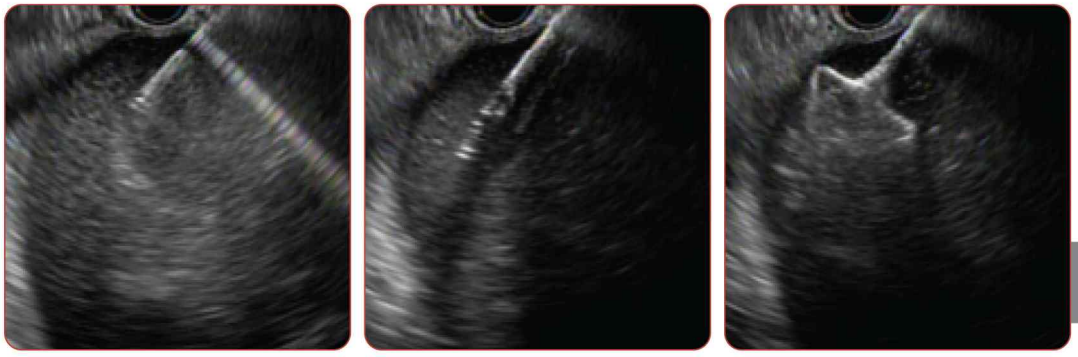
	EUS-guided PFC drainage (N = 11)
Median age (range), years	57 (42 76)
Male: Female	10 : 1
Etiology of PFC	
Acute pancreatitis†	4
Obstructive pancreatitis‡	2
Post-operative*	5
Location	
Head	1
Body	3
Tail	7
Indication for drainage	
Infected pseudocyst	5
Rapidly enlarging	2
Symptom§	4
Median PFC maturation (range), weeks	6 (3-30)
PFC debris	11
Median PFC size, long axis, mm	80 (60-160)

† Among patients with acute pancreatitis, etiology of acute pancreatitis were 1 with hypertriglyceridemia, 1 with alcohol, and 2 with gall stone pancreatitis.

‡ Obstructive pancreatitis of this entity includes only obstruction by pancreatic cancer

* Post-operative PFC was developed in 2 after PPPD, 1 after Whipple and 2 after distal pancreatectomy.

§ Symptoms were 3 with pain and 1 with dysphagia



Deployment SPAXUS™ under EUS-guidance

Result

The median age of 11 patients was 57 (42-76) and male was 10 of 11 patients. The median size of PFC was 80 mm (60-160 mm). SPAXUS™ was successfully placed all patients and PFC resolution was achieved in all 11 patients at median of 35 days after stent placement. The median procedure time was 7 min (5-10 min). Three cases of fever were developed during immediate post-procedure period and all of them were successfully treated with intravenous antibiotics. No other immediate post-procedure adverse events were seen. One case of stent occlusion was developed 40 days after procedure and endoscopic stent cleaning with retrieval balloon was conducted. Until now, no case of PFC recurrence was observed.

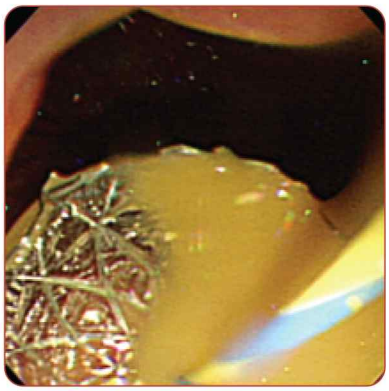
Table 2. Outcomes of EUS-guided PFC drainage with SPAXUS™

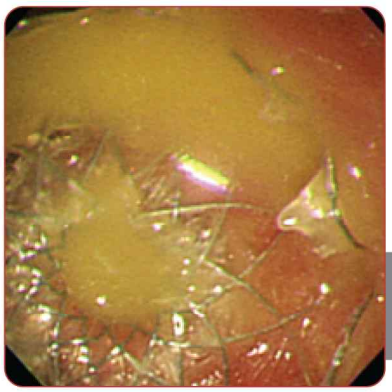
	EUS guided PFC drainage (N = 11)
Median procedure time (range), min	7 (5-10)
Needle knife	11 (100%)
Balloon dilatation	11 (100%)
Technical success	11 (100%)
Clinical success	11 (100%)
Immediate adverse event	
fever	3 (27%)†
Delayed adverse event	
Occlusion	1 (9%)‡
Migration	0
Median stent indwelling duration, days	35 (16-228)*

† All patients with fever after procedure were successfully treated with antibiotics.

