ACG Telehealth Survey
Your Input Needed

Telehealth Usage in GI: Before, During and After COVID-19

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Week 20: Management of Alcohol-Associated Liver Disease with Hepatology and Addiction Medicine
Ashwani K. Singal, MD, MS, FACG & Jessica L. Mellinger, MD
August 6, 2020 at Noon EDT

Week 21: Dysphagia: A Practical Approach
Kenneth R. DeVault, MD, FACG
August 13, 2020 at Noon EDT

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Type your questions here so that the moderator can see them. Not all questions will be answered but we will get to as many as possible.
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ABIM Board Certified physicians need to complete their MOC activities by **December 31, 2020** in order for the MOC points to count toward any MOC requirements that are due by the end of the year. No MOC credit may be awarded after **March 1, 2021** for this activity.

**ACG will submit MOC points on the first of each month. Please allow 3-5 business days for your MOC credit to appear on your ABIM account.**

**MOC QUESTION**

If you plan to claim MOC Points for this activity, you will be asked to: Please list specific changes you will make in your practice as a result of the information you received from this activity.

Include specific strategies or changes that you plan to implement. **THESE ANSWERS WILL BE REVIEWED.**
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Disclosures:

Moderator:
Kenneth R. DeVault, MD, FACG
Board of Directors: Mayo Clinic

Speaker:
John R. Saltzman, MD, FACG
Consultant: Cook Endoscopy
Vice President of Medical Affairs: 1Globe Health Institute

Update on the Management of Upper GI Bleeding

John R. Saltzman, MD, FACG
Professor of Medicine, part-time
Brigham and Women’s Hospital
Harvard Medical School
Objectives

• To understand initial management recommendations
• To know the timing and role of endoscopic therapy
• To be familiar with current endoscopic treatments
• To be aware of advances in endoscopic therapy
• To understand how to reduce rebleeding

GI bleeding burden

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Annual ED visits</th>
<th>% Change from 2006</th>
<th>Rate/100,000</th>
<th>Admitted to hospital with principal diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI Bleeding</td>
<td>844,500</td>
<td>+17%</td>
<td>265</td>
<td>456,900 (54%)</td>
</tr>
<tr>
<td>Upper GI bleed</td>
<td>231,600</td>
<td>-4%</td>
<td>73</td>
<td>181,600 (78%)</td>
</tr>
<tr>
<td>Lower GI bleed</td>
<td>367,900</td>
<td>+25%</td>
<td>115</td>
<td>144,400 (39%)</td>
</tr>
</tbody>
</table>

Peery AF. Gastroenterology 2019;156:254-272
Etiology of upper GI bleeding

- Peptic ulcer
- Esophageal varices
- Esophagitis/gastritis
- AVM/GAVE
- Mallory-Weiss syndrome
- Malignancy
- Dieulafoy lesion
- Rare: AEF, hemobilia, hemosuccus pancreaticus
Peptic ulcer etiology

- *Helicobacter pylori* infection
- Aspirin and NSAIDs
- Antithrombotic medications
  - P2Y<sub>12</sub> inhibitors (thienopyridines)
  - Anticoagulants (warfarin and direct oral anticoagulants)
  - Dual and triple antithrombotic therapies
- Malignancy (carcinoma, lymphoma, leiomyosarcoma)
- Acid hypersecretion (Zollinger-Ellison syndrome)
- Rare and idiopathic causes

Initial UGIB management

- Assess hemodynamic status immediately
- Insert 2 large bore IVs and begin resuscitation
- Blood transfusions
  - Target hemoglobin $\geq 7$ g/dL
  - $\geq 9$ g/dL if intravascular volume depletion or CAD
- Risk stratify patient (high-risk vs. low-risk)

IV flow rates

- Angiocatheter gauge: max infusion rate
  - 22 gauge: 35 ml/min
  - 20 gauge: 60 ml/min
  - 18 gauge: 105 ml/min
  - 16 gauge: 205 ml/min
  - 14 gauge: 333 ml/min

- Central triple lumen catheter
  - Large lumen (brown) = 52 ml/min
  - Other two lumens (blue/white) = 26 ml/min

