Statement	Median	MAD-M	Count in 1-3 range	Count in 4-6 range	Count in 7-9 range
Activity preceding interventional endoscopy fellowship					
Trainees should be competent in upper endoscopy and colonoscopy.	9.0	0	0	0	20
Trainees should have completed training in an ACGME (or equivalent) accredited fellowship in gastroenterology and hepatology.	9.0	0.2	0	0	20
Structure of interventional endoscopy programs					
A trainee should have a defined % of their effort/time devoted to supervised IE clinical activities and this should be no less than 80%.	9.0	0.7	0	2	18
A trainee is encouraged to develop and execute a mentored original research study.	7.0	1.2	1	5	14
An IEFP should have a minimum number of trainers (Agreed threshold 2)	9.0	1.1	1	3	16
An IEFP must offer training in both EUS and ERCP.	9.0	0.5	0	1	19
An IEFP must offer training in endoscopic mucosal resection.	8.5	0.9	0	1	19
Trainees should undergo competency assessments using validated tools (when available) at regular intervals and with documented feedback	9.0	1.0	1	1	18
IEFP directors should report on the number of trainers and trainees on the IEFP match website	9.0	0	0	0	20
Trainees should track outcomes related to participated procedures	9.0	0.3	0	0	20
Trainees should have a basic understanding of radiation safety and interpretation of fluoroscopy	9.0	0.2	0	0	20
ERCP Measures					
All ERCP trainees should also have received or be undergoing EUS training.	9.0	0.8	0	3	17
For ERCP trainees, IEFPs should have a minimum of two trainers who participate in hands-on training.	9.0	2.0	2	5	13
A trainee should have a minimum number of ERCP procedures that includes meaningful hands on exposure during training (Agreed threshold: 200)	9.0	0	0	0	20
Prior to an assessment of competence, a trainee should have participated in a minimum number of ERCPs with hands on exposure (Agreed threshold: 150)	9.0	0.8	0	2	18
Prior to an assessment of competence, a trainee should have participated in a minimum number of ERCPs with hands on exposure in patients with a native papilla. (Agreed threshold: 50)	9.0	0.8	0	3	17
Prior to an assessment of competence, a trainee should have performed a minimum number of sphincterotomies (Agreed threshold: 25)	9.0	0.6	0	3	17
An ERCP trainee should track technical quality metrics such as ability to cannulate independently during their training.	9.0	0.5	0	0	20

MAD-M, mean absolute deviation from the median; IPRAS, Inter-percentile Range Adjusted for Symmetry (IPRAS)

Table 1: Appropriate measures for minimum standards for interventional endoscopy fellowship programs (IEFPs) – activity preceding training, structure of training programs and ERCP training (all measures rated as appropriate using BIOMED, p-value and IPRAS)

Statement	Median	MAD-M	Count in 1-3 range	Count in 4-6 range	Count in 7-9 range
EUS training					
A trainee should have a minimum number of EUS procedures with hands-on exposure (Agreed threshold 200)	9.0	0	0	0	20
Prior to an assessment of competence, a trainee should have participated in a minimum number of EUSs with hands-on exposure (Agreed threshold 150)	9.0	0.4	0	2	18
Prior to an assessment of competence, a trainee should have participated in a minimum number of EUSs with hands-on exposure in patients for pancreaticobiliary indications (Agreed threshold 50)	9.0	0.4	0	2	18
Prior to an assessment of competence, a trainee should have participated in a minimum number of EUSs with fine needle aspiration/biopsy (FNA/FNB) (Agreed threshold 25)	9.0	0.4	0	1	19
A trainee should track EUS-specific quality metrics including: EUS-FNA/FNB adequacy rate, diagnostic yield	9.0	1.0	1	3	16
EMR training					
For EMR trainees, IEFPs should have a minimum number of trainers who participate in hands-on training (Agreed threshold 2)	9.0	1.3	1	4	15
Trainees learning EMR should be trained in upper and colon EMR	9.0	0.2	0	0	20
Trainees learning upper EMR should also be trained in ablative therapies	9.0	0.6	0	2	18
A trainee must also demonstrate competency in electrosurgical principles	9.0	0.5	0	2	18
A trainee should have a minimum of EMR procedures (upper GI and colon) with hands on exposure during training (Agreed threshold 20)	9.0	0.3	0	1	19
Prior to an assessment of competence, a trainee should have participated in a minimum number of upper and lower EMRs with hands on exposure (Agreed threshold 10)	9.0	0.5	0	1	19
A trainee should track quality metrics from EMR that include independent and complete resection rate	9.0	0.4	0	0	20
Luminal stenting					
For luminal stenting, IEFPs should have a minimum number of two trainers who participate in hands-on training.	9.0	2.1	4	2	14
Trainees learning luminal stenting should be trained in esophageal, gastroduodenal and colon stents.	9.0	0.2	0	1	19
A trainee should have a minimum number of luminal stenting procedures with hands on exposure during training.	9.0	0.2	0	0	20
Prior to an assessment of competence, a trainee should have participated in a minimum number of 10 luminal stenting procedures with hands on exposure.	9.0	0.9	0	3	17
Prior to assessment of competence, a trainee should demonstrate an understanding for the indication and placement of additional stents and retrieving/repositioning migrated stents.	9.0	0.3	0	1	19