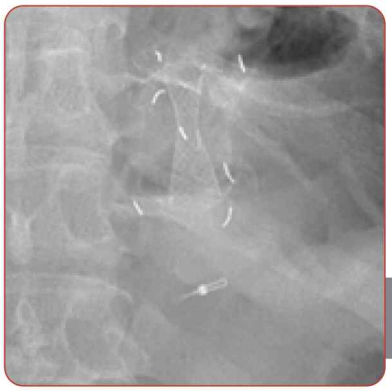
‡ The cases of stent occlusion developed at 40 days after procedure and successfully treated with endoscopic stent cleaning using retrieval balloon.

* Indwelling duration is still not confirmed because 2 patients are now on follow up.

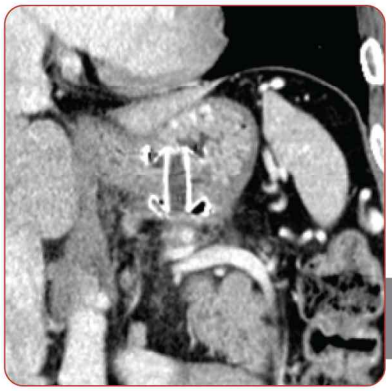




Endoscopic view of PFC drainage through SPAXUS™



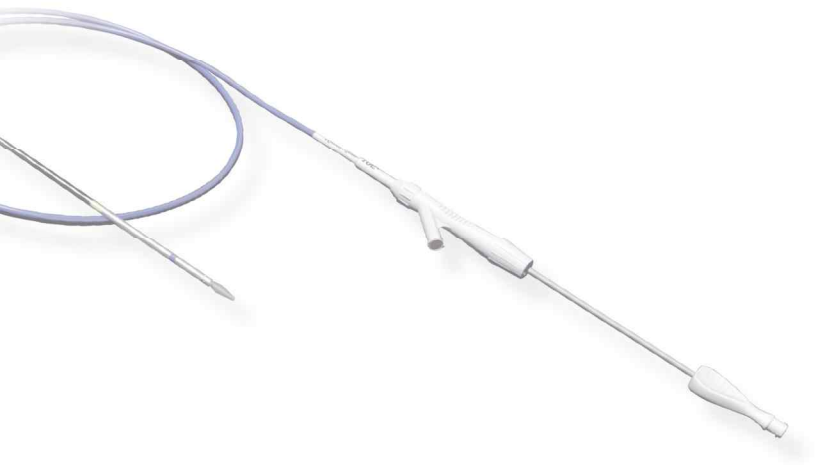
Fluoroscopic image of Fully deployed SPAXUS™



CT Scan of lumen apposition using SPAXUS™

Conclusion

EUS-guided pseudocyst drainage with SPAXUS™ was conducted effectively and safely in our institute until now. Further multicenter experience would be helpful to clarify the role of this procedure.



BETA™ Stent for the treatment of post laparoscopic sleeve gastrectomy leaks

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Introduction

Laparoscopic Sleeve Gastrectomy (LSG) is a restrictive bariatric intervention. Leaks following LSG occurs in 1-2% of the cases [(1)] and the management is usually endoscopic [(2)]. Treatment of post-LSG leaks by insertion of a specific "anti-migration" fully covered Self Expandable Metal Stent (SEMS) can obtain leak closure with 2 endoscopic procedures, short hospitalization and early resumption of oral feeding.