Kumar N. *Tech Gastrointest Endosc* 2016;18:170-176

Survival according to transfusion strategy

### Restrictive vs. liberal strategy

#### B) Death by 6 Weeks, According to Subgroup

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Restrictive Strategy</th>
<th>Liberal Strategy</th>
<th>Hazard Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>23/444 (5)</td>
<td>41/445 (9)</td>
<td>0.55 (0.33–0.92)</td>
<td>0.02</td>
</tr>
<tr>
<td>Patients with cirrhosis</td>
<td>15/139 (11)</td>
<td>25/138 (18)</td>
<td>0.57 (0.29–1.13)</td>
<td>0.08</td>
</tr>
<tr>
<td>Child–Pugh class A or B</td>
<td>5/113 (4)</td>
<td>13/109 (12)</td>
<td>0.30 (0.11–0.85)</td>
<td>0.02</td>
</tr>
<tr>
<td>Child–Pugh class C</td>
<td>10/26 (38)</td>
<td>12/29 (41)</td>
<td>1.64 (0.43–6.37)</td>
<td>0.91</td>
</tr>
<tr>
<td>Bleeding from varices</td>
<td>10/93 (11)</td>
<td>17/97 (18)</td>
<td>0.58 (0.27–1.27)</td>
<td>0.38</td>
</tr>
<tr>
<td>Bleeding from peptic ulcer</td>
<td>7/228 (3)</td>
<td>11/209 (5)</td>
<td>0.70 (0.26–1.25)</td>
<td>0.26</td>
</tr>
</tbody>
</table>

#### Risk stratification for upper GI bleeding

“Early risk stratification, by using validated prognostic scales”

International Consensus Guidelines

“Risk assessment should be performed to stratify patients into higher and lower risk categories”

ACG Practice Guidelines

Laine L, Jensen D. *Am J Gastroenterol* 2012;107:345-360
Validated pre-endoscopic risk scores

**Glasgow Blatchford score** (Blatchford O. *Lancet* 2000;356:1318-21)
- Assesses need for intervention (composite score)
- Has 8 categories with weighted scores 0-23
- Best validated to predict low-risk with score 0-1
- High-risk for rebleeding with score >10 and mortality with score >12

**AIMS65 score** (Saltzman JR. *Gastrointest Endosc* 2011;74(6):1225-9)
- Assesses mortality
- 5 discrete categories (Albumin <3.0, INR >1.5, Mental status change, SBP <90, age >65)
- Best to predict mortality and high-risk outcomes with score ≥ 2

### Glasgow Blatchford score (GBS)

<table>
<thead>
<tr>
<th>Value</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUN (mg/dL)</td>
<td></td>
</tr>
<tr>
<td>&gt;18.2 &lt;22.4</td>
<td>2</td>
</tr>
<tr>
<td>&gt;22.4 &lt;28</td>
<td>3</td>
</tr>
<tr>
<td>&gt;28 &lt;70</td>
<td>4</td>
</tr>
<tr>
<td>&gt;70</td>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hgb g/dL (men)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>≥12 &lt;13</td>
<td>1</td>
</tr>
<tr>
<td>≥10 &lt;12</td>
<td>3</td>
</tr>
<tr>
<td>&lt;10</td>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hgb g/dL (women)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>≥10 &lt;12</td>
<td>1</td>
</tr>
<tr>
<td>&lt;10</td>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Value</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic BP</td>
<td></td>
</tr>
<tr>
<td>100-109</td>
<td>1</td>
</tr>
<tr>
<td>90-99</td>
<td>2</td>
</tr>
<tr>
<td>&lt;90</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Markers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate</td>
</tr>
<tr>
<td>Melena</td>
</tr>
<tr>
<td>Syncope</td>
</tr>
<tr>
<td>Cardiac</td>
</tr>
<tr>
<td>Liver</td>
</tr>
</tbody>
</table>

Meta-analysis of GBS

Table 3. Well-Validated Clinical Prediction Rules Used to Determine the Need for Urgent Evaluation of UGIB

