

Q2 2021



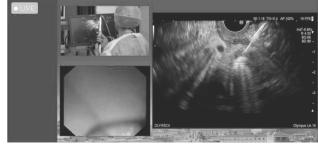














EUS STENTING BY EXPERTS

Please visit our online training website <u>www.taewoongotc.com</u> for more details and for the full interview.

Dr. Benedetto Mangiavillano from Humanitas

Medical Care, Italy is one of the frontier experts on

EUS-guided stenting in gastroenterology.

In this interview, Dr. Benedetto presents EUSguided pseudocyst drainage, EUS-guided
gastrojejunostomy, and EUS-guided biliary

drainage with HOT SPAXUS™ experience and he
shares his knowhows for the procedure as well.



Dr. Marc Giovannini from Paoli-Calmettes Institute,
France is well known as a pioneer in Endoscopy
Ultrasound. He is the most experienced doctor in
diagnosing and treating different gut, pancreas, and
liver by EUS. In this interview, he answers to various
questions regarding EUS-guided pseudocyst drainage
with HOT SPAXUS™ and EUS-guided
hepaticogastrostomy with Niti-S GIOBOR™ stent.



EXPERT'S INTERVIEWDr. Benedetto Mangiavillano



EXPERT'S INTERVIEW

Dr. Marc Giovannini



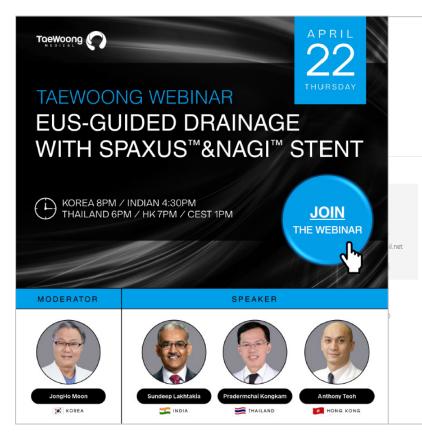


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WEBINAR REVIEW

TAEWOONG WEBINAR

EUS GUIDED DRAINAGE WITH SPAXUS AND NAGI STENT

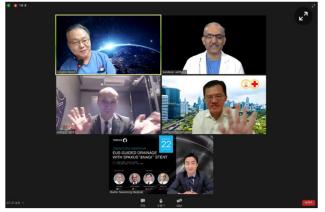


새로운 금속배액관 세계 석학들 극찬

순천향대부천병원 문종호 교수 개발...췌장 담관 질환 효과적 시술



KOREAN NEWS LINK (CLICK HERE)



직접 개발한 새 금속 배액관을 주제로 국제 웨비나를 개최한 순천향대 부천병원 소화기내과 문종호 교수(좌측 상단)

최신기사

의약품·의료기기 인허가 과정 '개선' 추진

백신기업혐의체 17일 출범 50대 접종 본격화 … 1차목표 3000만명 의협, 국민건강보호위원장에 최재욱 교수 위촉 강재영 부천세종병원 내과부장, 병협회장 표창 …

이기기사

- 01 사회적 거리두기 수도권 2단계·비수도권 1.5...
-)2 해외 예방접종 완료자 '격리면제' 추진
- 03 대리수술 논란 인천 척추전문병원, '인증 선..
- 04 '코로나 바이러스2 항체 검사' 신의료기술 통과
- 05 아주대병원 고위험산모 치료센터 개소 심포..
- 06 추무진 이사장, 신현영 의원과 북한 보건의.

The webinar held on April 22nd showed a high attendance rate with 342 registered and 178 participating. The webinar was also reported in the Korean newspaper the next day.

Please join #TaewoongOTC to watch full video of the webinar



#NAGI

2 ENDO LIVE 2021 LIVE CASE OF HOT SPAXUS & EUSRA

At Endo Live 2021, which was held

from May 5th to 7th, Dr. Giovannini from France performed the live procedure of HOT SPAXUS™ and EUSRA™.

HOT SPAXUS™ was inserted for pancreatic fluid collection and EUSRA™ was used for a pancreatic neuroendocrine tumor.