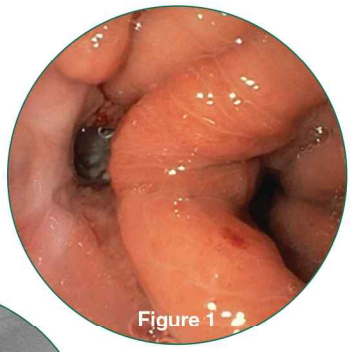

Figure 1

Patient History

A 27-year-old lady (BMI 42) underwent LSG that was complicated from a dehiscence of the surgical staple-line requiring a percutaneous drainage of an infected collection. The patient was referred to our unit 3 weeks later.

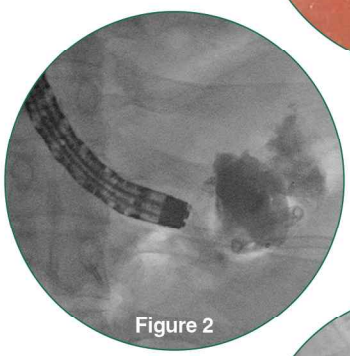

Figure 2

Procedure

The procedure was performed under endoscopic and fluoroscopic control and general anesthesia. CO_2 insufflation was used. The leak was visible at the cardia (Figure 1) and the fistula was seen after contrast injection (Figure 2). After placement of a stiff guidewire, a specific bariatric SEMS (Niti-S™ BETA™ stent; Taewoong Medical, Seoul, Korea) was inserted under fluoroscopic control: the leak resulted immediately closed without evidence of contrast extravasation (Figure 3). The BETA™ stent has 2 anti-migration bumpers, a 32 mm proximal flared end that adhere to the esophageal wall and a length between 18 and 23 cm to bypass the gastric pouch. The patient was discharged 2 days later tolerating a liquid diet. One month later the BETA™ stent was easily removed with a foreign forceps and healing of the fistula was documented (Figure 4, 5). After 32 months follow-up the patient is asymptomatic.

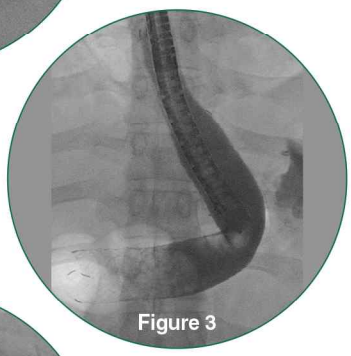

Figure 3

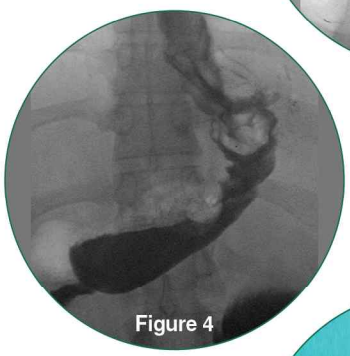

Figure 4

Discussion

Endoscopic treatment of post-LSG leaks is challenging. Available options include OTSC clip placement [(3)] and the insertion of double pigtails stents [(4)]; these approaches need repeated procedures [(3, 4)], long hospitalization and parenteral/enteral nutrition[(4)]. The BETA™ stent can obtain post-LSG leaks closure with 2 endoscopic procedures, short hospitalization and the patient can tolerate a liquid diet.

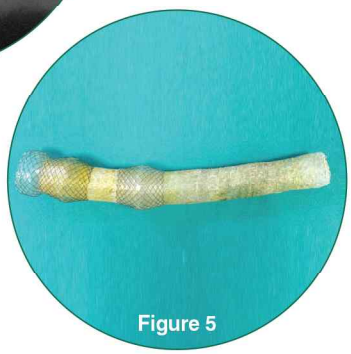

Figure 5

References

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(2) Christophorou D, Valats J, Funakoshi N et al. Endoscopic treatment of fistula after sleeve gastrectomy: results of a multicenter retrospective study. Endoscopy 2015; 47: 988–996
(3) Keren D, Eyal O, Sroka G et al. Over-the-scope clip (OTSC) system for sleeve gastrectomy leaks. Obes Surg 2015; 25: 1358–1363
(4) Donatelli G, Dumont J, Cereatti F et al. Treatment of leaks following sleeve gastrectomy by endoscopic internal drainage (EID). Obes Surg 2015; 25: 1293–1301

Feasibility, efficacy and safety of a new intraductal radiofrequency ablation device in patients with inoperable biliopancreatic tumors complicated with obstructive jaundice: results of an open label phase 2 trial (IGNITE-1)

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Introduction

Endoscopic stenting of unresectable malignant bile duct obstruction is generally accepted as the primary approach to reestablish biliary drainage and saveguard the patient from jaundice and cholangitis and maintain quality of life. Unfortunately, jaundice re-appears in over 50% of patients within 6 months because of stent-dysfunction due to tumor ingrowth or clogging or tumor extension in more proximal bile ducts/branches.