<table>
<thead>
<tr>
<th>Clinical Score</th>
<th>Threshold</th>
<th>Specificity, % (95% CI)</th>
<th>Sensitivity, % (95% CI)</th>
<th>Positive LR (95% CI)</th>
<th>Negative LR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blatchford score(^a)</td>
<td>2</td>
<td>99.6 (99.5 – 99.6)</td>
<td>21 (9.34 – 27)</td>
<td>1.2 (1.0 – 1.3)</td>
<td>0.02 (0.01 – 0.05)</td>
</tr>
<tr>
<td>Blatchford score(^b)</td>
<td>0</td>
<td>99.0 (98.6 – 100.0)</td>
<td>21 (9.34 – 27)</td>
<td>1.4 (1.1 – 1.8)</td>
<td>0.08 (0.01 – 0.41)</td>
</tr>
<tr>
<td>Preendoscopic Rockall score(^c)</td>
<td>0</td>
<td>91 (88–95)</td>
<td>21 (9–34)</td>
<td>1.20 (0.97–1.30)</td>
<td>0.41 (0.12–0.70)</td>
</tr>
<tr>
<td>Modified Blatchford score(^d)</td>
<td>≤1</td>
<td>95 (93–96)</td>
<td>12 (11–13)</td>
<td>1.1 (1.0–1.1)</td>
<td>0.45 (0.31–0.66)</td>
</tr>
</tbody>
</table>

Abbreviations: LR, likelihood ratio; UGIB, upper gastrointestinal bleeding.\(^a\) Heterogeneity for univariate random effects (positive LR, \(I^2 = 86\%\); \(P = .001\); negative LR, \(I^2 = 45\%\); \(P = .16\)).\(^b\) Because sensitivity was 99% to 100% in every study, sensitivity was treated as a fixed effect. Heterogeneity (positive LR, \(I^2 = 97\%\); \(P = .001\); negative LR, \(I^2 = 0\%\); \(P = .59\)).\(^c\) Heterogeneity (positive LR, \(I^2 = 92\%\); \(P < .001\); negative LR, \(I^2 = 70\%\); \(P < .001\)).

ESGE Guideline

Srygley FD. JAMA 2012;307(10):1072-9

European Society of Gastrointestinal Endoscopy (ESGE) Guideline

- ESGE recommends the use of the GBS for pre-endoscopy risk stratification
- Outpatients determined to be at very low risk, based upon a GBS score of 0–1, do not require early endoscopy nor hospital admission
- Discharged patients should be informed of the risk of recurrent bleeding & advised to maintain contact with the discharging hospital

Gralnek IM. Endoscopy 2015;47:a1–a46

American College of Gastroenterology
AIMS65 score

1. Albumin <3.0 mg / dL
2. INR >1.5
3. Mental status change (GCS <15)
4. Systolic blood pressure <90 mmHg
5. Age >65 years

Saltzman JR. Gastrointest Endosc 2011;74(6):1225-9

Mortality correlates with AIMS65 score

Mortality (%) vs Number of Risk Factors Present

Area under ROC curve=0.80
AIMS65 score vs. GBS vs. Rockall score

- Retrospective evaluation of AIMS65 vs. GBS vs. Rockall scores
- 424 patients in Australia
- Results
  - AIMS65 (AUROC=0.80) superior to both GBS (p<0.03) and pre-endoscopy Rockall (p=001) in predicting mortality
  - AIMS65 superior in predicting need for ICU admission and hospital length of stay

Robertson M. Gastrointest Endosc 2016;83(6):1151-60

ACG guideline PPI recommendations

After successful endoscopic hemostasis, IV PPI therapy with 80 mg bolus followed by 8 mg/hour continuous infusion for 72 hours should be given to patients who have an ulcer with active bleeding, a non-bleeding visible vessel, or an adherent clot.