All operations were successfully completed.

#HOTSPAXUS

#EUSRA

#Euromedical







Marcos Eduardo Lera

Hospital da clinicas da faculdade de medicina da USP-HC são paulo









EUS guided pseudocyst drainage using HOT SPAXUS™

Congratulations for the successful 1st case of HOT SPAXUS™ by the Brazilian Team, Dr. Marcos Eduardo Lera, Dr. Igor Proença and Dr. Spencer Cheng!

They successfully completed the procedure of HOT SPAXUS™ for the patient with pancreatic fluid collection.

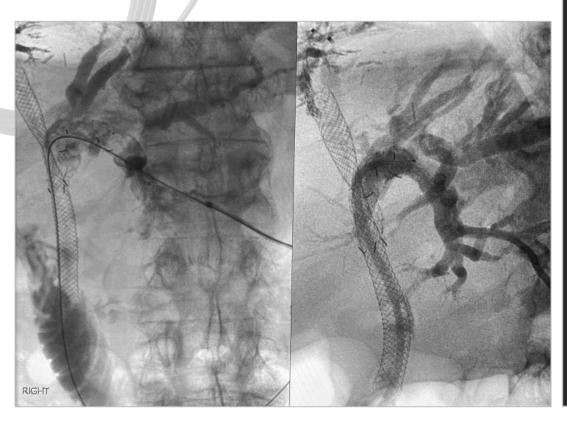
#HOTSPAXUS

#Prosurgery

ACTIVITIES

Mayur Kumar

Consultant gastroenterologist at king's college hospital NHS foundation trust



Combined ELRA[™] case with Endoscopy and Interventional Radiology

The Endoscopy Department at Princess Royal University Hospital/King's College Hospital Foundation Trust carried out one of our first ERCP and RFA cases using the ELRA™ radiofrequency ablation system from Taewoong Medical for a patient with tumor ingrowth and overgrowth diagnosed with Inoperable Hilar Cholangiocarcinoma and metal stents in situ. This was a joint procedure with IR colleagues starting with an endoscopic 4-ring 18mm ELRA™ probe, used for three intra-stent ablations to treat tumor ingrowth inside one of the Taewoong Medical Niti-S LCD biliary stents imbricated with another stent at the hilum. This was followed by percutaneous access through a 7Fr sheath with a 4-ring 33mm short shaft ELRA™ probe for two more ablations. This combined approach led to a successful result for the patient as demonstrated in the fluoroscopy images.

#ELRA

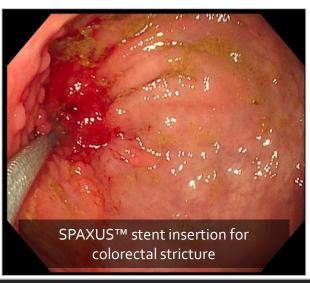
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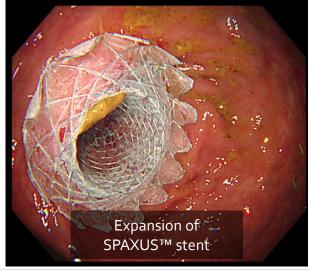
第2第38

ACTIVITIES

Emad Aljahdli

Chairman of GI oncology unit at king abdulaziz university hospital at king abdulaziz university







Endoscopic treatment for Colorectal anastomotic stricture using SPAXUS™

Amazing response to endoscopic therapy for a refractory colorectal anastomotic stricture after using lumen apposing metal stent LAMS.

The patient was a 64 y/o post colon cancer resection who suffered severe stenosis at the site of anastomosis. He had failed multiple endoscopic interventions using uncovered and covered SEMSs, CRE TTS balloon dilation and stricturotomy. The LAMS used in this case was cold SPAXUS and was placed for 4 weeks. From the pictures you can tell the dramatic response. I believe the role of LAMS continues to grow as an alternative solution to many endoscopic challenges. Case done at King AbdulAziz University Hospital.