Aims & Methods

In this single center open-label phase-2 study we aimed to test feasibility, efficacy and safety of a new endoscopically applied intraductal radiofrequency ablation (RFA) device (ELRA-Electrode+VIVA combo RF Generator, STARmed; Goyang-si, Gyeonggi-do, Republic of Korea) prior to biliary stenting in patients with inoperable biliopancreatic tumors complicated with obstructive jaundice and compare these results to a matched historical control group without RFA (NCT02468076). The historical control group was matched for age, sex, tumor type, AJCC stage, bilirubin level, chemotherapy and time from diagnosis tumor till ERCP.

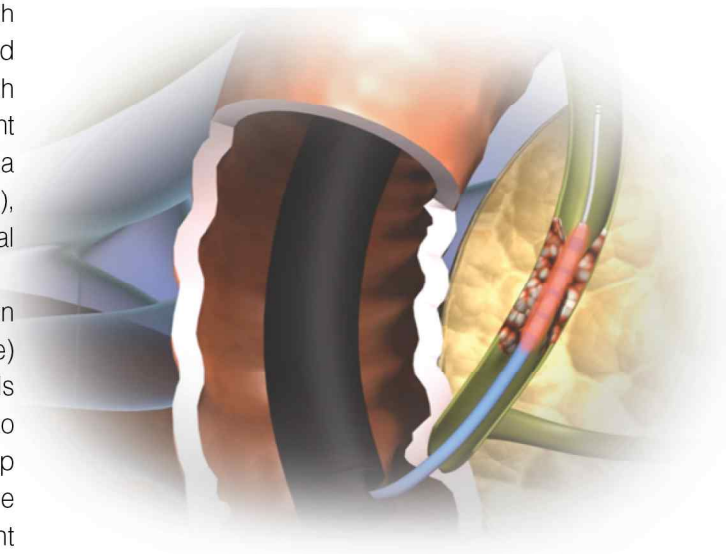
Results

Between December 2014 and November 2015, 18 patients (9 with distal and 9 with hilar malignant obstruction) underwent ERCP-directed RFA and were compared to a matched historical control group with stenting alone. RFA-patients were on average 72 years old, predominant male (15M/3F) and diagnosed with inoperable pancreas carcinoma (n=7), distal (n=2) or hilar cholangiocarcinoma (n=9, Bismuth 3a (n=3), 3b (n=3), 4 (n=3)). Eleven of 18 patients were treated with additional chemotherapy.

All RFA-applications were succesfully applied to the intended region without immediate complications (i.e. hemobilia, infarction, leakage) within 72 hours or during first 3 months post-RFA. Bilirubin levels post-RFA and stenting decreased significantly within 7 days (7.8±1 to 1.7±0.4mg%, P<0.0001) and turned out lower in the control group with only stenting (P=0.02). The average stent patency proved more sustained after RFA (170±28 vs 106±10 days, P<0.001) with stent dysfunction occurring in 4/18 RFA-patients compared to 9/18 controls (P=0.08) with similar average time to dysfunction (112±31 vs 112±23, P=0.997). In terms of survival, application of RFA delivered a survival benefit in comparison to the control group (median survival 230 vs 145 days, P=0.0078) with the best outcome for the subgroup treated with RFA in combination with chemotherapy (P=0.0064).

Conclusion

Intraductal RFA using the ELRA-device in patients with inoperable biliopancreatic complicated with jaundice appeared 100% feasible and safe. Additionally, RFA resulted in a more efficient relief of bile duct obstruction and maintenance of stent patency compared to a historical matched control group with only stenting. Moreover, a surival benefit is suggested when RFA is combined with palliative chemotherapy.