Laine L, Jensen D. Am J Gastroenterol 2012;107:345-60
Continuous vs. intermittent PPIs

<table>
<thead>
<tr>
<th>Source</th>
<th>Intermittent Bolus, No.</th>
<th>Continuous Infusion, No.</th>
<th>Risk Ratio (M-H, Fixed, 95% CI)</th>
<th>Favor Bolus %</th>
<th>Favor Infusion %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andrucci et al., 2008</td>
<td>19/239</td>
<td>28/243</td>
<td>0.69 (0.40-1.20)</td>
<td>43.2</td>
<td>56.8</td>
</tr>
<tr>
<td>Chen et al., 2012</td>
<td>6/101</td>
<td>7/100</td>
<td>0.85 (0.30-2.44)</td>
<td>11.0</td>
<td>89.0</td>
</tr>
<tr>
<td>Choi et al., 2009</td>
<td>3/21</td>
<td>1/19</td>
<td>2.71 (0.31-23.93)</td>
<td>1.6</td>
<td>98.4</td>
</tr>
<tr>
<td>Jang et al., 2006</td>
<td>0/19</td>
<td>2/19</td>
<td>0.20 (0.01-3.91)</td>
<td>3.9</td>
<td>96.1</td>
</tr>
<tr>
<td>Javid et al., 2009</td>
<td>4/53</td>
<td>4/53</td>
<td>1.00 (0.26-3.79)</td>
<td>6.2</td>
<td>93.8</td>
</tr>
<tr>
<td>Kim et al., 2012</td>
<td>2/54</td>
<td>1/52</td>
<td>1.93 (0.18-20.60)</td>
<td>1.6</td>
<td>98.4</td>
</tr>
<tr>
<td>Sung et al., 2012</td>
<td>3/105</td>
<td>2/95</td>
<td>1.36 (0.23-7.95)</td>
<td>3.3</td>
<td>96.7</td>
</tr>
<tr>
<td>Ucbilek et al., 2013</td>
<td>3/37</td>
<td>10/36</td>
<td>0.29 (0.09-0.97)</td>
<td>15.8</td>
<td>84.2</td>
</tr>
<tr>
<td>Yamada et al., 2012</td>
<td>4/13</td>
<td>5/15</td>
<td>0.92 (0.31-2.73)</td>
<td>7.1</td>
<td>92.9</td>
</tr>
<tr>
<td>Yuksel et al., 2008</td>
<td>3/49</td>
<td>4/50</td>
<td>0.77 (0.18-3.24)</td>
<td>6.2</td>
<td>93.8</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>47/691</td>
<td>64/682</td>
<td>0.74 (0.52-1.06)</td>
<td>100.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Heterogeneity: χ² = 5.96 (P = .74) I² = 0%
Test for overall effect: z = 1.65 (P = .10)

For patients who present with ulcer bleeding at high risk of rebleeding (i.e., ulcer that required endoscopic therapy followed by 3 days of high-dose IV PPI therapy, we suggest using twice daily oral PPI (vs. once daily) through 14 days followed by once daily.

Endoscopy in upper GI bleeding

- Optimal timing of upper endoscopy
- How to detect the bleeding source
- Endoscopic therapeutic techniques
  - Standard / traditional therapies
  - New techniques
- Techniques to reduce rebleeding

Timing of endoscopy

“Early endoscopy within 24 hours of presentation is recommended for most patients with acute upper gastrointestinal bleeding”

International Consensus Guidelines

“Patients with upper GI bleeding should generally undergo endoscopy within 24 hours of admission, following resuscitative efforts to optimize hemodynamic parameters”

ACG Practice Guidelines
ESGE guideline on endoscopy timing

• Following hemodynamic resuscitation, ESGE recommends early (≤24 hours) upper GI endoscopy
• Very early/emergent endoscopy (<12 hours) upper endoscopy may be considered in patients with high risk clinical features
  – Hemodynamic instability
  – In-hospital bloody emesis/nasogastric aspirate
  – Contraindication to the interruption of anticoagulation

Gralnek IM. *Endoscopy* 2015;47:a1–a46

Worse outcomes may occur with emergent endoscopy

• Inadequate resuscitation
• Procedure without usual supports
  – Endoscopy RNs and techs
• Procedure done at off hours (i.e. 11 PM to 7 AM)
  – Endoscopist may be fatigued
  – Decrease in endoscopy performance quality
• Lack of back-up support immediately available
  – Interventional radiology and surgery
Mortality and time to endoscopy