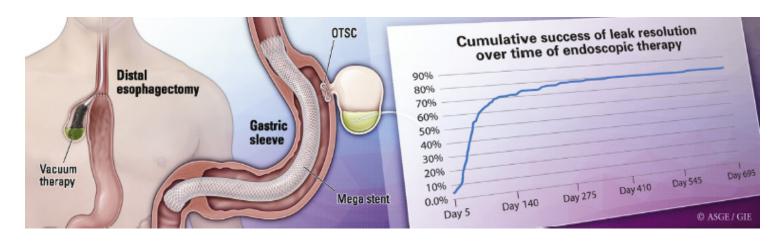
CLINICAL UPDATES

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NITI-S MEGA STENT / EUSRA / ELRA

Retrospective multicenter study on endoscopic treatment of upper GI postsurgical leaks

by Eduardo Rodrigues-Pinto et al. [Multicenter Study Gastrointest Endosc. 2021 Jun;93(6):1283-1299.e2.]



BACKGROUND AND AIMS

Therapeutic endoscopy plays a critical role in the management of upper GI (UGI) post-surgical leaks. Data are scarce regarding clinical success and safety. Our aim was to evaluate the effectiveness of endoscopic therapy for UGI postsurgical leaks and associated adverse events (AEs) and to identify factors associated with successful endoscopic therapy and AE occurrence.

METHODS

This was a retrospective, multicenter, international study of all patients who underwent endoscopic therapy for UGI postsurgical leaks between 2014 and 2019. Results: Two hundred six patients were included. Index surgery most often performed was sleeve gastrectomy (39.3%), followed by gastrectomy (23.8%) and esophagectomy (22.8%).

The median time between index surgery and commencement of endoscopic therapy was 16 days. Endoscopic closure was achieved in 80.1% of patients after a median follow-up of 52 days (interquartile range, 33-81.3). Seven hundred seventy-five therapeutic endoscopies were performed. Multimodal therapy was needed in 40.8% of patients. The cumulative success of leak resolution reached a plateau between the third and fourth techniques (approximately 70%-80%); this was achieved after 125 days of endoscopic therapy. Smaller leak initial diameters, hospitalization in a general ward, hemodynamic stability, absence of respiratory failure, previous gastrectomy, fewer numbers of therapeutic endoscopies performed, shorter length of stay, and shorter times to leak closure were associated with better outcomes. Overall, 102 endoscopic therapy—related AEs occurred in 81 patients (39.3%), with most managed conservatively or endoscopically. Leak-related mortality rate was 12.4%.

CONCLUSIONS

Multimodal therapeutic endoscopy, despite being time-consuming and requiring multiple procedures, allows leak closure in a significant proportion of patients with a low rate of severe AEs.

Long-term outcome after EUS-guided radiofrequency ablation: Prospective results in pancreatic neuroendocrine tumors and pancreatic cystic neoplasms

by Authors Marc Barthet et al. [Endosc Int Open 2021; 09: E1–E8]

BACKGROUND AND STUDY AIMS

Endoscopic ultrasound guided radiofrequency ablation (EUS-RFA) for pancreatic neuroendocrine tumors (NETs) and intraductal pancreatic mucinous neoplasia (IPMN) with worrisome features or high-risk stigmata (WF/HRS) has been evaluated in few series with short-term outcomes. This study's primary endpoint was to assess the long-term efficacy of EUS-RFA in patients with NETs or pancreatic cystic neoplasms (PCNs) over at least 3 years.

► Table 3 PCN follow-up

| Inclusion | One year FU | | → 3 years FU | |
|--|---|--------|--|---|
| | Disappearance 11 cases Significant response | 64.7 % | | Disappearance 6 cases 40% (Median initial size 18 mm [11–37 mm]) |
| 17 patients Efficacy 1 year Significant response 70.5% | 1 case Failure 5 cases | 5.8% | 15 patients Followed Efficacy 3 years Significant response 66.6% | Significant response 4 cases 26.6% (Median initial size 12 mm [9–32 mm]) Failure 5 cases 33.3% (Median initial size 35 mm [25–76mm]) |
| Mural nodules (12 cases) | Disappearance 100% | | Mural nodules 100% | Disappearance 100% |
| | 0 mural nodules | | | 0 mural nodules |