Safety and Efficacy of Endobiliary Radiofrequency Ablation in Swine Model

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Introduction

Long-term biliary drainage is the most important factor for survival in patients with malignant biliary obstruction. There have been many attempts to modify the stent design and additional methods to prolong the stent patency, but no effective method has been proven. Endobiliary radiofrequency ablation (EB-RFA) is a new endoscopic palliation and adjunctive tool, however, there is a possibility of a possible iatrogenic thermal injury leading to perforation or bleeding.

Aim&Methods

Aim to assess the effects of thermal and coagulation injury after in vivo EB-RFA using a novel RFA catheter with a temperature sensor in a swine model. Twelve mini pigs were divided into four groups according to power (33mm 10W electrode vs 18mm 7W electrode) and RFA target temperature (75℃ vs 80℃). All mini pigs underwent endoscopic retrograde cholangiography (ERC) and target temperature controlled EB-RFA for 120 seconds. Additional cholangiogram was taken immediately after RFA, and all pigs were sacrificed after 24 hours to assess the macroscopic/microscopic RFA injury.

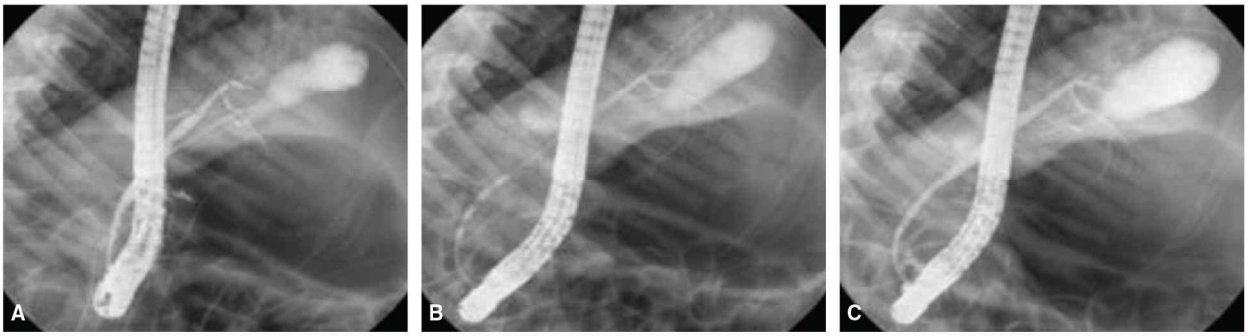
Results

The ERC and application of the EB-RFA was successful in 100%, and post-RFA cholangiogram did not show the contrast leakage. Macroscopic ablation length and microscopic maximal injury depth of 10 watts using 22mm RFA electrode is significantly longer and deeper than 7 watts using 18mm electrode (24.3±2.0 vs. 18.5±3.3mm, p=0.015; 2.93±0.67 vs. 2.05±0.27mm, p=0.002). Microscopic ablation area (microscopic ablation length x maximal injury depth) of 10 watts is also significantly larger than 7 watts (55.0±13.3mm^2 vs. 36.5±8.0mm^2, p=0.015). However, there are no statistically differences of macroscopic/microscopic ablation related parameters according to target temperature. In addition, the assessment of resected specimen at 24 hour after RFA did not show any perforation or bleeding.

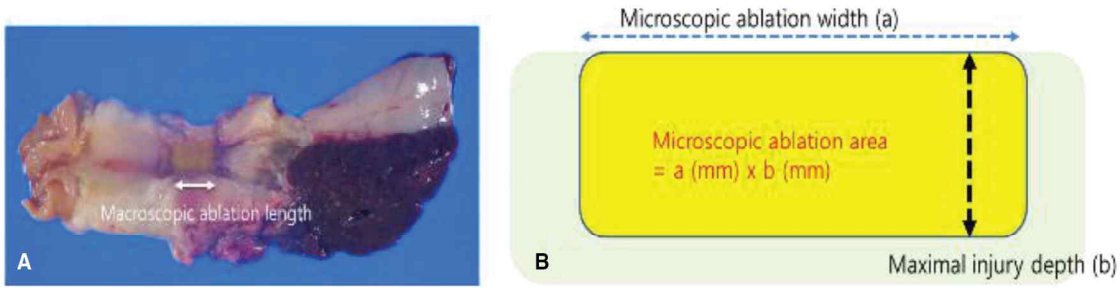
[Table 1] Efficacy of radiofrequency ablation according to different RFA power and target temperatures