Table 2: Appropriate measures for minimum standards for interventional endoscopy training programs – EUS, EMR and luminal stenting training (all measures rated as appropriate using BIOMED, p-value and IPRAS).

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ASGE Presidential Plenary

DUODENAL MUCOSAL REGENERATION INDUCED BY ENDOSCOPIC PULSED ELECTRIC FIELD TREATMENT IMPROVES GLYCEMIC CONTROL IN PATIENTS WITH TYPE II DIABETES - INTERIM RESULTS FROM A FIRST-IN-HUMAN STUDY

Adrian Sartoretto, David O'Neal, Bronte Holt, Fiona Napier-Flood, Arti Rattan, Cheng Yi Yuan, Georgie Cameron, George Marinos, Barham Abu Dayyeh

Institutions: The BMI Clinic, Australia; St Vincent's Health Australia Ltd Fitzroy, Australia; Mayo Clinic Minnesota, USA.
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Background: Type 2 diabetes (T2D) affects 462 million people worldwide. Non-pharmacological interventions that can improve glycemic control in patients inadequately controlled with glucose-lowering medications (GLMs) have a potential to delay insulin initiation and modify disease progression. Duodenal mucosal regeneration (DMR) induced by thermal ablation has been associated with improved glycemic control in T2D patients. Pulsed electric field (PEF) is a unique non-thermal modality that can selectively affect cells via electroporation. This first-in-human study evaluates the safety, feasibility and preliminary efficacy of endoscopic application of PEF to elicit DMR in T2D patients inadequately controlled on GLMs and is the first PEF application in gastrointestinal tract. Method: This is an ongoing multicenter, open-label, treatment-only study. Key eligibility criteria are 18-70 years of age, history of T2D for $\leq$10 years, HbA1c of 7.5%-11.0%, BMI of 24 – 40 kg/m2, C-peptide $\geq$ 333 pmol/l, and on 1-4 non-insulin GLMs. The primary endpoint is the incidence of device- or procedure-related serious adverse events (SAEs) at 12 wks. Secondary endpoints include technical success and changes in glycemic control at 24 wks. The procedure is performed endoscopically using the ReCET™ device (Endogenex Inc.). Patients are followed for 48 wks, with endoscopic follow up at 4 wks. The GLMs are maintained stable for $\geq$12 wks before and $\geq$24 wks after the procedure. Results: To date, 30 patients have been enrolled (Table 1). Technical success was 100%, with a mean treated length of 11.0 $\pm$ 1.9 cm, and median procedure time of 59 min (IQR 42 – 78). No device/procedure-related SAEs occurred. Forty-five device/procedure-related adverse events (AEs) were reported in 23/30 patients. Most reported AEs were sore throat (17/30) and transient diarrhea (9/30). AEs were mild (80%) or moderate (20%) in severity. At 4 wks, the treated areas showed complete healing, mostly unidentifiable endoscopically, with no signs of stricture, ulceration, or other significant findings. The first 12 patients were treated with single energy application (single Tx). The subsequent 18 patients received double energy application (double Tx) and 14 have reached 24 wks. Clinically significant improvements in glycemic control were observed in these 14 patients. At 24 wks, mean HbA1c was 7.5% $\pm$ 1.1% vs. 8.4% $\pm$ 1.0% at baseline ($p<0.01$), FPG 7.5 $\pm$ 1.7 mmol/l vs. 9.8 $\pm$ 2.2 mmol/l ($P<0.01$), and HOMA-IR 4.5 $\pm$ 3.6 vs. 7.4 $\pm$ 3.3 ($p<0.01$). Weight loss was 5.1% $\pm$ 4.1% ($p<0.01$) at 24 wks. An energy dose-response relationship was observed between the single Tx and double Tx dose levels ($P < 0.05$) (Figure 1). Conclusions: This first GI application of PEF in human demonstrated that the technology is feasible, safe, well tolerated by patients, and is associated with clinically meaningful improvement in glycemic control.