PATIENTS AND METHODS

Twelve patients had 14 NETs with a mean 13.4-mm size (10–20) and 17 patients had a cystic tumor (16 IPMN, 1 MCA) with a 29.1-mm mean size (9–60 were included. They were treated with EUS-guided RFA, evaluated prospectively at 1 year, and followed annually for at least 3 years. Results The mean duration of follow-up was 42.9 months (36–53). Four patients died during follow-up (17–42 months) from unrelated diseases. At 1-year follow-up, and 85.7 % complete disappearance was seen in 12 patients with 14 NETs. At the end of follow up (45.6 months), complete disappearance of tumors was seen in 85.7 % of cases. One case of late liver metastasis occurred in a patient with initial failure of EUS-RFA. At 1-year follow-up, a significant response was seen in 70.5 % of 15 patients with PCNs. At the end of the follow-up, there was a significant response in 66.6 % with no mural nodules. Two cases of distant pancreatic adenocarcinoma unrelated to IPMN occurred.

CONCLUSIONS

EUS-RFA results for pancreatic NETs or PCNs appear to be stable during 42 months of follow-up.

EFFICACY AND SAFETY OF TEMPERATURE-CONTROLLED ENDOBILIARY RADIOFREQUENCY ABLATION IN ADVANCED MALIGNANT HILAR BILIARY OBSTRUCTION: A MULTICENTER RANDOMIZED COMPARATIVE TRIAL

by Huapyong Kang et al.

Non-RFA group

Abstract Body

PURPOSE

Endobiliary radiofrequency ablation (EB-RFA) is an emerging palliative treatment for malignant biliary obstruction. However, the applicability of EB-RFA to advanced malignant hilar biliary obstruction (MHBO) is not yet clear. We aimed to evaluated the efficacy and safety of EB-RFA for advanced MHBO using temperature-controlled RFA system.

METHODS

Patients with inoperable MHBO by advanced hilar cholangiocarcinoma or gallbladder cancer were randomly assigned to the RFA group or the non-RFA group. In both groups, bilateral plastic stent (PS) was placed during the index procedure, and exchanged to bilateral self-expanding metal stent (SEMS) during the sequential procedure after three months or as soon as possible when premature stent occlusion was occurred before three months. EB-RFA was performed before stent placement in the RFA group. Total event-free stent patency (PS+SEMS), overall survival (OS), and adverse events rate were analyzed. (Clinical trial registration - cris.nih.go.kr; KCTooo3275).

RESULTS

A total of 30 patients were enrolled in three tertiary-care hospitals. Total event-free stent patency and OS did not differ between the groups (RFA vs. non-RFA; 178 days vs. 123 days [P=0.102], 223 days vs. 145 days [P=0.609], respectively). More patients received elective exchange to SEMS without PS occlusion in the RFA group than the non-RFA group (69.2% vs. 23.1%, P=0.018). There were no differences in early (\leq 30 days) and late (>30 days) adverse event rates between the groups. In the RFA group, repeated EB-RFA when exchange to SEMS was performed in two (13.3%) patients. No thermal injury-related adverse events were reported after RFA, such as hemobilia or bile duct perforation.

CONCLUSIONS

Temperature-controlled EB-RFA for advanced MHBO was safe and feasible, and it may prevent premature occlusion of bilateral PS, until patients receive scheduled exchange to SEMS.