	RFA power and electrode length			RFA target temperature		
	10 W 33-mm (Group A/B, n=3/3)	7 W 18-mm (Group C/D, n=3/3)	p-value	75℃ (Group A/C, n=3/3)	80℃ (Group B/D, n=3/3)	p-value
Macroscopic ablation length (mm)	24.3 ± 2.0	18.5 ± 3.3	0.019	20.5 ± 3.8	22.3 ± 4.3	0.373
Microscopic ablation length (mm)	18.8 ± 1.7	17.7 ± 2.3	0.224	19.3 ± 1.9	17.2 ± 1.6	0.065
Microscopic maximal injury depth (mm)	2.9 ± 0.7	2.1 ± 0.3	0.004	2.7 ± 0.8	2.3 ± 0.5	0.589
Microscopic ablation area (mm^2)	55.0 ± 13.3	36.5 ± 8.0	0.016	51.6 ± 16.4	39.8 ± 9.7	0.200

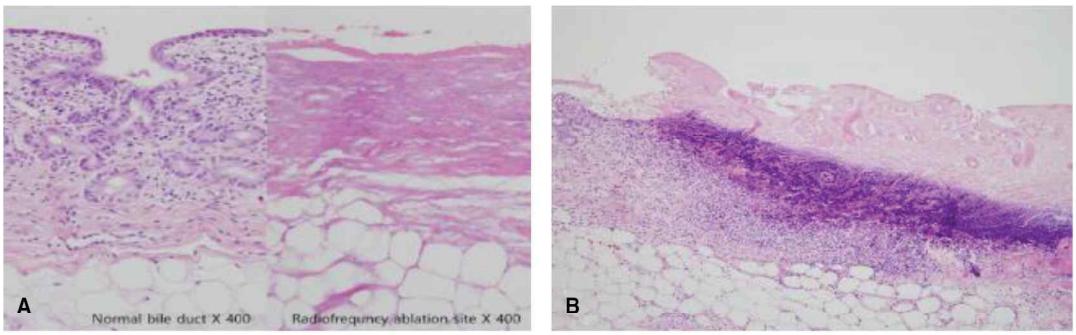
[Figure 2] Endobiliary radiofrequency ablation in miniature pig. (A) Index cholangiogram was taken in order to identify adequate contact site of bile duct for EB-RFA (B) EB-RFA was performed for 120 seconds. (C) Immediate post-RFA cholangiogram was taken to rule out perforation and bleeding.



[Figure 3] Macroscopic and microscopic variables for comparing the results of endobiliary RFA. (A) Macroscopic ablation length (B) Microscopic ablation area was calculated as the product of microscopic ablation width (a) and maximal injury depth (b)



[Figure 4] Histologic images of bile duct after radiofrequency ablation (A) In the radiofrequency ablation area, tissue and cells are converted into a dry, dull, fairly homogenous eosinophilic area without unclear staining as a result of the coagulation of proteins that occurs due to heating effects. (B) In the trasition zone, a distinct dense inflammatory cell infiltration was found.