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Table 1. Baseline Characteristics

	Single Tx	Double Tx	Total
N	12	18	30
Age (yrs)	50.5 ± 9.5	51.5 ± 8.8	51.1 ± 9.9
Male (%)	66.7%	77.8%	73%
BMI (kg/m^2)	30.1 ± 4.8	32.2 ± 3.0	31.4 ± 3.9
HbA1c (%)	8.8 ± 0.9	8.6 ± 0.9	8.7 ± 0.9
FPG (mmol/L)	9.1 ± 1.3	10.3 ± 2.5	9.8 ± 2.1
T2D duration	5.1 ± 3.0	5.8 ± 2.6	5.5 ± 2.8
Background GLMs (n, %)			
Metformin	12 (100%)	16 (89%)	28 (93%)
Sulfonylureas	6 (50%)	5 (28%)	11 (37%)
SGLT2i	6 (50%)	12 (67%)	18 (60%)
GLP-1a	3 (25%)	1 (6%)	4 (13%)
DPP4	1 (8%)	5 (28%)	6 (20%)
No. of background GLMs			
1	3 (25%)	5 (28%)	8 (27%)
2	4 (33%)	6 (33%)	10 (33%)
3	3 (25%)	6 (33%)	9 (30%)
4	2 (17%)	1 (6%)	3 (10%)

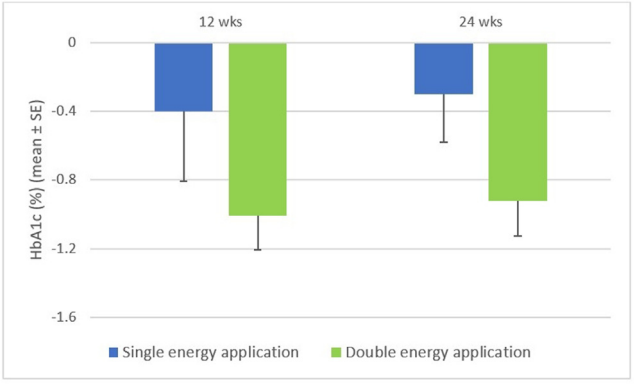

Figure 1. Changes in HbA1c from baseline between energy dose levels

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EVALUATION OF THE IMPACT OF AN AI-AIDED ENDOSCOPIC DIAGNOSIS SYSTEM ON IMPROVING ENDOSCOPY QUALITY AND INCREASING THE LEARNING CURVE FOR BEGINNING COLONOSCOPY TRAINEES: A PROSPECTIVE RANDOMIZED MULTI-CENTER STUDY

Daisuke Yamaguchi, Koichi Miyahara, Takahiro Yukimoto, Ayako Takamori, Yumi Mizuta, Yutaro Fujimura, Suma Inoue, Michito Tomonaga, Yuya Ogino, Kohei Eguchi, Kei Ikeda, Yuichiro Tanaka, Hironobu Takedomi, Hidenori Hidaka, Takashi Akutagawa, Nanae Tsuruoka, Yasuhisa Sakata, Ryo Shimoda, Takahiro Noda, Seiji Tsunada, Motohiro Esaki

Institutions: Karatsu Sekijuji Byoin, Japan; Saga Daigaku Igakubu Fuzoku Byoin, Japan; Kokuritsu Byoin Kiko Ureshino Iryo Center, Japan. Disclosure compliance: I understand. Participant disclosure: Daisuke Yamaguchi: NO financial relationship with a commercial interest; Koichi Miyahara: NO financial relationship with a commercial interest; Takahiro Yukimoto: NO financial relationship with a commercial interest; Ayako Takamori: NO financial relationship with a commercial interest; Yumi Mizuta: NO financial relationship with a commercial interest; Yutaro Fujimura: NO financial relationship with a commercial interest; Suma Inoue: NO financial relationship with a commercial interest; Michito Tomonaga: NO financial relationship with a commercial interest; Yuya Ogino: NO financial relationship with a commercial interest; Kohei Eguchi: NO financial relationship with a commercial interest; Kei Ikeda: NO financial relationship with a commercial interest; Yuichiro Tanaka: NO financial relationship with a commercial interest; Hironobu Takedomi: NO financial relationship with a commercial interest; Hidenori Hidaka: NO financial relationship with a commercial interest; Takashi Akutagawa: NO financial relationship with a commercial interest; Nanae Tsuruoka: NO financial relationship with a commercial interest; Yasuhisa Sakata: NO financial relationship with a commercial interest; Ryo Shimoda: NO financial relationship with a commercial interest; Takahiro Noda: NO financial relationship with a commercial interest; Seiji Tsunada: NO financial relationship with a commercial interest; Motohiro Esaki: Grant/Research Support: Alfresa Pharma Co., Mitsubishi Tanabe Pharma, EA pharma Co., Abbvie GK, Takeda Pharmaceutical Co. Ltd; Speaking and Teaching: Mitsubishi Tanabe pharma Co., Abbvie GK, Janssen Pharmaceutical K.K, EA Pharma Co., Takeda Pharmaceutical Co., Ltd