Baseline characteristics

| Variables | KrA group | Non-KrA group | P |
|-------------------------------|------------------|------------------|-------|
| variables | (n=15) | (n=15) | |
| Age, years | 76 (71-84) | 72 (59-77) | 0.177 |
| Male | 10 (66.7) | 10 (66.7) | >.999 |
| ECOG-PS | | | |
| 0 | 2 (13.3) | 4 (26.7) | 0.651 |
| 1 | 13 (86.7) | 11 (73.3) | 0.651 |
| Primary site of malignancy | | | |
| Hilar cholangiocarcinoma | 13 (86.7) | 13 (86.7) | >.999 |
| Gallbladder cancer | 2 (13.3) | 2 (13.3) | |
| Bismuth type | | | |
| II. | 2 (13.3) | 3 (20.0) | |
| Ш | 6 (40.0) | 8 (53.3) | 0.640 |
| IV | 7 (46.7) | 4 (26.7) | |
| Metastatic disease | 6 (40.0) | 7 (46.7) | 0.815 |
| Hyperbilirubinemia (≥2 mg/dL) | 12 (80.0) | 14 (93.3) | 0.598 |
| Stricture length, mm | | | |
| Rt. IHD | 21.0 (14.8-29.3) | 17.2 (12.0-22.0) | 0.141 |
| Lt. IHD | 24.5 (15.3-30.0) | 18.0 (12.8-25.6) | 0.213 |
| Temporary biliary drainage | 15 (100.0) | 14 (93.3) | >.999 |
| Palliative Chemotherapy | 2 (13.3) | 8 (53.3) | 0.050 |

RFA group

Abbreviations – ECOG PS, Eastern Cooperative Oncology Group performance status; IHD, Intrahepatic duct. Data presented as median (ICR) or n (%)

ABLATIVE EFFECT OF ENDOBILIARY RADIOFREQUENCY ABLATION FOR HILAR CHOLANGIOCARCINOMA: EVALUATION BY USING PERORAL CHOLANGIOSCOPY AND INTRADUCTAL ULTRASONOGRAPHY

by Yun Nah Lee et al.

Abstract Body

BACKGROUND AND STUDY AIMS

Recently, the endobiliary radiofrequency ablation (RFA) has been showed clinical efficacies in terms of stent patency and/or survival in a management of malignant biliary stricture (MBS). However, there are limitation in evaluating the thermal ablative effect of RFA in the bile duct only using ERCP and radiological diagnostic methods. In this study, we studied the efficacy of RFA by using peroral cholangioscopy (POC) and intraductal ultrasonography (IDUS) before and after endobiliary RFA in hilar cholangiocarcinoma.

PATIENTS AND METHODS

Total 20 patients diagnosed with hilar cholangiocarcinoma were enrolled prospectively. POC using a digital single operator cholangioscopy and IDUS was performed before and 4 weeks after RFA, respectively. IDUS measured maximum wall thickness of tumor. POC confirmed the extent of tumor necrosis and the presence of macroscopic residual tumor in the bile duct. Endobiliary RFA was performed by using an automatically temperature controlled RFA catheter (ELRA®, STARmed, Goyang, Korea).

RESULTS

In 20 patients (median age 73.5 year, 13 males), endobiliary RFA was technically successful in all patients. Before RFA, maximum wall thickness of tumor measured by IDUS was median 5.9 mm (IQR, 4.9-8.2). The maximum wall thickness of tumor was decreased by median 1.1 mm (IQR, 0.5-1.8) after RFA. After RFA, improvement of bile duct patency was observed in 18 patients (90.0%) by POC. During POC after RFA, tumor necrosis was confirmed in all patients. However, macroscopic residual tumor in the bile duct was also observed in 12 patients (60.0%). The stent placed at the time of 4 weeks evaluation after RFA showed median cumulative patency duration of 8.0 months (IQR, 4.0-12.0).

CONCLUSIONS

POC and IDUS was useful to confirm the ability of endobiliary RFA for the thermal ablation of intraductal tumor in patients with hilar cholangiocarcinoma.

OUTCOME AND SAFETY OF ENDOSCOPIC RADIOFREQUENCY ABLATION FOR AMPULLARY ADENOMA WITH INTRADUCTAL EXTENSION: A LARGE SINGLE-CENTER EXPERIENCE

by Sung Hyun Cho et al.

Abstract Body

BACKGROUND AND AIMS

Conventional endoscopic treatment of ampullary adenoma with intraductal extension is challenging. Endoscopic intraductal radiofrequency ablation (ID-RFA) might be treatment of choice for intraductal (common bile duct, CBD or pancreatic duct, PD) extension of ampullary adenoma. The aim of this study was to evaluate the outcome and safety of endoscopic ID-RFA for ampullary adenoma with intraductal extension.

