Advanced Endoscopy Abstracts

EMR/ESD/FTRD/Closure/Third Space/Bariatrics

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Disclosures

- Consultant for:
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  - Olympus America
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EMR/ESD/Closure devices - Colon

- Has revolutionized how we treat dysplastic and early cancers of the GI tract.
- However, these procedures can be technically challenging.
- The data presented in this section will address ***whether***:
  - Clipping proximal colon EMR sites reduces bleeding
  - There is a superior suturing device for reducing post-ESD bleeding
  - There is an advantage of cold or hot EMR in the colon

Clip Placement Does Not Prevent Delayed Bleeding After EMR (Clipper) for Large Polyps in the Proximal Colon: A Multicenter, RCT

Gijs Kemper, Ayla S Turan, Ramon-Michel Schreuder, Ruud WM Schrauwen, Muhammed Hadithi, Paul Didden, Barbara AJ Bastiaansen, Bas W van der spek, Jochim S Terhaar sive Droste, Mattthijis P Schwartz, Wouter L Hazen, Jan Willem Straathof, Jurjen J Boonstra, Alaa Alkhalaf, Fia J Voogd, Daud Allajar, Wilmar de Graaf, Parweez Koehestanie, Robert Roomer, Rogier JJ de Ridder, Leon MG Moons, Peter D Siersema, Erwin JM van Geenen

Colorectal EMR

Colorectal EMR

- Standard treatment for large (≥20mm) colonic non-pedunculated polyps
- Delayed bleeding (2-10%)
- Prophylactic clipping (PC) reported to reduce delayed bleeding in large proximal polyps
- These trials were mainly performed in tertiary centers

CLIPPER Study - Design

- Randomized controlled trial
- 19 hospitals
- Prophylactic clipping vs no clipping
- EMR of non-pedunculated polyps ≥ 20mm in the proximal colon

CLIPPER – Baseline characteristics

	PC (n=177)	No PC (n-179)
Age, year, mean (SD)	67.8 (8.8)	66.6 (7.9)
Sex, male	117 (66.1)	107 (59.8)
Antiplatelet agents	31 (17.5)	29 (16.2)
Anticoagulants	22 (12.4)	19 (10.6)
Polyp size, mm, mean (SD)	33.3 (10.2)	33.0 (10.7)
Location		
- Splenic flexure	3 (1.7)	0(0)
- Transverse colon	15 (8.5)	38 (21.2)
- Hepatic flexure	26 (14.8)	12 (6.7)
- Ascending colon	92 (52.3)	85 (47.5)
- Cecum	40 (22.7)	44 (24.6)

CLIPPER - Results

			P value
Delayed bleeding (%)			0.30
Yes	16 (9.0)	1 (6.1)	
No	161 (91.0)	93.8)	
Values are n (%)			

My takeaway points…

- Perhaps we can be more selective about which patients to clip after EMR

- I will continue to clip proximal EMR sites on patients who are:
  - High risk for bleeding
  - Numerous co-morbidities

A randomized trial comparing gastric and colorectal endoscopic submucosal dissection defect closure using novel through the scope suturing system with over-the-scope suturing system

Agnihotri, Abhishek; Mitsuhashi, Shuji; Holmes, Ian; Kamal, Faisal; Chiang, Austin L; Loren, David E.; Kowalski, Thomas E.; Schlachterman, Alexander; Kumar, Anand

Jefferson Health
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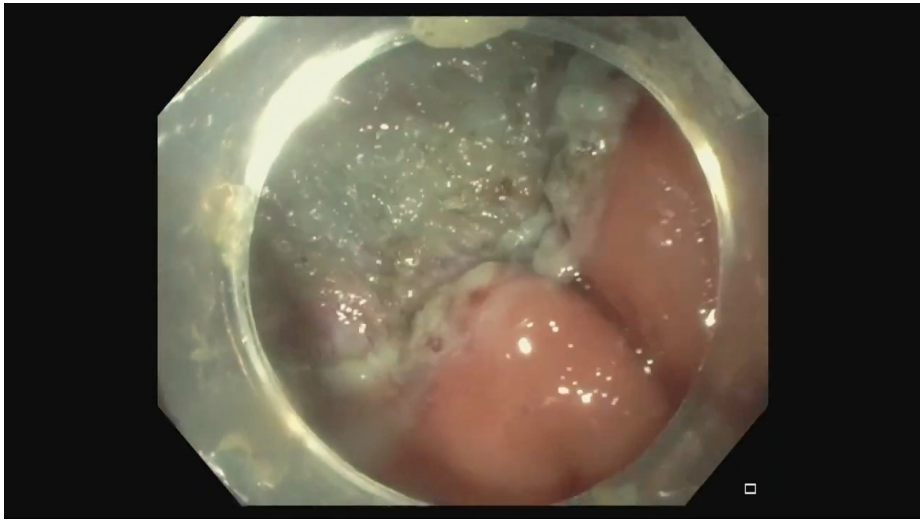
INTRODUCTION

- Perforation (2.9 – 10.4%) and delayed bleeding (1.5 – 8.1%) are known adverse events of ESD.[1]
- Prophylactic defect closure post ESD reduces risk of delayed bleeding (0.9%) compared to no closure (5.2%).[2]

[1]Gastroenterology 2021;160:2317-2327
[2]J Gastroenterol Hepatol 2020;35:1869-1877

AIM

To assess the closure time, technical success, and cost-effectiveness between through the scope helix tack suture system (TTSS) and Over the scope suturing system (OTSS) for closure of gastric and colorectal ESD defects.



METHODS and OUTCOMES

- **Trial Design:**
  - Single center randomized trial (NCT04925271)
  - Consecutive adults for ESD resection of lesions in the stomach, colon and rectum
  - Endoscopist blinded until resection completed
  - Randomized 1:1
  - Crossover after failure allowed
- **Primary outcome:**
  - **Closure time (CT)**: Time from first bite/tack application to the last suture cinch or endoclip application.
  - **Overall closure time (OCT):** End of dissection/hemostasis time to the last suture cinch or endoclip application.
- **Secondary outcomes**
  - Technical success
  - Intraprocedural or delayed AE's
  - Cost effectiveness analysis

RESULTS

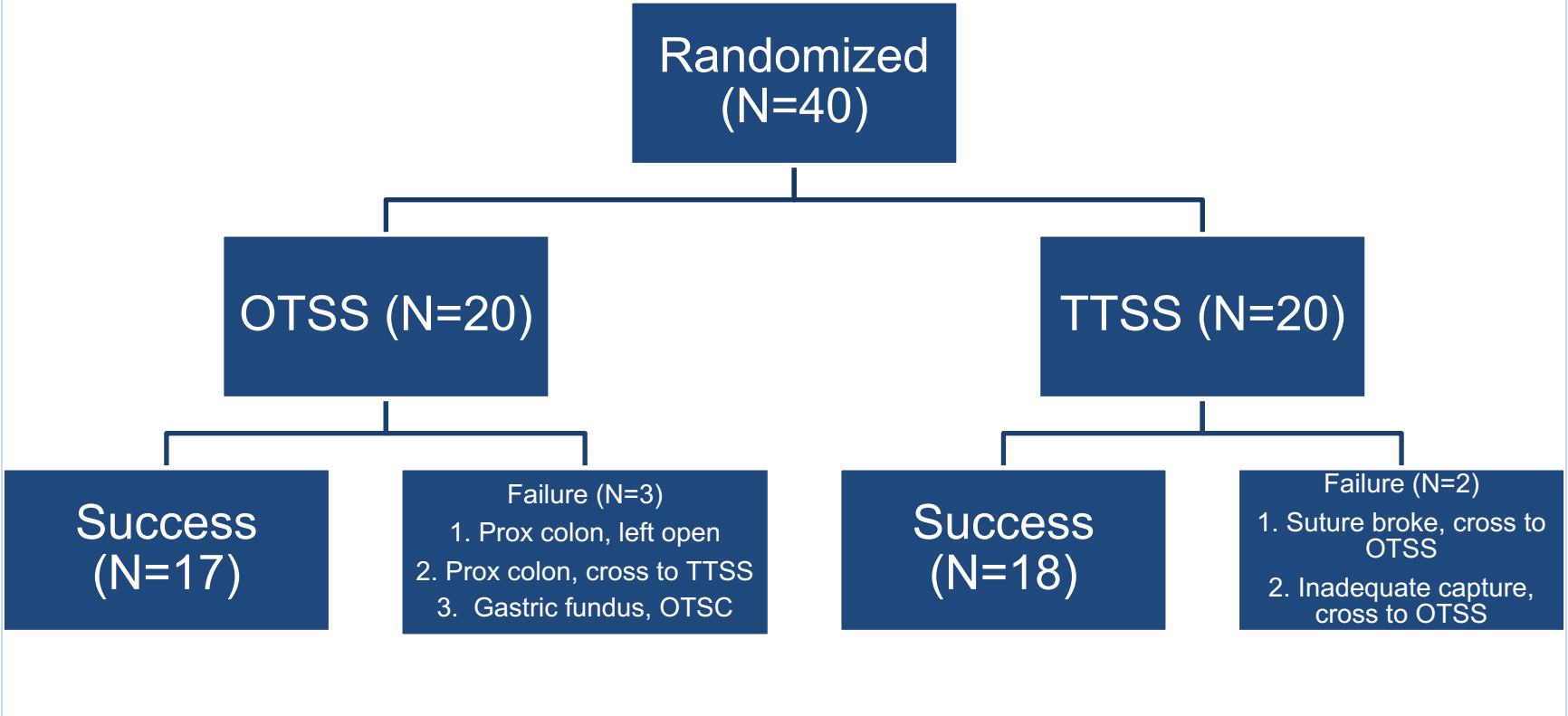
- Patient demographics

Variable	OTSS	TTSS	P value
Age in yrs; mean ± SD	62.2±12.2	61.8±13.5	0.92
Gender			0.75
Male	11 (55.0%)	10 (50.0%)	
Female	9 (45.0%)	10 (50.0%)	
Ethnicity			0.40
Caucasian	16 (80.0%)	14 (70.0%)	
African American	1 (5.0%)	4 (20.0%)	
Asian	2 (10.0%)	2 (10.0%)	
Hispanic	1 (5.0%)	0 (0%)	