Background: The recently developed CAD EYE system (Fujifilm, Tokyo, Japan), which provides artificial intelligence (AI) -aided endoscopic diagnosis, has the potential to improve the detection for colorectal polyps. It is essential that gastroenterology trainees improve the quality of total colonoscopy (CS) operations and accelerate their technical progress. The aim of this study was to determine the utility of CAD EYE for CS by comparing endoscopic observation using CAD EYE with conventional endoscopic observation (i.e., white light imaging) in outpatients undergoing CS performed by gastroenterology trainees (i.e., beginner endoscopists). Methods: This was a multi-center, randomized controlled trial at Ureshino Medical Center, Karatsu Red Cross Hospital and Saga University Hospital (UMIN000044031). The study received an academic research grant from the Japanese Society of Gastrointestinal Endoscopy in 2021. Patients were divided into group A (observed using CAD EYE) and group B (observed using white light imaging). Six gastroenterologists with limited experience in CS (i.e., trainees in their third or fourth year after graduation) performed CS using a back-to-back method in pairs with a gastroenterology specialist. The primary endpoint was the adenoma detection rate. The secondary endpoints were the adenoma miss rate (AMR) and 14 assessment of competency in endoscopy tool scores. The learning curve of each trainee was evaluated using the cumulative sum control chart. Results: We analyzed 231 cases (113 in group A, 118 in group B) enrolled from May 2021 to March 2022. There was no difference in the adenoma detection rate of trainees between group A and group B (58.4% versus 61.0%, respectively; p=0.690). There was a significantly lower AMR (26.6% versus 39.7%, respectively; p=0.036) and number of missed adenomas per patient (0.5 versus 0.9, respectively; p=0.004) in group A compared with group B. Group A also scored significantly higher than group B on two items of the assessment of competency in endoscopy tool score—i.e., pathology identification (2.26 versus 2.07, respectively; p=0.030) and interpretation and identifying location of pathology (2.18 versus 2.00, respectively; p=0.038). For the cumulative sum learning curve of trainees, the number of cases in which multiple adenomas were missed by the six trainees who performed CS was lower in group A. Even after accumulating cases, the number of missed adenomas remained consistently lower in group A. Conclusions: The use of CAD EYE can decrease the AMR and improve the ability to accurately locate and identify colorectal adenomas. Thus, CAD EYE is particularly useful for CS in beginning endoscopists.

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MULTICENTER STUDY EVALUATING LEARNING CURVES AND COMPETENCE IN COLORECTAL ENDOSCOPIC MUCOSAL RESECTION (C-EMR) AMONG ADVANCED ENDOSCOPY TRAINEES USING AN EMR STANDARDIZED ASSESSMENT TOOL (EMR-STAT): INTERIM ANALYSIS

Dennis Yang, Muhammad Hasan, Jianbin Zhu, Artur Viana, Sanmeet Singh, Antonio Costantino, Arvind Trindade, Mark Radlinski, Daniel Hogan, Elizabeth Brindise, Rebecca Burbridge, Sam Seleq, Jeffrey Mosko, Danial Shaikh, Pushpak Taunk, Yonathan Hillman, Lionel D'Souza, Fares Ayoub, Salmaan Jawaid, Mohamed Othman, Mohammad Alshelleh, Graham Appelbe, David Diehl, Harshit Khara, Rashmi Advani, Muhammad Mubarak, Srinivas Gaddam, Samuel Burton, Harry Aslanian, Shreyans Doshi, Shailendra Chauhan, Jaehoon Cho, Andrew Joelson, Amrita Sethi, Usman Rahim, Jason Samarasena, Isaac Perry, Ali Ahmed, Shifa Umar, Uzma Siddiqui, Samuel Igbinedion, Sultan Mahmood, Erik Holzwanger, Moamen Gabr, Maham Hayat, Mustafa Arain,

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