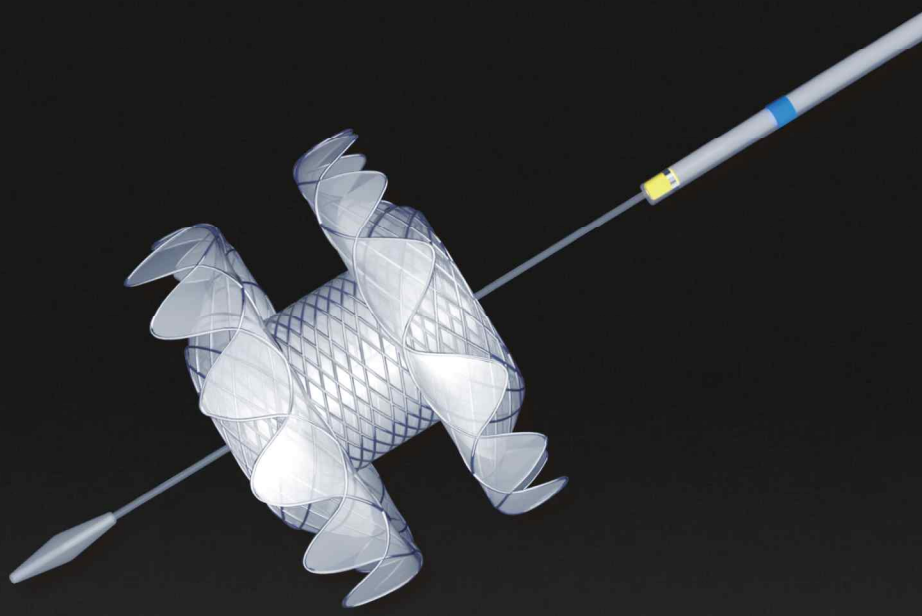
Conclusions

Endobiliary radiofrequency ablation with novel RFA catheter ELRA™ successfully ablates the normal bile duct wall without complications in vivo swine model. The optimal power setting of radiofrequency ablation was 7-10 watts at target temperature of 75℃- 80℃ for 2minutes. Further prospective human clinical studies are warranted in order to validate the effectiveness of EB-RFA treatment in patients with malignant biliary obstruction

[Efficacy of endobiliary RFA according to power and electrode length]

	10 watts (33mm length)	7 watts (18mm length)	p-value
Macroscopic ablation length (mm)	24.3 ± 2.0	18.5 ± 3.3	0.019
Microscopic ablation length (mm)	18.8 ± 1.7	17.7 ± 2.3	0.224
Microscopic maximal injury depth (mm)	2.93 ± 0.67	2.05 ± 0.27	0.004
Microscopic ablation area (mm^2)	55.0 ± 13.3	36.5 ± 8.0	0.016

Taewoong NiTi-S™



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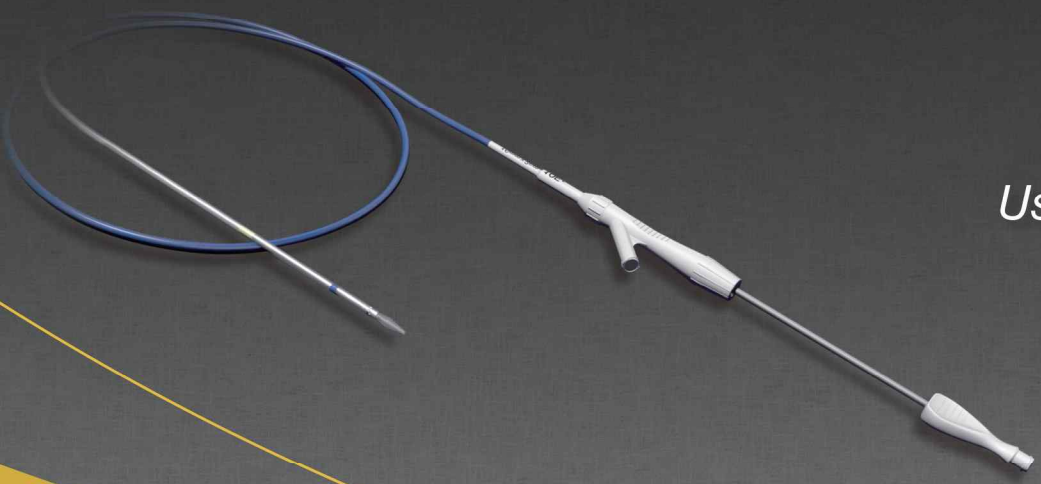
or a gallbladder



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by Takao Itoi et al [Gastrointest Endosc 2013;78:934-939]

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