- Location and specimen size

Variable	OTSS	TTSS	P value
Anatomic site:			0.91
Stomach	4 (20.0%)	3 (15.0%)	
Proximal colon	7 (35.0%)	7 (35.0%)	
Distal colon and rectum	9 (45.0%)	10 (50.0%)	
Average size of specimen:			
Length (mm); mean ± SD	40.9±17.0	40.4±17.5	0.92
Width (mm); mean ± SD	29.8±12.7	26.0±8.5	0.27

RESULTS


Randomized (N=40)
OTSS (N=20)
TTSS (N=20)
Success (N=17)
Failure (N=3)
1. Prox colon, left open
2. Prox colon, cross to TTSS
3. Gastric fundus, OTSC
Success (N=18)
Failure (N=2)
1. Suture broke, cross to OTSS
2. Inadequate capture, cross to OTSS

RESULTS – NO DIFFERENCE…

Variable	OTSS (N=20)	TTSS (N=20)	P value
Closure time (mean±SD mins)	18.4±16.9; N=17	23.3±13.9; N=18	0.36
Overall closure time (mean±SD mins)	32.0±21.7; N=17	39.5±20.9; N=18	0.31

The study was not powered to evaluate delayed AEs of bleeding and perforation

COST ANALYSIS

- A single short TTSS was assigned a value of 1 and cost of other equipment and accessories were calculated relative to this.

Variable	OTSS (N=20)	TTSS (N=20)	P value
Mean cost (± SD) of closure	1.66 ± 0.28	1.77 ± 0.91	0.61

My takeaway points…After Gastric or colorectal ESD…

- Defect closure can be performed with either the novel TTSS or OTSS
  - Dictated by skill set, device availability, and location of the defect
- Closure time, efficacy, and adverse events are similar
- TTSS is more cost-effective for lesions smaller than 35 mm
  - Consider its use in smaller defect size

EMR Technique - Colon

"Doctor, how may colon polyps
HAVE you removed?"

Superiority of Cold Snare EMR Compared to Traditional EMR for Large Colorectal Polyps: A Systemic Review and Meta-Analysis

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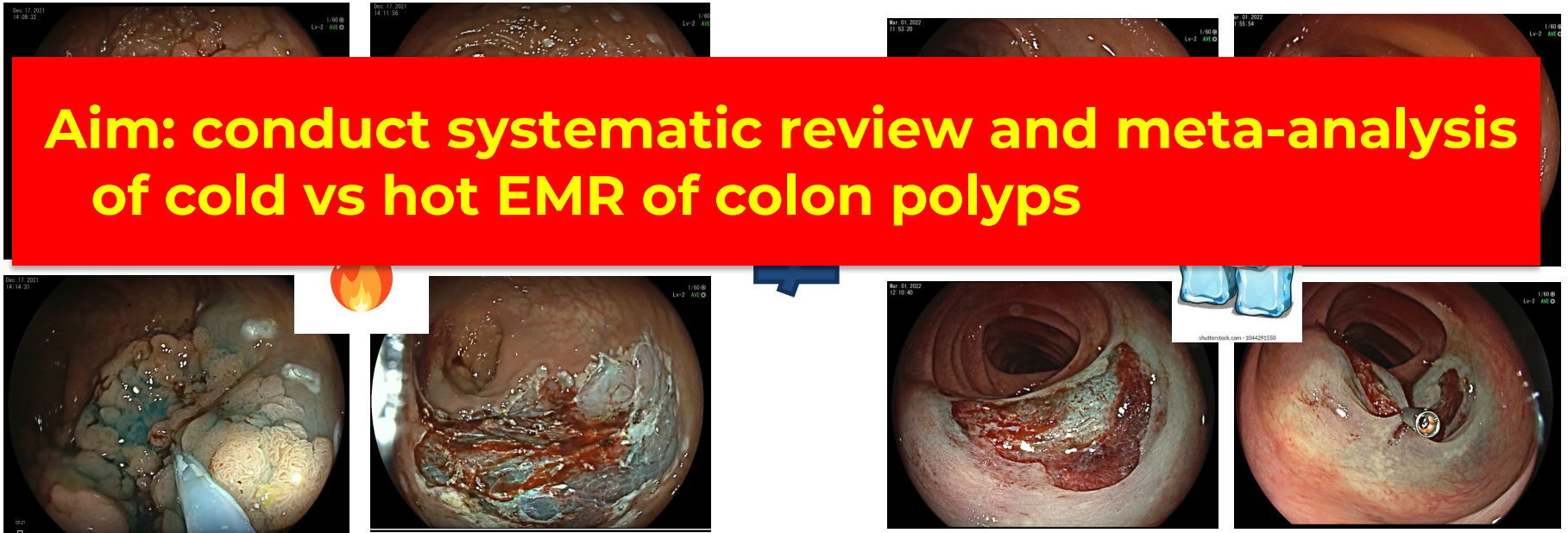
4. Charlotte Edwards Maguire Medical Library, Florida State University

Background

- EMR safe and effective in resection of large colon polyp
- Hot EMR remains in common practice for large polyps
- Emerging data for cold EMR

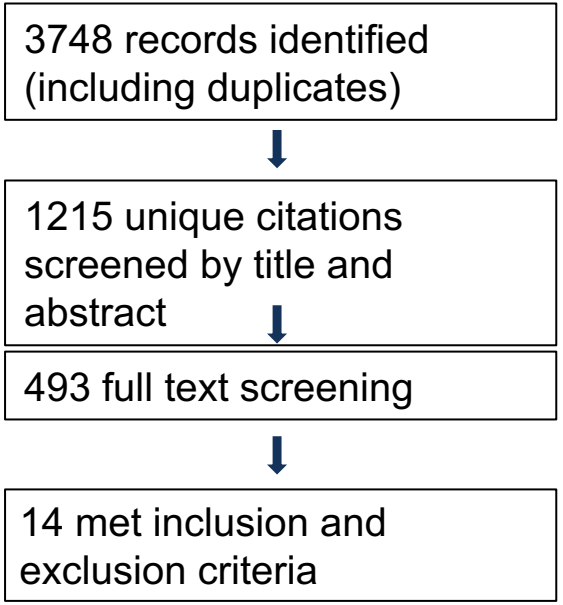


Aim: conduct systematic review and meta-analysis of cold vs hot EMR of colon polyps

Methods

- Comprehensive literature search
- Ended September 2022
- Inclusion criteria:
  - AE post C-EMR vs. h-EMR
  - AE post C-EMR

- Meta-analysis with random effect modeling



Results

- 14 studies
  - 4 comparative (compared cold
  - vs hot)
  - 10 cohort studies (c-EMR)

- 3,406 patients
- Mean size 10 – 26mm
- 87 adverse events

Study	Study type	Sample size (# of patients)
Van Hattem 2020	Prospective, comparative	474
Li 2020	RCT	132
Rex 2022	RCT	235
Le 2020	Retrospective, comparative	209
Muniraj 2015	Retrospective, non-comparative	30
Tutticci 2018	Prospective, non-comparative	99
Britto 2019	Retrospective, non-comparative	93
Rameshshanker 2021	Prospective, non-comparative	149
Mangira 2020	Retrospective, non-comparative	186
Britto 2020	Retrospective, non-comparative	93
Mickenbecker 2021	Retrospective, non-comparative	119
Yabuchi 2020	Prospective, non-comparative	72
Mangira 2022	Prospective, non-comparative	295
Kanaan 2022	Retrospective, non-comparative	266

