New Technology and Advances in Endoscopy

Disclosure

<table>
<thead>
<tr>
<th>Commercial Interest</th>
<th>Relationship</th>
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<tbody>
<tr>
<td>Apollo</td>
<td>Consultant</td>
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<td>Boston Scientific</td>
<td>Consultant</td>
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<tr>
<td>Covidien</td>
<td>Consultant/Endoluminal Advisory Board</td>
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<tr>
<td>IGEL Medical</td>
<td>Consultant/Advisory Board</td>
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<tr>
<td>GI Windows</td>
<td>Member/Research Support</td>
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<tr>
<td>Olympus</td>
<td>Research support/Consultant</td>
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<td>Vysera</td>
<td>Consultant/Research support</td>
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<tr>
<td>Beacon Endoscopic</td>
<td>Consultant/Stock/BOD</td>
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1805 Lichtleiter
1868 Gastroscopy
1881 Esophagoscope
1957 Fiberscope
1968 ERCP
1985 Aranz
1977 Billi and FBR
1987 'Sendzick and Mace
1990 ENDO

A Brief History of Endoscopy, 2000, P11
### Emerging Endoscopic Techniques

<table>
<thead>
<tr>
<th>Endoscopy has replaced</th>
<th>Endoscopy is replacing</th>
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<tr>
<td>Surgical excision of benign polyps</td>
<td>Surgical pancreatic necrosectomy (DEN)</td>
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<tr>
<td>Hemostasis</td>
<td>Surgical drainage in failed ERCP</td>
</tr>
<tr>
<td>Biliary drainage</td>
<td>Treatment of perforation and leaks (clips, suturing, stents)</td>
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<tr>
<td>- Treatment of choledocholithiasis, cholangitis, malignant and benign obstruction</td>
<td>Excision of early GI malignancy (ESD, FTR)</td>
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<tr>
<td>Pseudocyst drainage</td>
<td>Treatment of Zenker’s Diverticula (Septoplasty)</td>
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<tr>
<td>Staging for malignancy</td>
<td>Heller myotomy (POEM)</td>
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<td>GERD?</td>
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<td>Bariatric Surgery?</td>
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### EUS techniques
- Necrosectomy, EUS rendezvous / direct access, anastomosis formation (GI disease, palliation), Fine Needle Injection (FNI)
- Tissue dissection
  - Resection (ENM, ISD, FTR), Myotomy (Zenker’s, Achalasia - POEM), other
- Tissue apposition (clipping/sewing/other)
  - Perforation and leak closure, ulcer treatment, obesity, and GERD

### Pancreatic Necrosis
**DEN (Direct Endoscopic Necrosectomy)**
- Retrospective multicenter trial (6 centers, 104 patients), record review from 2003-2010
  - Initial debridement 63 days after onset
    - Successful resolution 91%
    - Time to resolution 4 months
  - Complication rate 14%
    - 3 required surgery
    - 5 deaths (1 periprocedure)

Pancreatic Necrosis
DEN (Direct Endoscopic Necrosectomy)

RCT (4 hospitals, 2008-210) Surgery vs. DEN (N=22)
- Composite clinical endpoint better with DEN vs. surgery

Pancreatic Necrosis
DEN (Direct Endoscopic Necrosectomy)

Technique

EUS
Fluoroscopy
CO2
Anesthesia

Equipment
- 19G needle
- Aspirate
- Inject
- IAG
- Hurricane
- CRE
- Scope
- Debride
- Abx Lavage
- Stent

Pancreatic Necrosis
DEN (Direct Endoscopic Necrosectomy)

Complications

Bleeding
- Access site
- Intra-cavity
Perforation
Air embolus
Sepsis
Pancreatic Necrosis
DEN (Direct Endoscopic Necrosectomy)

Case series (N60)
• Success 85%
• Complications 11.7%
• Mortality 0%

Comparison to Step-up – matched cohort study
• Success of initial procedure
  - DEN 11/12, Step-up 3/12 (p<0.01)
• Complications
  - DEN 1/12, Step-up 8/12 (p<0.01)