Laursen SB. *Gastrointest Endosc* 2017;85(5):936-944;
Kumar N. *Gastrointest Endosc* 2017;85(5):945-952

Consensus recommendations for timing of endoscopy

- For patients admitted with acute UGIB we suggest performing early endoscopy (within 24 hours)
- For patients at high risk of rebleeding or mortality, the group could not make a recommendation for or against performing endoscopy within 12 hours vs. performing endoscopy later

RCT of emergent endoscopy

- 516 high-risk (GBS ≥ 12) patients with acute UGIB
- Endoscopy performed within 6 hours vs. 24 hours

**Summary of timing**

**Emergent endoscopy (within 12 hours)**
- More endoscopic therapy performed
- No improvement in overall patient outcomes
- Benefits only patients with active bleeding
- May be associated with worse outcomes

**Urgent / early endoscopy (within 24 hours)**
- Decreases length of stay and costs
- Similar patient outcomes to emergent endoscopy
Prophylactic endotracheal intubation

- Massive hematemesis
- Altered mental status
- Airway protection
- May increase aspiration pneumonia
- May increase cardiac adverse events (shock)

Hayat U. Gastrointest Endosc 2017;86(3):500-509

Detection of the bleeding source:
We can only treat what we see

- Double or large channel endoscopes
- External large suction device
- IV erythromycin
- Water pump/jet
Erythromycin improves gastric visualization

- IV erythromycin powerful prokinetic
- Erythromycin 3 mg/kg or 250 mg IV over 30 minutes 1-hour before upper endoscopy
- Quality of gastric exam significantly better
- Decreased need for repeat upper endoscopy
- No difference in:
  - Length of hospital stay
  - Need for surgery
  - Adverse events

Barkun AN. *Gastrointest Endosc* 2010;72:1138-1145

### Stigmata of recent hemorrhage (SRH)

<table>
<thead>
<tr>
<th>Stigma</th>
<th>Forrest class</th>
<th>Prevalence (%)</th>
<th>Rebleeding w/o endotherapy (%)</th>
<th>Surgery (%)</th>
<th>Mortality (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active bleeding</td>
<td>IA IB</td>
<td>12% (spurting and oozing)</td>
<td>55 (range 17-100%)</td>
<td>35</td>
<td>11</td>
</tr>
<tr>
<td>Nonbleeding visible vessel</td>
<td>IIA</td>
<td>8%</td>
<td>43</td>
<td>34</td>
<td>11</td>
</tr>
<tr>
<td>Adherent clot</td>
<td>IIB</td>
<td>8</td>
<td>22</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Pigmented spot</td>
<td>IIC</td>
<td>16</td>
<td>10</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Clean base</td>
<td>III</td>
<td>55</td>
<td>5</td>
<td>0.5</td>
<td>2</td>
</tr>
</tbody>
</table>

Laine L, Jensen D. *Am J Gastroenterol* 2012;107:345-360
Re-evaluation of the Forrest classification (SRH)

Rebleeding post endoscopic therapy
Analysis from a large multicenter PPI study

![Graph showing rebleeding rates after endoscopic hemostasis at 72h in placebo-treated patients.]

Jensen DM. *Am J Gastroenterol* 2017;112:441-46

Indications for endoscopic therapy

<table>
<thead>
<tr>
<th>Stigmata</th>
<th>Endoscopic therapy?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active bleeding</td>
<td>Yes</td>
</tr>
<tr>
<td>Non-bleeding visible vessel</td>
<td>Yes</td>
</tr>
<tr>
<td>Adherent clot</td>
<td>+/-</td>
</tr>
<tr>
<td>Flat spot</td>
<td>No</td>
</tr>
<tr>
<td>Clean ulcer base</td>
<td>No</td>
</tr>
</tbody>
</table>

Laine L, Jensen D. *Am J Gastroenterol* 2012;107:345-60
Traditional endoscopic therapies