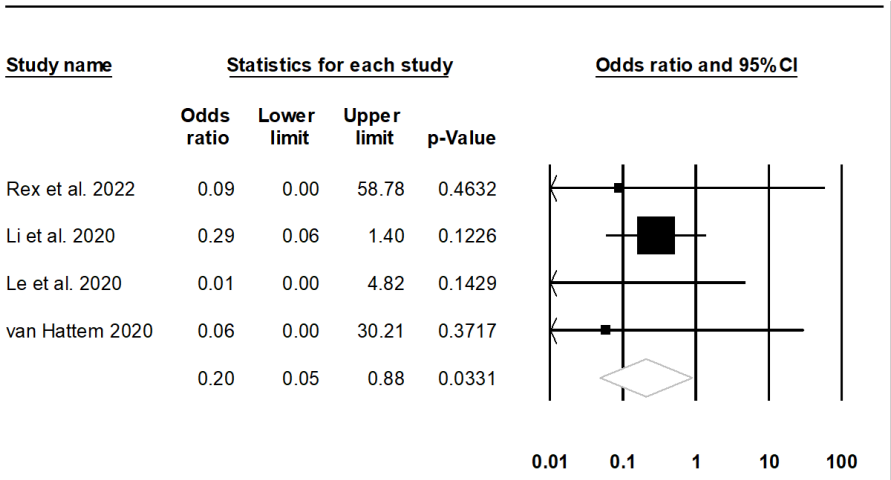
Delayed bleeding

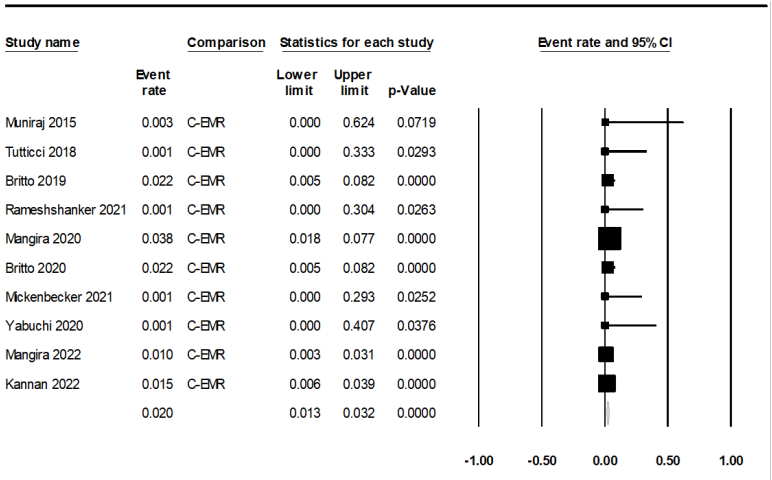
Comparative data: 1,071 patients

- 2/413 in c-EMR vs. 34/658 in h-EMR
- OR = 0.02 (CI: 0.05 – 0.88)
- P = 0.033
- I^2 = 0%

Cohort studies: 1,366 patients

- 18/1,366
- Pooled rate of delayed bleeding 2% [1.3 – 3.2%], I^2 = 0%





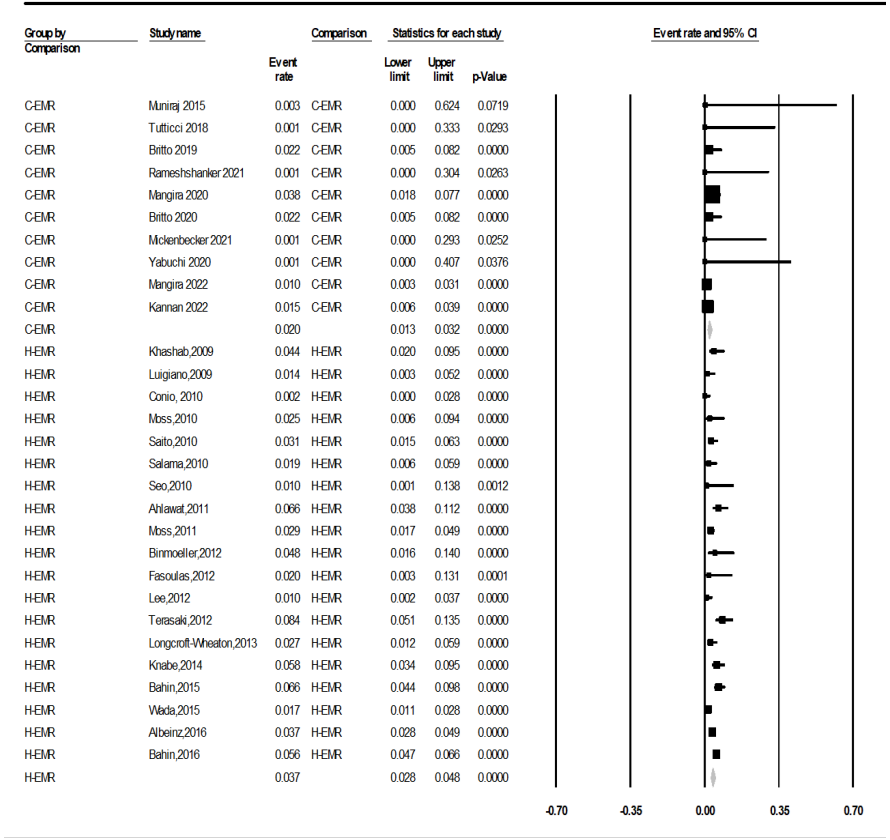
Historical comparison

- Existing meta-analysis of rates of delayed bleeding post h-EMR

(Kothari et al., GIE, 2019)

- Included 19 EMR studies: 7,756 patients

- Delayed bleeding rate lower in c-EMR: (2% vs. 3.7%, p=0.023)



Group by Comparison	Study name	Event rate	Comparison	Lower limit	Upper limit	p-Value
C-EMR	Muniraj 2015	0.003	C-EMR	0.000	0.624	0.0719
C-EMR	Tutticci 2018	0.001	C-EMR	0.000	0.333	0.0293
C-EMR	Britto 2019	0.022	C-EMR	0.005	0.082	0.0000
C-EMR	Rameshshanker 2021	0.001	C-EMR	0.000	0.304	0.0263
C-EMR	Mangira 2020	0.038	C-EMR	0.018	0.077	0.0000
C-EMR	Britto 2020	0.022	C-EMR	0.005	0.082	0.0000
C-EMR	Mckenbecker 2021	0.001	C-EMR	0.000	0.293	0.0252
C-EMR	Yabuchi 2020	0.001	C-EMR	0.000	0.407	0.0376
C-EMR	Mangira 2022	0.010	C-EMR	0.003	0.031	0.0000
C-EMR	Kannan 2022	0.015	C-EMR	0.006	0.039	0.0000
C-EMR		0.020		0.013	0.032	0.0000
H-EMR	Khashab,2009	0.044	H-EMR	0.020	0.095	0.0000
H-EMR	Luigiano,2009	0.014	H-EMR	0.003	0.052	0.0000
H-EMR	Conio, 2010	0.002	H-EMR	0.000	0.028	0.0000
H-EMR	Moss,2010	0.025	H-EMR	0.006	0.094	0.0000
H-EMR	Saito,2010	0.031	H-EMR	0.015	0.063	0.0000
H-EMR	Salama,2010	0.019	H-EMR	0.006	0.059	0.0000
H-EMR	Seo,2010	0.010	H-EMR	0.001	0.138	0.0012
H-EMR	Ahlawat,2011	0.066	H-EMR	0.038	0.112	0.0000
H-EMR	Moss,2011	0.029	H-EMR	0.017	0.049	0.0000
H-EMR	Binmoeller,2012	0.048	H-EMR	0.016	0.140	0.0000
H-EMR	Fasoulas,2012	0.020	H-EMR	0.003	0.131	0.0001
H-EMR	Lee,2012	0.010	H-EMR	0.002	0.037	0.0000
H-EMR	Terasaki,2012	0.084	H-EMR	0.051	0.135	0.0000
H-EMR	Longcroft-Wheaton,2013	0.027	H-EMR	0.012	0.059	0.0000
H-EMR	Knabe,2014	0.058	H-EMR	0.034	0.095	0.0000
H-EMR	Bahin,2015	0.066	H-EMR	0.044	0.098	0.0000
H-EMR	Wada,2015	0.017	H-EMR	0.011	0.028	0.0000
H-EMR	Albeinz,2016	0.037	H-EMR	0.028	0.049	0.0000
H-EMR	Bahin,2016	0.056	H-EMR	0.047	0.066	0.0000
H-EMR		0.037		0.028	0.048	0.0000

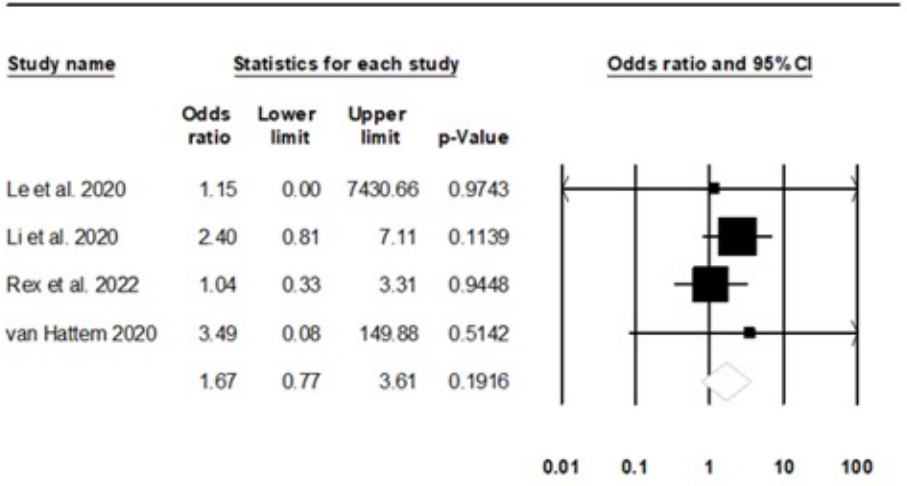
Results

Perforation

- Cold EMR: Zero perforations
- Hot EMR :16 perforations
- OR 0.02 (CI: 0.0 – 2.03)
- P=0.100