Other outcomes
• DEN: less new antibiotic use, pulmonary failure, endocrine insufficiency, shorter ICU and floor LOS (p<0.05)
• Health care utilization lower after DEN by ratio of 5.2:1 (p<0.01)
• $54k vs 283k total charges

Kumar N, Thompson CC. Pancreas in press

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EUS Rendezvous

EUS can provide access to the biliary and pancreatic ducts when ERCP fails
Multiple points of access
Particularly important with strictured pancreaticojejunostomy and malignancy

Kumar YS, et al. Endoscopy 2010 Apr 23

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EUS Rendezvous / PANK

Pancreatic Rendezvous
• n=21 – 14 dilated PD
• Rendezvous success (33%)
• Tight stricture, poor angle
• ERP possible with methylene blue visualization
• Complications: 1 Peripancreatic abscess, 1 mild pancreatitis

Pancreatic Antegrade Needle Knife (PANK)
• 3 patients
• All failed ERCP and rendezvous
• 100% success
• Symptom free at 2 years
• No complications


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Direct Access Cost-effective Analysis

ERCP failure rates of 3.6-7.5%
Options include repeat ERCP, DA-ERCP, PTC
Major difference in cost is fully-covered metal stent

Favored strategy depends on the suspected etiology of obstruction

- In benign biliary obstruction, repeat ERC is most cost-effective
- In malignant biliary obstruction, DA-ERC is more cost-effective than ERC and PTC as the next step

Anastomosis

Video provided by Ken Binmueller

Anastomosis
FNI: Fiducial Markers

Fiducials are placed at time of outpatient staging EUS in anticipation of external beam radiation therapy.

Tumors are soft and mobile and not easily seen on fluoroscopy used to guide radiation therapy.

Fudicial markers can be placed to demarcate proximal/distal borders.

Allows tighter field for radiation therapy with lower total radiation dose.

Fig 1: Preloaded FNA platform with VisiCoil fiducials (inset: magnified view of fiducial)

Fig 2: PET shows optimal fiducial positioning

FNI: Fiducial Markers

Fig 1: Fiducial marking proximal mass

Fig 2: PET shows optimal fiducial positioning
FNI of polymer into vascular system

FNI: Chemotherapeutics

Image Guided EUS

Emerging Endoscopic Techniques

EUS techniques
- Necrosectomy, lesion ablation, EUS rendezvous, anastomosis formation (GB disease, palliation)

Tissue dissection
- Resection (EMR, ESD, FTR), Myotomy (Zenker's, Achalasia - POEM), other

Tissue apposition (clipping/sewing/other)
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EMR / ESD Techniques

Cap-Assisted EMR
Freehand ESD

Tools of the Trade
Japanese Society of GI Endoscopy ’93–’97
- Comp rate for upper EMR 0.5% (190 / 37127)
- Comp rate for colonic EMR 0.14% (198 / 142,254)
Colon ESD retrospective series 2007–2009
- 189 patients, 12% (23/189) complication rate
- Perforation 7/189 (3.7%), Bleeding 5/189 (2.6%)
A more efficient and safer approach is needed for ESD

EMR / ESD
Countertraction methods
EMR / ESD
Countertraction methods: Suture-pulley

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EMR / ESD
Countertraction methods: Suture-pulley

Total procedure time (sec ± SEM)

* p<0.003

Suture-pulley (510±101.2 sec)
Control (108±155.9 sec)

* Statistically significant, unpaired
EMR / ESD
Countertraction methods: Suture-pulley

• The suture-pulley method provided direct vision of the submucosal dissection line regardless of lesion location
• Adjustability of tension force: advantage of this technique
• This assistive technique led to a reduction of ESD time and improved endoscopist’s mental and physical efforts

EMR / ESD
Countertraction methods: Injectables

Reverse phase polymer
• More durable elevation
• Better visualization of submucosal layer
• Ease of use
• Shorter procedure time
• Added safety

EMR / ESD
Countertraction methods: Direct Drive
Zenker’s Diverticula
Cricopharyngeal Myotomy and Septoplasty

Myotomy for Achalasia

Peroral Endoscopic Myotomy (POEM)
- N=43
- 12cm myotomy of circular muscle fibers (2cm cardia)
- Resting lower esophageal sphincter (LES) pressure (from mean 52.1 mmHg to 18.8 mmHg; P = 0.0001)
- No complications