METHODS

We reviewed the prospectively collected endoscopic ID-RFA database at Asan Medical Center to analyze consecutive patients with ampullary adenoma who underwent ID-RFA for intraductal extension of ampullary adenoma between January 2018 and August 2020. Technical success, adverse events, and residual or relapsed tumor were evaluated.

RESULTS

A total of 12 patients (9 CBD, 1 PD, 2 CBD&PD) were analyzed. All of them had underwent endoscopic snare papillectomy before ID-RFA. Single session of ID-RFA for residual or relapsed intraductal extension of ampullary adenoma was performed successfully (technical success 100%). Biliary or pancreatic stenting was routinely performed after ID-RFA to prevent ductal stricture. At least twice (range 2-3) follow-up endoscopic biopsy was carried out after procedure. During median follow-up of 204 days, no residual or relapsed tumor was noted on follow-up biopsy specimens (clinical success 100%). 5 patients experienced adverse events (2 acute pancreatitis, 2 bleeding, 1 CBD stricture) which were improved after medical or endoscopic treatment, and no life-threatening adverse events occurred.

CONCLUSIONS

In ampullary adenoma with intraductal invasion, endoscopic ID-RFA was technically feasible and, showed good efficacy and safety profile. Further study for long term outcome of ID-RFA is needed.

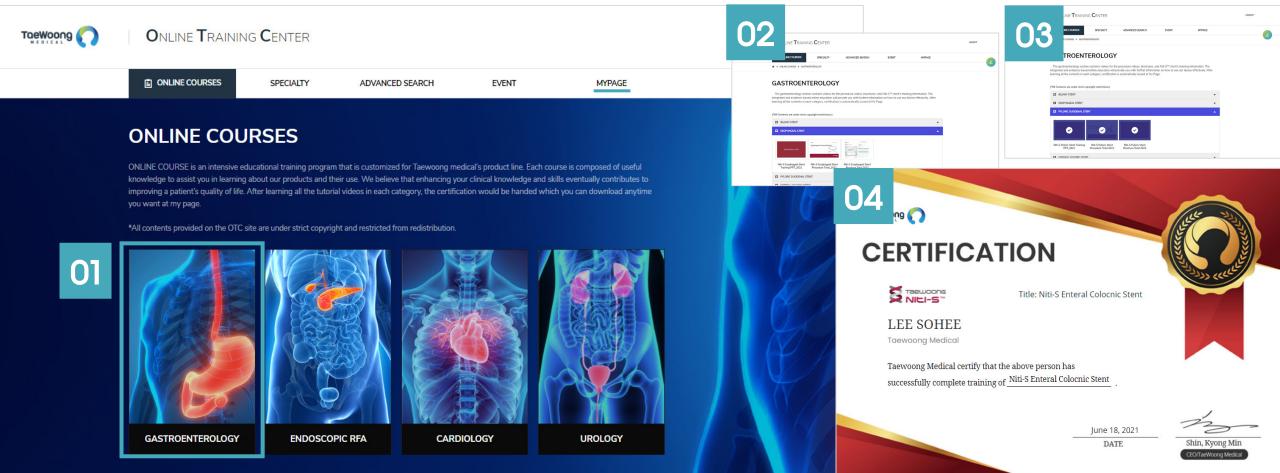
TW OTC UPDATE NEWS

#TWOTC

Taewoong OTC is constantly uploading various contents.

On June 1st, the "ONLINE COURSES – **GASTROENTEROLOGY**" was finally open.

ONLINE COURSE is an intensive educational training program that is customized for Taewoong medical's product line. Each course is composed of useful knowledge to assist you in learning about our products and their use. We believe that enhancing your clinical knowledge and skills eventually contributes to improving a patient's quality of life. After learning all the tutorial videos in each category, a certification would be handed which you can download anytime you want at MYPAGE.





ANASTOMOTIC STRICTURE

AFTER LIVER TRANSPLANTATION

KAFFES STENT

FOR INTRADUCTAL STENT PLACEMENT