Early bleeding

- No difference: OR= 1.7 (CI: 0.8 - 3.6)
  - P = 0.192
  - I^2 = 26%

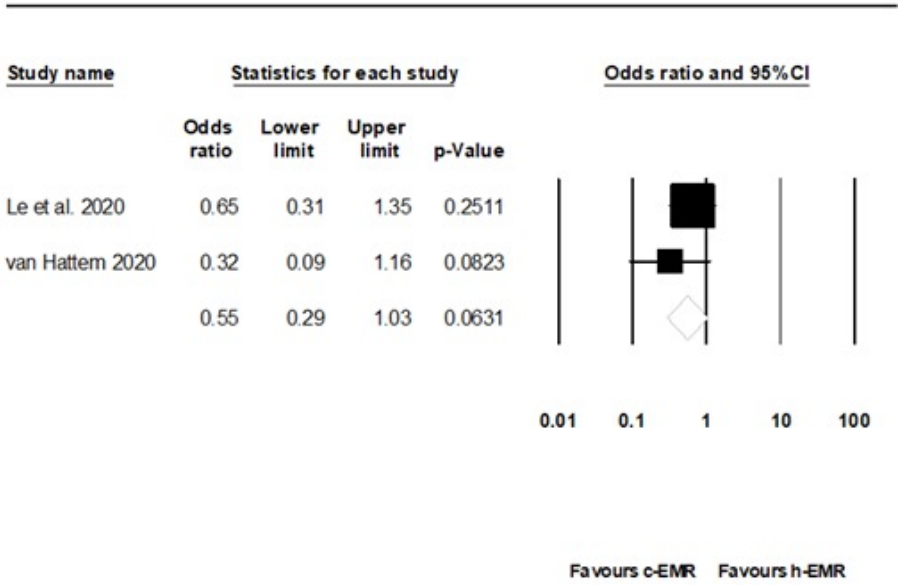


Recurrent & Residual polyps

Recurrence rates:

1) Comparative studies
   - 3/85 cold vs. 7/81 hot
   - OR: 0.55 (CI: 0.29 – 1.03)
   - P = 0.063
   - I^2 = 0%

2) Cohort studies:
   - Pooled recurrence rate: 2.4% (CI: 0.9 – 6.4%)



Residual Polyp rate:

- Rex *et al:* C-EMR 1/82 vs H-EMR 4/65, NS

Summary & Conclusions

- Cold EMR associated with lower risk of delayed bleeding & perforation (NS)
- No difference in early bleeding, residual polyp, or polyp recurrence
- More cost effective

- **C-EMR should become routine standard of care for removal of most large non-pedunculated colorectal polyps**

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EXHIBIT DATES: MAY 7-9, 2023

COLD VERSUS HOT SNARE ENDOSCOPIC MUCOSAL RESECTION FOR COLORECTAL POLYPS A SYSTEMATIC REVIEW AND META-ANALYSIS

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INTRODUCTION

The field of colorectal endoscopic resection is currently undergoing a "cold revolution," with several advancements and innovations emerging. The polypectomy technique known as cold snare polypectomy (CSP), which does not utilize electrocautery, is currently considered a safe and effective m
of small polyps measuring <10 mm in size,
delayed bleeding. Furthermore, many stud
that cold snare EMR (CS-EMR) may offer a
remove large colorectal polyps (size ≥10 m
EMR as the former does not involve the us

AIM

This meta-analysis aims to investigate the
EMR compared with HS-EMR for colorecta

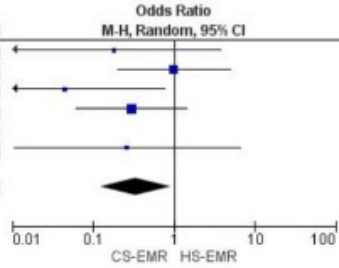
METHOD

Five databases, including Medline/PubMed, the Cochrane Library, Web of Science, Scopus, and Embase, were searched from inception to October 2022. All published articles compare the efficacy and complications associated with CS-EMR vs. HS-EMR for colorectal polyps. Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines were followed in this meta-analysis. A random-effects model was used to pool odds ratios (ORs). The primary outcome was the complete resection rate. In addition, the complications, including perforation, delayed bleeding, and immediate bleeding rate, were also calculated.

RESULTS

Six studies, including two randomized control trials and four observational studies, were eligible and enrolled in this meta-analysis. A total of 733 lesions received CS-EMR, and 737 lesions received HS-EMR.

Study or Subgroup	CS-EMR Events	CS-EMR Total	HS-EMR Events	HS-EMR Total	Weight	Odds Ratio M-H, Random, 95% CI
Boeva I 2022	0	85	2	79	10.2%	0.18 [0.01, 3.84]
Guo X 2022	3	128	3	128	33.7%	1.00 [0.20, 5.05]



Cold EMR is safer with lower incidence of delayed bleeding. Complete resection rate is comparable.

CONCLUSIONS

Compared with HS-EMR, CS-EMR is a safer technique for the resection of colorectal polyps, with a lower incidence of delayed bleeding rate. Meanwhile, between CS-EMR and HS-EMR, the complete resection rate is comparable. However, further prospective studies are required to evaluate the local recurrence rate following CS-EMP.

REFERENCES

1. Kawamura T, Takeuchi Y, Asai S, et al. A comparison of the resection rate for cold and hot snare polypectomy for 4-9 mm colorectal polyps: a multicentre randomised controlled trial (CRESCENT study). Gut 2018;67:1950-1957.
2. van Hattem WA, Shahidi N, Vosko S, Hartley I, Britto K, Sidhu M, Bar-Yishay I, Schoeman S, Tate DJ, Byth K, Hewett DG, Pellisé M, Hourigan LF, Moss A, Tutticci N, Bourke MJ. Piecemeal cold snare polypectomy versus conventional endoscopic mucosal resection for large sessile serrated lesions: a retrospective comparison across two successive periods. Gut. 2021 Sep;70(9):1691-1697. doi: 10.1136/gutjnl-2020-321753. Epub 2020 Nov 10. PMID: 33172927.

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CONTACT INFORMATION

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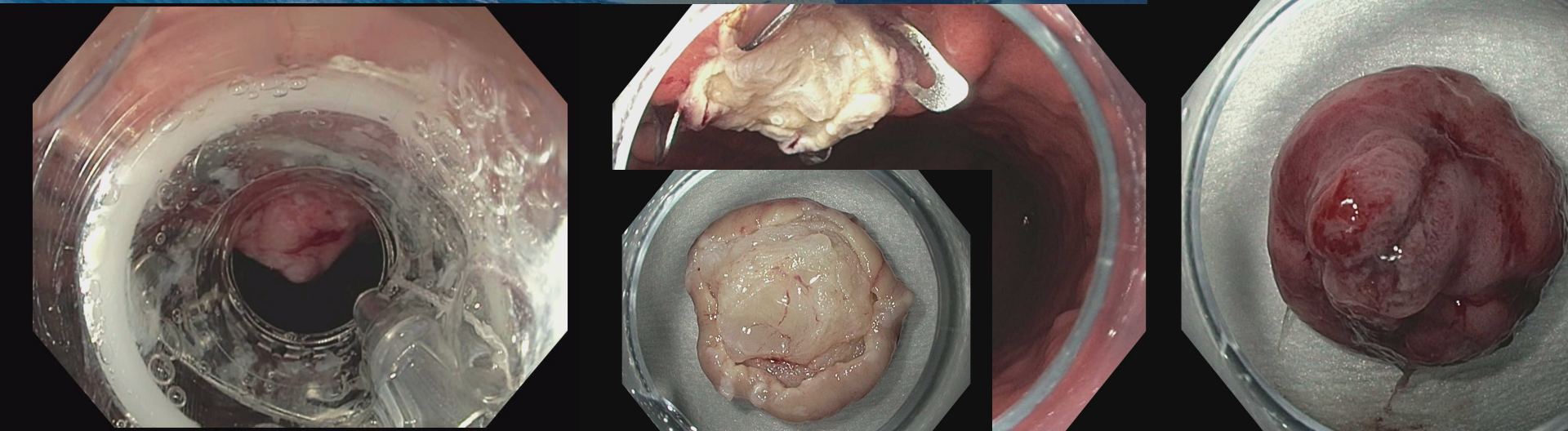
Upper GI tract - Full-thickness resection devices (FTRD), Endoscopic treatment of Barrett's and early cancer

- The data presented in this section will address ***whether***:
  - A new device used to resect upper GI mucosal and submucosal lesions is efficacious
  - Endoscopic therapy is enough in patients with Barretts and T1a cancers

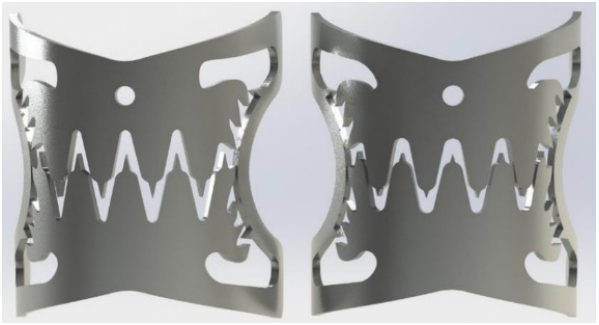
Clinical Efficacy and Safety of a Novel OTC Gastroduodenal Full Thickness Resection Device (GFTRD) for the Treatment of Upper Gastrointestinal Tract Lesions: A Large Multicenter Experience

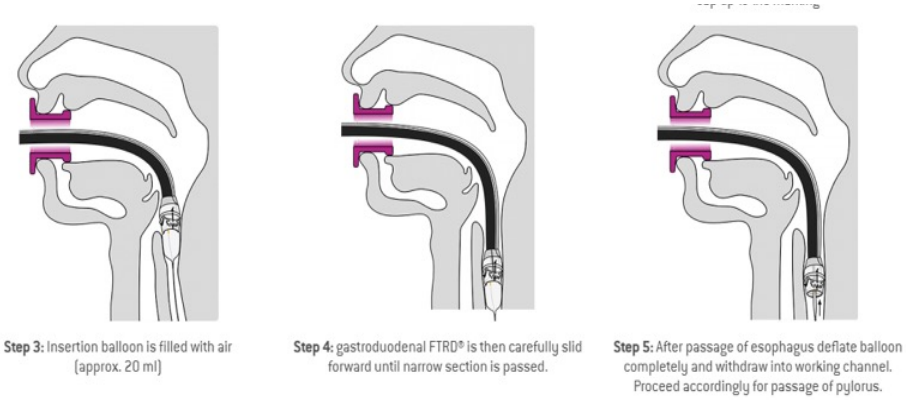
Peter H. Nguyen MD, Alyssa Y. Choi MD, Jaehyun Kim MD, Julie Yang MD, Sherif A. Andrawes MD, Jean Chalhoub MD, Anastasia Chahine MD, Amirali Tavangar MD, Andrew Q. Giap MD, David P. Lee MD MPH, Kenneth H. Park MD, Quin Liu MD, Srinivas Gaddam MD, Kendrick Che MD, Michael Lajin MD, Wasseem Skef MD, John K. Kim MD MS, Jason B. Samarasena MD