- **Injection**
- **Thermal (contact)**
  - Bipolar probe
  - Monopolar
- **Thermal (non-contact)**
  - Argon plasma coagulation (APC)
- **Mechanical**
  - Hemostatic clips
- **Combination**
  - Epinephrine + bicap or clip

Injection

- Reduce blood flow by local tamponade
- Vasoconstricting agents reduce blood flow
  - Epinephrine 1:10,000 - 1:100,000
- Various agents can be injected
  - Ethanol
  - Sclerosants
    - Ethanolamine
    - Polidocanol
  - Tissue adhesives
    - N-butyl-2-cyanoacrylate
    - Fibrin glue
    - Thrombin

Epinephrine injection monotherapy not recommended
Thermal therapy

- Bi-polar (Bicap) commonly used
- **Coaptive coagulation**: Compress vessel and then coagulate to seal vessel
- Larger 10 French probes more effective than smaller 7 Fr. probes
- 10-15 Watts for multiple 8-12 second pulses
- Optimal therapy is 4-6 pulses

Monopolar and soft coag

- Coagulation forceps and soft coagulation
- 3 small RCTs in peptic ulcer patients
- **Methods** Treatment with monopolar cautery with soft coagulation vs. hemoclips (2 studies) or heater probe
- **Results**
  - Overall similar or better efficacy compared to hemoclips, heater probe or injection
  - Monopolar therapy was safe
- **Monopolar with soft coag is an effective therapy**
  
  Arima S. *J Gastroenterol* 2010;45(5):501-5
  Toka B. *Gastrointest Endosc* 2019;89(4):792-802
Argon plasma coagulation
Best for AVMs and watermelon stomach

Hemostatic clips
Be familiar with clips

Consensus recommendations for endoscopic therapy

- For patients with acutely bleeding ulcers with high-risk stigmata, we recommend endoscopic therapy with thermocoagulation or sclerosant injection.
- For patients with acutely bleeding ulcers with high-risk stigmata, we suggest endoscopic therapy with (through the scope) clips.

New therapies

OTSC for primary control

• 251 patients with severe NVUGIB
• 49 patients randomized to OTSC or SOC
• Rebleeding with OTSC 4% vs. SOC 28%, p = 0.02
  (85% lower than SOC); NNT = 4.2
• Severe complications with OTSC 0% vs. SOC 16%, p=0.04
• ICU days with OTSC 1.5 ± 2.9 vs. SOC 4.3 ± 7.9 (p=0.17)
OTSC primary treatment benefits high-risk NVUGIB patients

Jensen D. American College of Gastroenterology
Presidential Plenary October 2019
OTSC for rebleeding

**STING Study**

- Recurrent peptic ulcer bleeding (n=66)
- Hemostasis with OTSC (n=33)
- Hemostasis with Standard Therapy (n=33)

**Primary endpoint:**
- Further Bleeding 15.2%
- Further Bleeding 57.6%
- p=0.001

Schmidt A. *Gastroenterology* 2018;155(3):674-686

Topical hemostatic agents

<table>
<thead>
<tr>
<th>Agent</th>
<th>Trade Name</th>
<th>Composition</th>
<th>Mechanism of action</th>
<th>Approved human application</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC-325</td>
<td>Hemospray</td>
<td>Granular mineral-based</td>
<td>Adsorbs H₂O, mechanical tamponade, activates clotting cascade</td>
<td>Recently approved for nonvariceal GI bleed in Canada, Hong Kong, Europe</td>
<td>CO₂ pressurized handheld canister (20 g)</td>
</tr>
<tr>
<td>EndoClot</td>
<td>EndoClot</td>
<td>Absorbable modified polymers</td>
<td>Absorbs H₂O and concentrates cells, activates clotting cascade</td>
<td>Intended for adjunctive hemostatic therapy</td>
<td>Pressurized air compressor</td>
</tr>
</tbody>
</table>

RBCs, Red blood cells.