Myotomy for Achalasia
Hybrid Knife
Myotomy for Achalasia
Other Devices

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Treatment of Perforations

Early recognition, immediate management

Most perforations can be managed endoscopically
- Hemostatic clips
- Over-the-scope clips
- Endoloops

Currently, complex perforations that are large, irregular, or complicated by peritoneal contamination are referred for surgery
Treatment of Perforations
Over the scope clips

Nitinol cap-mounted clip
Designed for tissue opposition
Case reports and series
• N 188, L 32, F 108, P 48
• Clinical success: 64%
  L 80%, F 45%, P 95%
Hard to remove

Suturing: Perforation and Ulcer Closure
OverStitch
Other applications

Endoluminal Antireflux
Graveyard?

GERD Plication

Prospective trial (N=79)
- 12 lost, 1 unrelated death, 12 revisions, 54 patients.

Discontinuation of daily PPIs was sustained in 74%
pH normal in 9/11 (89%) patients at 3 years

- Median GERD-HRQL score off proton pump inhibitors (PPIs)
improved significantly to 4 (0-32) from both off (25 [13-38], P < .0001) and on (9 [0-22], P < .0001) PPIs.

Gastroesophageal Reflux Disease (GERD) Stapling

N=27 (11 SRS, 16 LARS)
6 months mean follow up
- PPI use not sig different
- GERD-HRQL
  - 87% LARS (29.3 to 4.4)
  - 64% SRS (24.8 to 8.9) (P = 0.016)

Obesity

- Obesity is a metabolic disease
- Severe toll of comorbid illness
- Obesity more prevalent hunger
- Underserved group that requires a multidisciplinary treatment approach

Space Occupying Balloons
Space Occupying Balloons

- Weight loss at time of removal
  - Total weight loss 94.3 kg
  - 22%-52% less
- Small studies have shown variable weight loss 3-15 months after removal

Meta-analysis
- 15 trials (N=3608 total)
- RCT (n=75)

Gastric Remodeling Suturing

<table>
<thead>
<tr>
<th></th>
<th>1 mo</th>
<th>3 mo</th>
<th>12 mo</th>
</tr>
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<tbody>
<tr>
<td>N</td>
<td>18</td>
<td>18</td>
<td>14</td>
</tr>
<tr>
<td>Mean Loss (kg)</td>
<td>+/-.9</td>
<td>+/-.4.8</td>
<td>+/-.10.1*</td>
</tr>
<tr>
<td>Waist Circ (cm)</td>
<td>+/-.9</td>
<td>+/-.5.4</td>
<td>+/-.9.5*</td>
</tr>
<tr>
<td>%EWL</td>
<td>+/-.9</td>
<td>+/12.3</td>
<td>+/21.9*</td>
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* p<0.05 compared to baseline

Gastric Remodeling Suturing

- Full-thickness suturing
- May be more durable
- Repeatable
- 2 abstracts DDW 2014
- Encouraging early results
**Gastric Remodeling**

Plication

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**Gastric Aspiration Therapy**

US pilot RCT (N=18)

- Aspiration (11), Diet / lifestyle (7)
- EWL Aspiration 49.0% ± 7.7%
- EWL Lifestyle 14.9% ± 12.2 % (P < .04)

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**Duodenal Sleeve**

Randomized blinded pilot study (N=18), 24 week follow-up

- 12 sleeve
- 6 sham

Endpoints

- Primary HbA1c
- 7 point glucose profile
- DM medication use
- Weight loss
Duodenal Sleeve

- 42% off DM meds vs 37% in sham
- No sig difference in weight loss
- Device migration problematic

New Paradigm in Obesity Management

Risk / benefit ratio is of increased importance

Procedures viewed as tools to help manage a chronic condition, not as the ‘cure’

Repeatability is becoming accepted as a means to achieve durable results
  - May improve continuity of care
Conclusion

Therapeutic endoscopy is evolving to become more invasive and surgical in nature.

Several surgical procedures are currently making their way out of the OR and into endoscopy units.

Adoption will continue to grow as new technology makes these procedures safer and easier to perform.

Thank you