Updates to gFTRD from colonic FTRD

- Smaller cap size (19.5 mm vs. 21 mm)
- Compatible with small-diameter endoscopes (10.5mm)
- Updated design to the OTSC with decreased interdental space to reduce the risk of bleeding
- Optional balloon device and guidewire





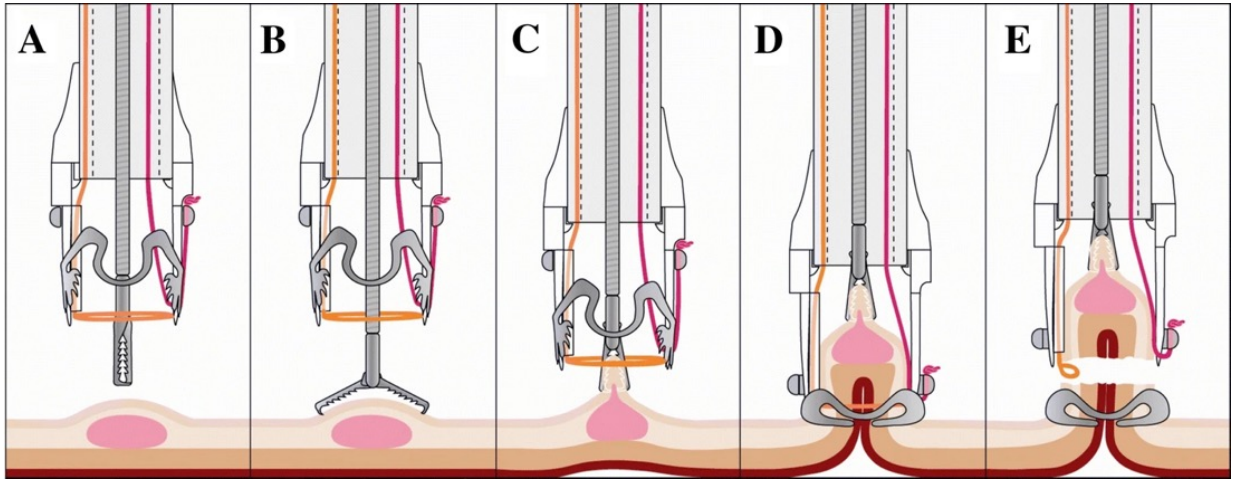
Step 3: Insertion balloon is filled with air (approx. 20 ml)

Step 4: gastroduodenal FTRD® is then carefully slid forward until narrow section is passed.

Step 5: After passage of esophagus deflate balloon completely and withdraw into working channel. Proceed accordingly for passage of pylorus.

Aims

- To evaluate the efficacy and safety of a newly designed gFTRD device for resection of UGIT lesions.



Methods

- Multicenter retrospective study including patients age > 18 years who have undergone gFTRD of an UGIT lesion from 6/2020 to 8/2022 at eight U.S. centers
- Outcomes evaluated:
  - Technical success rate
  - En-bloc resection rate
  - R0 resection rate (negative histological margin)
  - Lesion size pre/post-resection
  - Foregut Location
  - Wall layer
  - Adverse events

Lesion Characteristics

Location, n (%)	
Esophagus	0 (0)
Stomach	35 (80)
Duodenum	9 (20)
Layer, n (%)	
Mucosa	10 (22.7)
Muscularis Mucosa	4 (9.1)
Submucosa	19 (43.2)
Muscularis propria	11 (25)
Lesion size pre-resection, mean in mm (range)	11.8 (5-20)
Resected tissue size post-resection, mean in mm (range)	17.6 (5-29)

Resection Outcomes

Total number of gFTRD, n	45
Technical success, n (%)	
En-bloc resection	41 (91)
Partial resection	2 (4)
Incomplete procedure	2 (4)
Device failure	0 (0)
Histological margin, n (%)	
R0	32 (71)
R1	11 (24)
Rx	1 (2)
N/A	2 (4)
Follow up endoscopy, n (%)	24 (55)

Pathology, n (%)	
Neuroendocrine tumors	14 (32)
GIST	10 (23)
Mesenchymal neoplasm other than GIST	5 (11)
Adenocarcinoma	4 (9)
Ectopic pancreas	4 (9)
Any adenoma with HGD	3 (7)
Tubular adenoma	2 (7)
Oxyntic gland neoplasm	1 (2)
Calcifying fibrous tumor	1 (2)

Results- Adverse Events

Complications, n (%)	
Immediate minor bleeding	17 (38)
Immediate major bleeding	0 (0)
Delayed minor bleeding (self resolved)	1 (2)
Delayed major bleeding (needing endoscopic treatment)	1 (2)
Perforation	1 (2)
Organ injury	0 (0)
Stricture	0 (0)
Complication requiring surgery	0 (0)

Conclusions

- In this multicenter study, the novel gFTRD system showed a high technical success rate with a high en-bloc resection rate for upper GI tract lesions
- A significant number of patients showed immediate minor bleeding that required minimal intervention
- The risk for major events was low
- Overall, this data supports the safety and efficacy of gFTRD for UGIT lesions
- Further prospective studies are warranted

Outcomes after endoscopic management of low-risk and High-risk T1a esophageal adenocarcinoma: A multicenter study

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Study Aim

- Assess and compare outcomes after EET of low- risk and high-risk T1a EAC including intraluminal EAC recurrence, extra-esophageal metastases, and overall survival.

Methods

- Endoscopic resection (ER) with pathology demonstrating T1a EAC between 1996-2022 at 3 Mayo Clinic sites
- **High-risk** T1a EAC: poor differentiation grade and/or presence of LVI
- **Low-risk** T1a EAC: well or moderately differentiated without LVI
- Clinical outcomes:
  - Intraluminal EAC recurrence: recurrence of EAC
  - Extra-esophageal metastases: lymph node and/or distant
  - Overall survival
- Statistical Analysis: Kaplan-Meier (KM) estimates are used to compare outcomes in groups

Results

- 188 patients underwent ER with pathology demonstrating T1a EAC
  - High-risk: 45 (24%)
  - Low-risk: 143 (76%)

- No difference in median (IQR) time to last follow-up or death
  - Low-risk **4.7** (2.3, 8.1 years) vs. high-risk **5.7** (2.9, 10.2), p=0.30

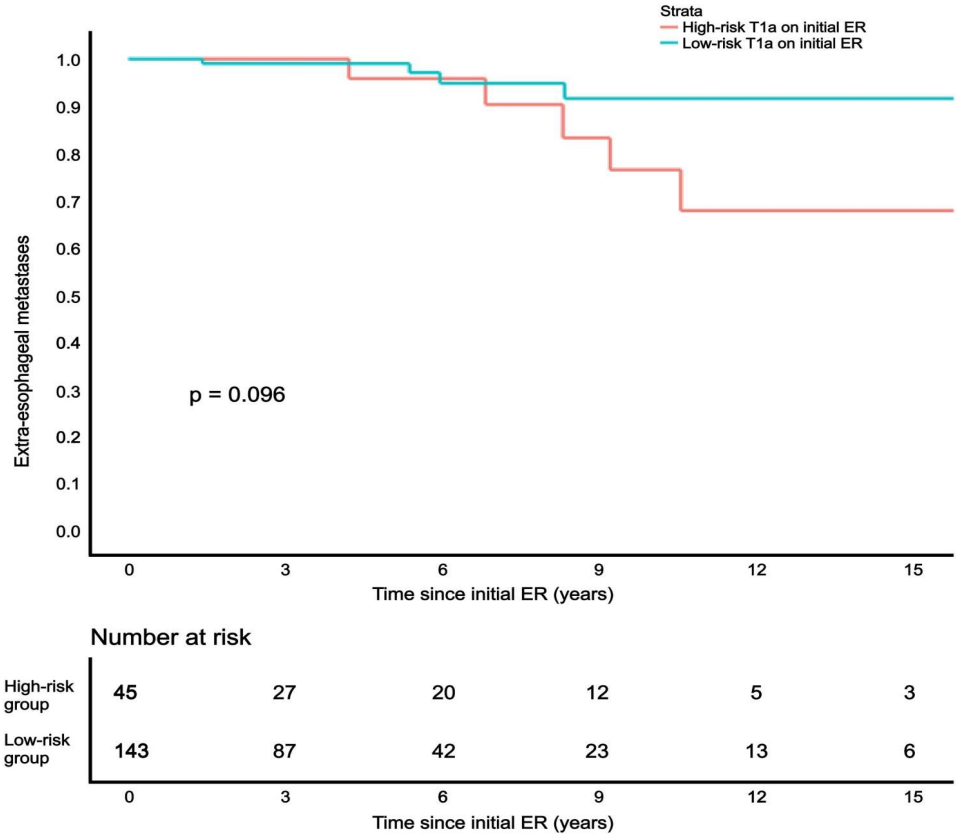
Baseline characteristics	Low-risk T1a EAC (n=143)	High-risk T1a EAC (n=45)	P-value
Age (y), median (IQR)	70.6 (65.1, 77.9)	68.8 (62.0, 74.2)	0.06
Male gender, n (%)	119 (83.2%)	38 (84.4%)	0.85
H/o tobacco use, n (%)	98 (68.5%	35 (77.8%)	0.40
Max BE length (cm), median (IQR)	5 (2.0, 8.0)	3 (2.0, 7.0)	0.38
Lesion size (mm), median (range)	15 (10.0, 20.0)	20 (10.0, 30.0)	0.25
Endoscopic treatment - Cap assisted EMR, n (5) - ESD, n (%)	 116 (81.1%) 27 (18.9%)	 39 (86.7%) 6 (13.3%)	0.39
Grade of differentiation - Well diff, n (%) - Mod diff, n (%) - Poorly diff, n (%)	 32 (22.4%) 111 (77.6%) 0	 1 (2.2%) 8 (17.8%) 35 (77.8%)	<0.01
Presence of LVI, n (%)	0	14 (31.1%)	<0.01

Clinical outcomes	Low-risk T1a EAC (n=143)	High-risk T1a EAC (n=45)	P-value*
Intraluminal EAC recurrence, n (%)	18 (12.6%)	7 (15.6%)	0.66
Extra-esophageal mets, n (5)	4 (2.8%)	5 (11.1%)	0.10
Extent of mets - Lymph node only, n (5) - Distant, n (%)	 1 (25.0%) 3 (75.0%)	 2 (40.0%) 3 (60.0%)	1.0
Intraluminal EAC recurrence and/ or extra-esophageal mets, n (5)	19 (13.3%)	10 (22.2%)	0.25
Death from any cause, n (5)	48 (33.6%)	16 (35.6%)	0.73
EAC-related deaths , n (%)	3 (2.1%)	3 (6.7%)	0.13

*p-value was based on KM analysis.

Extra-esophageal metastases

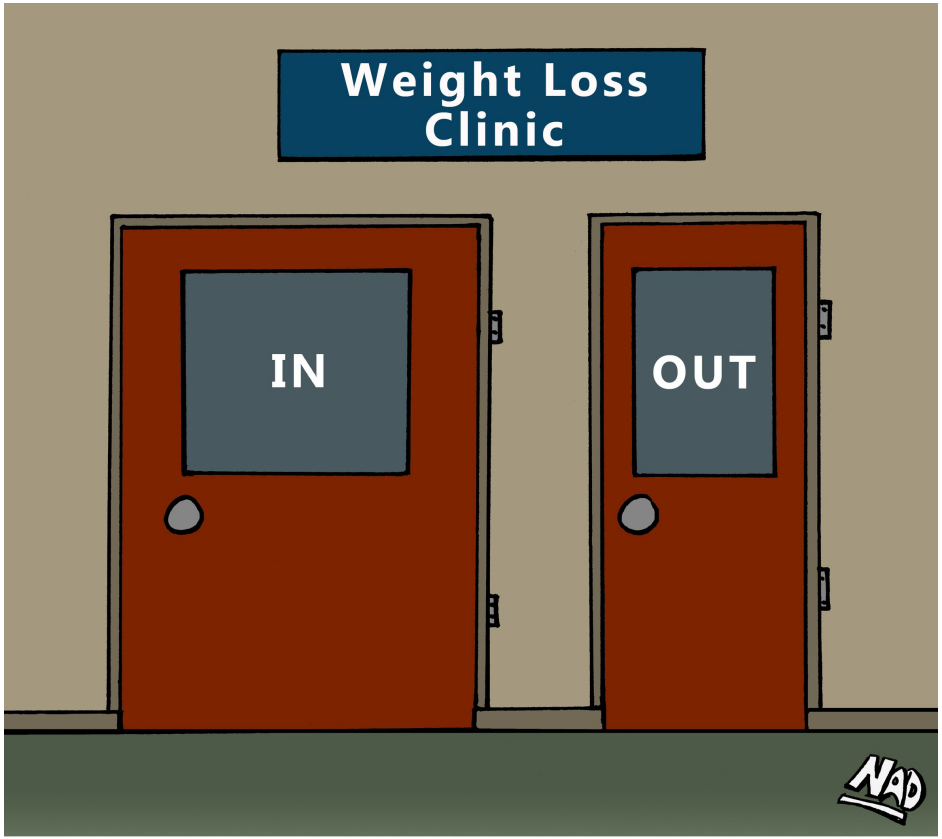
- High-risk: 11%
- Low-risk: 3%
- Four-fold numerical higher rate in the high-risk group
- Trend towards significance (p=0.096)



Conclusion

- Largest study to date on patients with high-risk T1a EAC (n=45)
- **Four-fold higher numerical rate of extra-esophageal metastases in the high-risk group with trend towards significance**
- No difference in intraluminal EAC recurrence or overall survival
- These data should be factored into discussions with patients while selecting treatment approaches
- Additional data in this area are critical

Bariatrics and more…



Duodenal Mucosal Regeneration Induced by Endoscopic Pulsed Electric Field Treatment Improves Glycemic Control in Patients with Type 2 Diabetes

Interim Results from a First-in-Human Study

Adrian Sartoretto MBBS, David O'Neal MD, Bronte Holt MBBS, PhD, Cheng Yi Yuan MD, Georgie Cameron MBBS, BMus, PhD, FRACP, Barham Abu Dayyeh MD

AIM

- To assess feasibility, safety, and efficacy of endoscopic electroporation – a novel non-thermal endoscopic ablative modality – applied to the duodenum in the treatment of type 2 DM

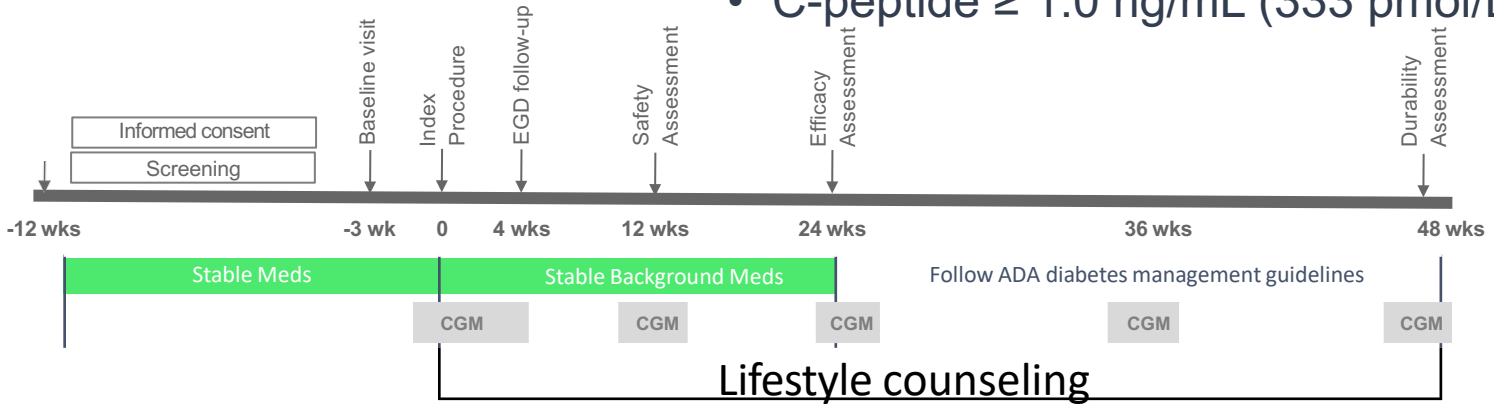
REGENT-1 Study Overview

Study Design

- Multicenter, open-label, treatment-only
- Stable background meds 12 wks before and 24 wks post procedure
- Treat to target after 24 wks

Study Population

- Age: 18-70 yrs
- BMI: 24-40 kg/m^2
- T2D: ≤10 yrs, on 1-4 noninsulin glucose-lowering medications
- HbA1C: 7.5% – 11%
- C-peptide ≥ 1.0 ng/mL (333 pmol/L)



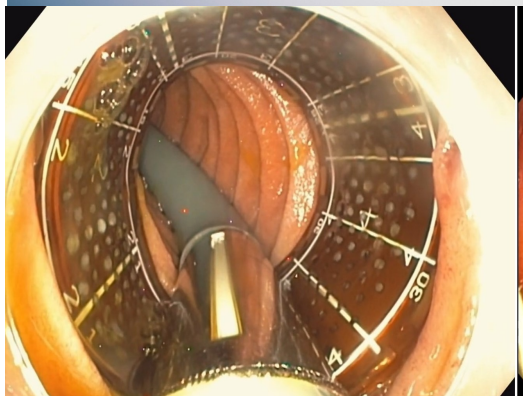
Baseline Characteristics

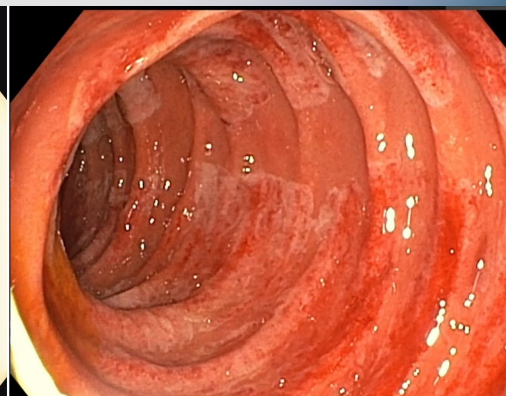
	Mean ± SD, %	Range
N	41	-
Age (years)	52.4 ± 8.6	30.0, 68.0
Male	78%	-
Weight (Kg)	93.7 ± 15.9	66.6, 130.0
BMI (Kg/m^2)	31.3 ± 3.7	24.1, 39.8
HbA1c (%)	8.7 ± 0.9	7.5, 10.5
FPG (mmol/L)	9.9 ± 2.2	6.8, 14.7
Insulin (IU/L)	12.5 ± 7.1	1.0, 35.0
HOMA-IR	5.5 ± 3.2	0.3, 13.2
C-peptide (pmol/L)	865 ± 355	440, 1900
Duration of T2D (years)	5.5 ± 2.6	<1, 9

	N (%)
Background GLMs	
Metformin	39 (95%)
Sulfonylureas	12 (29%)
SGLT2i	23 (56%)
GLP-1a	4 (10%)
DPP4	10 (24%)
No. of background GLMs	
1	11 (27%)
2	17 (41%)
3	9 (22%)
4	4 (10%)

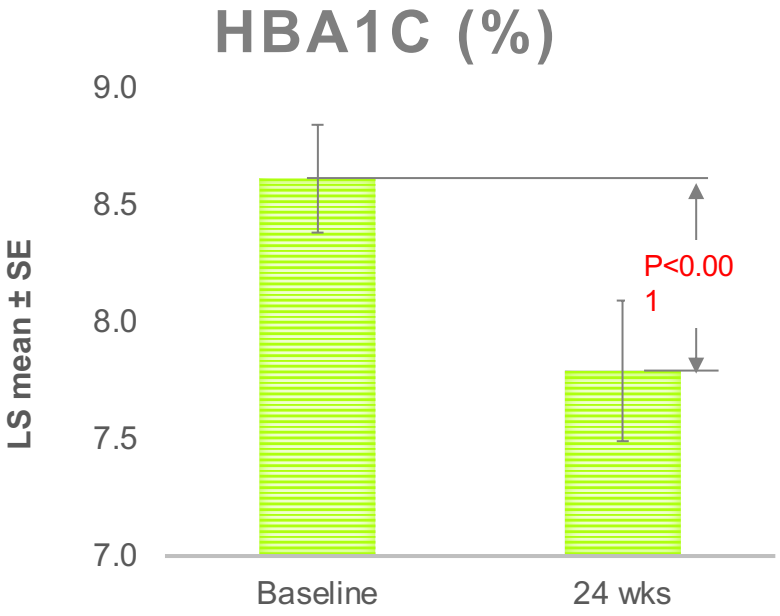
Recellularization via Electroporation Therapy (ReCETTM)

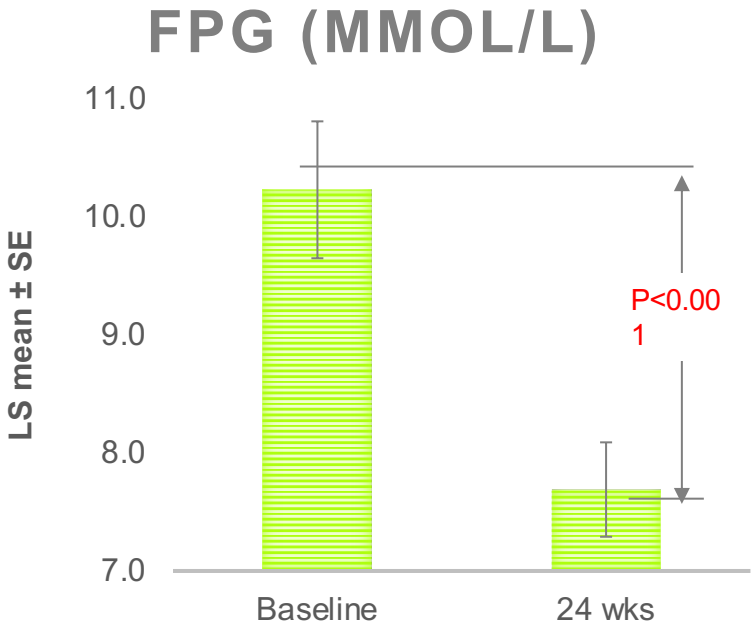
- High voltage, ultra-short pulse field
- Increases cell permeability resulting in mucosal cellular apoptosis
- Preserves extracellular matrix and myocytes
- Non-thermal
- Controlled depth of penetration
- Advanced over a guidewire, direct endoscopic vision, and fluoroscopic guidance
- Treatment delivered in 2cm segments





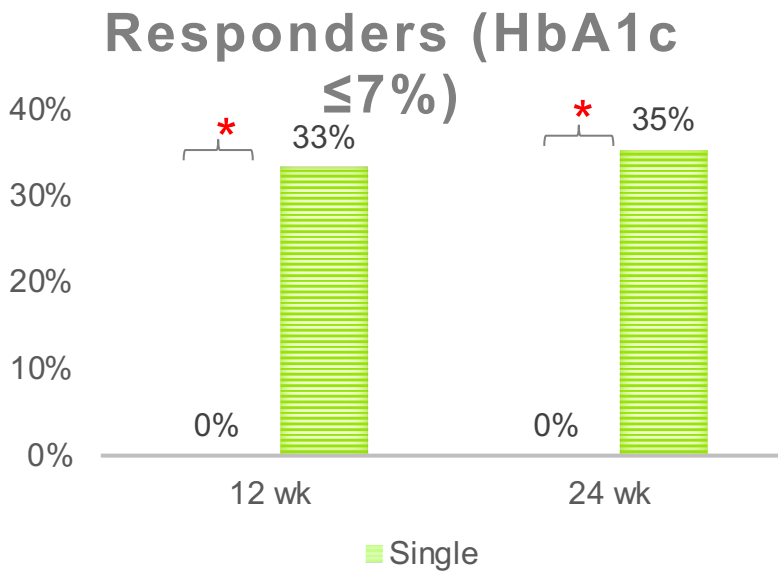
Improvement in Glycemic Control

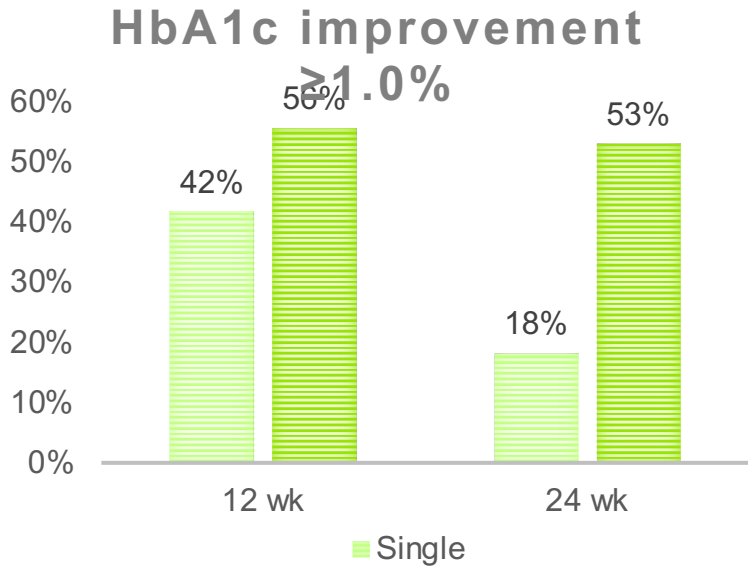




N=18, double Tx, stable background medications, except 2 patients had reduction of sulfonylurea doses, and 2 patients discontinued SGLT2i.

Responder Rate by Energy Doses





*p<0.05

US commercial cost-effectiveness analysis of endoscopic sleeve gastroplasty (ESG) versus lifestyle modification (LM) alone for adults with class II obesity

Reem Z. Sharaiha, Erik B. Wilson, Andre Teixeira, Bradley Thaemert, Christopher G. Chapman, Vivek Kumbhari, Michael Ujiki, Christopher C. Thompson, Barham K. Abu Dayyeh

Cost-effectiveness model for adults with class II obesity (BMI 35–40 kg/m^2) with a US payer perspective

Background

>40% of US adults are patients with obesity

Prior Studies have shown ESG

- Significant and durable excess weight loss vs LM in adults with class I & II obesity*
- Improvements in obesity-related comorbidities
- Durability for up to five years in single arm analysis

Significant economic burden of obesity in the US

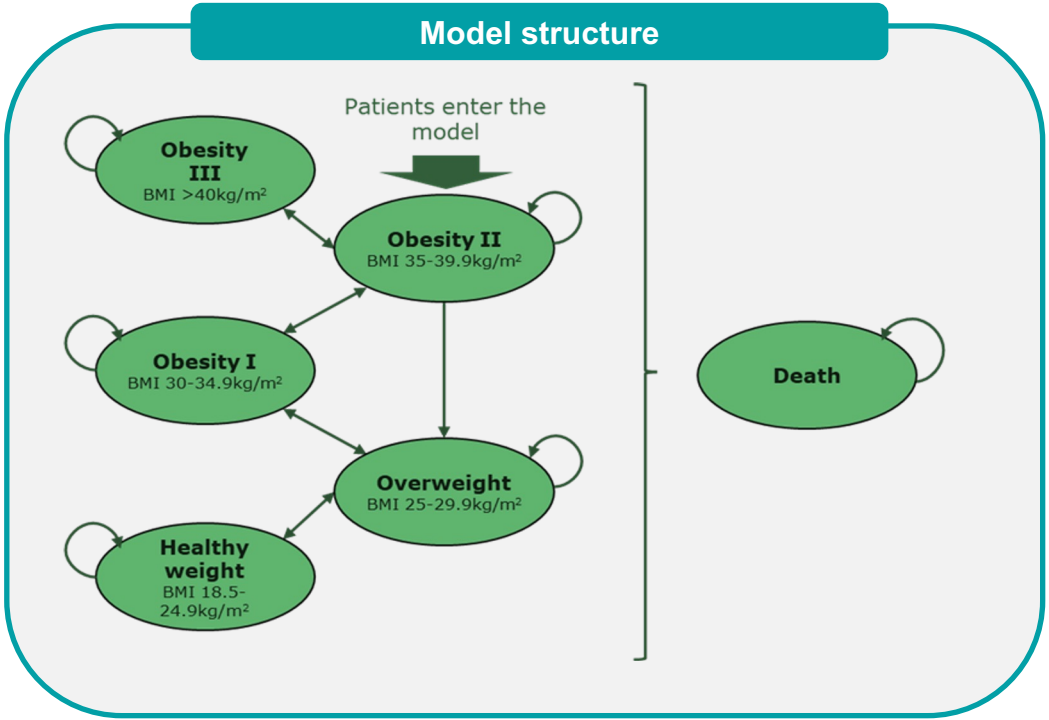
*Class I obesity: BMI 30.0–34.9 kg/m^2; class II obesity: BMI 35.0–39.9 kg/m^2.

BMI, body mass index; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year.

1. Centers for Disease Control and Prevention. Adult obesity facts. Available at: https://www.cdc.gov/obesity/data/adult.html [accessed Apr 2023]. 2. Abu Dayyeh BK, et al. Lancet 2022;400:441–51. 3.Sharaiha et al CGH 2020

Aim: Provide the first US cost-utility analysis of ESG vs LM among people with class II obesity

Cost-effectiveness model for adults with class II obesity (BMI 35–40 kg/m^2) with a US payer perspective



*Class I obesity: BMI 30.0–34.9 kg/m^2; class II obesity: BMI 35.0–39.9 kg/m^2.

BMI, body mass index; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year.

1. Centers for Disease Control and Prevention. Adult obesity facts. Available at: https://www.cdc.gov/obesity/data/adult.html [accessed Apr 2023]. 2. Abu Dayyeh BK, et al. Lancet 2022;400:441–51.

Primary outcome:

- ICER: Incremental Cost Effectiveness Ratio

  calculated as the Cost per QALY* for ESG compared with LM

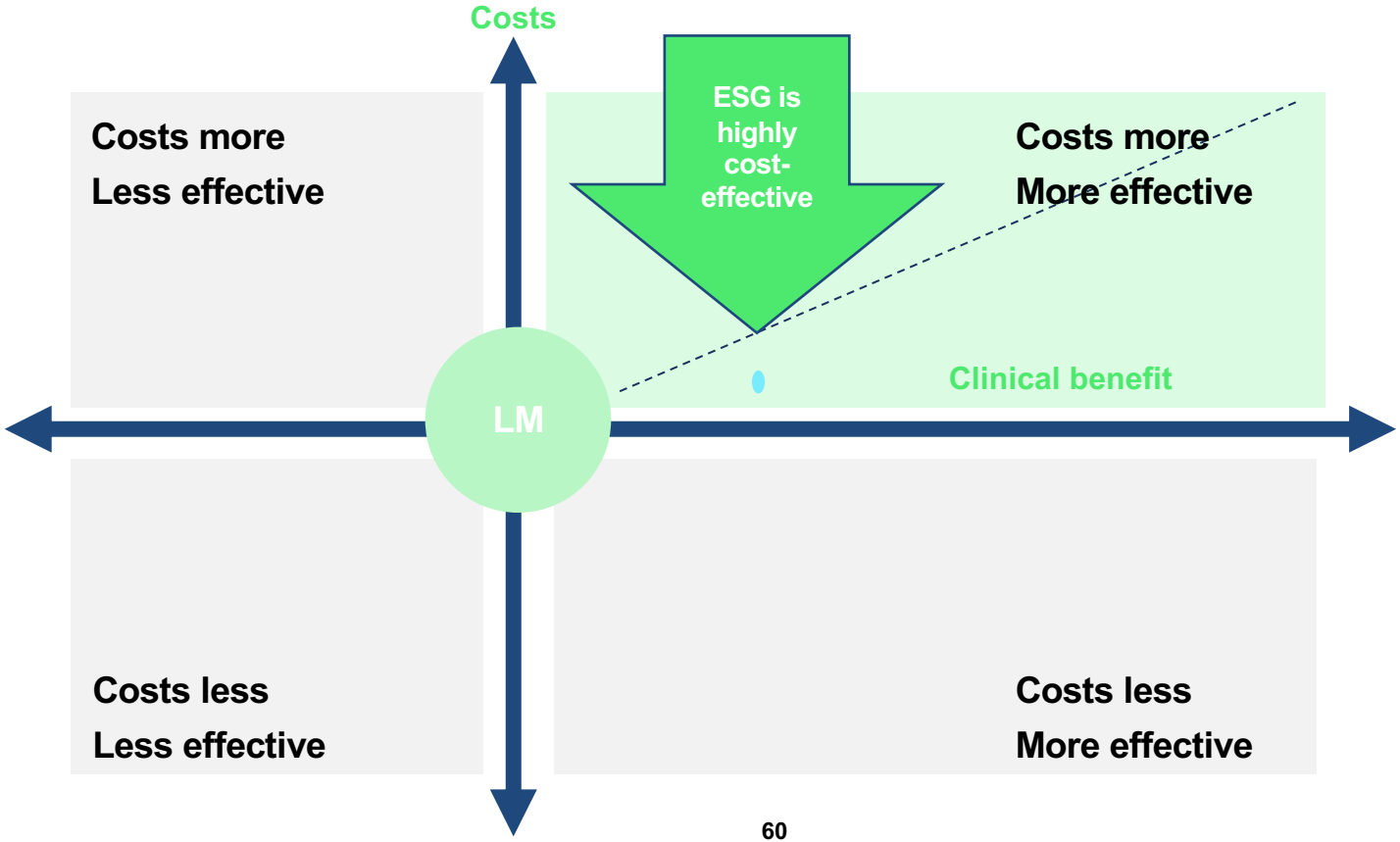
*QALY = Quality Adjusted life years

Results

	Costs ($)	Life Years	QALYs	ICER ($/QALY)
LM	151,004	19.909	13.952	
ESG	158,421	21.131	16.012	
Incremental (ESG vs LM)	**7,417**	**1.222**	**2.060**	**3,600**

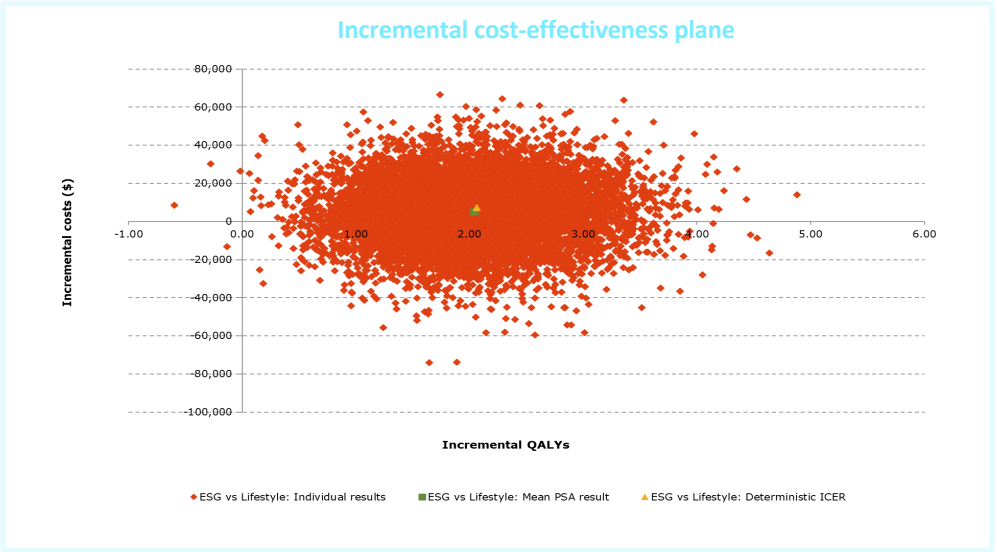
QALY = Quality Adjusted life years

Results


Costs
Costs more
Less effective
ESG is highly cost-effective
Costs more
More effective
Clinical benefit
LM
Costs less
Less effective
Costs less
More effective

ESG is consistently cost effective across all sensitivity analyses

PSA: ESG remained cost effective in 99.78% of iterations at a willingness-to-pay threshold of $50,000/QALY



PSA is consistent with the base-case ICER ($2,502 vs $3,600), demonstrating that the analysis is robust

*OWSA run using NMB as the outcome, as some ICERs were non-numerical and could not be displayed on the tornado diagram.

GERD, gastroesophageal reflux disease; HR, hazard ratio.

Summary

1. ESG resulted in an ICER of 3,600 vs LM
2. ESG was consistently cost effective across all sensitivity analyses
3. ESG remained cost effective in 99% of iterations at a willingness-to-pay threshold of $50,000/QALY gained

ESG is currently undergoing review by NICE to assess whether the procedure can be used in the NHS[1]

1. NICE, 2023. Endoscopic sleeve gastroplasty for severe obesity. Available at: https://www.nice.org.uk/guidance/indevelopment/gid-ipg10300 [Accessed Apr 2023].

Thank you!