Barkun A. *Gastrointest Endosc* 2013;77:692-700
**TC-325 data for FDA approval**

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Hemostasis on Index Endoscopy (%)</th>
<th>Re-bleed Rate (%)</th>
<th>30-day Mortality (%)</th>
<th>Bowel Perforation (%)</th>
<th>Powder Impaction (%)</th>
<th>Thromboembolic Event</th>
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</thead>
<tbody>
<tr>
<td>Feasibility Study</td>
<td>20</td>
<td>95</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>SEAL Survey</td>
<td>89</td>
<td>100</td>
<td>19</td>
<td>5.6</td>
<td>3.4</td>
<td>0</td>
<td>0</td>
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<tr>
<td>HALT Study</td>
<td>64</td>
<td>97</td>
<td>20</td>
<td>3.2</td>
<td>3.1</td>
<td>0</td>
<td>0</td>
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<tr>
<td>APPROACH Study</td>
<td>50</td>
<td>100</td>
<td>10</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Hemospray* Literature*</td>
<td>522</td>
<td>97.4</td>
<td>22</td>
<td>10.7</td>
<td>0.4</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Emergency Use</td>
<td>5</td>
<td>100</td>
<td>0</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Total</td>
<td>750</td>
<td>97.8</td>
<td>20.2</td>
<td>11.6</td>
<td>0.9</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Includes patients from the Feasibility Study and SEAL survey

[www.cookmedical.com/products/35a4a7f2-867b-4c81-a983-44ea06277852/](http://www.cookmedical.com/products/35a4a7f2-867b-4c81-a983-44ea06277852/)
TC-325 experience in Spain

- 261 cases with 219 (84%) patients with UGIB
  - Peptic ulcer 28%
  - Malignancy 18%
  - Therapeutic endoscopy related 18%
  - Rescue therapy in 191 (73%)
- Immediate hemostasis: 93.5% (CI 90%-96%)
- Rebleed rate: 21% at day 3 and 27% at day 30
- Predictors of rebleeding: Spurting bleeding and hypotension

Rodriguez de Santiago E. Gastrointest Endosc 2019;90(4):581-590

TC-325 in malignant bleeding

- Prospective, multicenter RCT in Canada in malignant bleeding
- 20 patients randomized 1:1 to TC-325 or SOC
  - Upper GI malignancy in 85% and bleeding was active oozing in 95%

Results

- Immediate hemostasis was achieved in 90% of patients treated initially with TC-325 versus 40% in the SOC group (P = 0.057)
- In SOC group 5/6 patients crossed over to TC-325, with hemostasis then achieved in 80% (4/5 patients)
- Hemostasis at index endoscopy (before or after crossover) was obtained in 87% of patients treated with TC-325
- Rebleeding in TC-325 arm in 20% at 6 months (60% in SOC)

Chen YI. Gastrointest Endosc 2020;91(2):321-328
TC-325 considerations

- Does not require special expertise
- May be effective in difficult locations
- Can be rapidly used after polypectomy or sphincterotomy
- Role in malignant bleeding
- Effective only in actively oozing or spurting bleeding lesions
- Second treatment modality needed if high risk of rebleeding
- Approved by FDA for upper and lower bleeding

Consensus recommendations for TC-325 endoscopic therapy

- In patients with actively bleeding ulcers, we suggest using TC-325 as a temporizing therapy to stop bleeding when conventional endoscopic therapies are not available or fail
- In patients with actively bleeding ulcers, we suggest AGAINST using TC-325 as a single therapeutic strategy vs. conventional endoscopic therapy (clips alone, thermocoagulation alone, or combination therapy)

TC-325 primary UGIB RCT

- 224 cases with NVUGIB from multiple centers
  - Peptic ulcer 61%
  - Malignancy 15%
  - Other causes 24%
- Immediate hemostasis
  - TC-325 97% vs. standard of care 90%
- Rebleeding at 30 days
  - Hemostatic spray monotherapy (8%)
  - Standard treatment group (9%)

TC-325 not inferior to SOC Rx in control of NVUGIB

Lau JY. DDW 2020

Repeat endoscopy for rebleeding

- Endoscopic therapy
  - Initial control 80-90%
  - Permanant control
  - Rebleeding 10-20%
  - Endoscopic therapy 50-75%
  - Permanent control
  - Angiography
  - Surgery
Reducing rebleeding: Doppler probes

- First report in upper GI bleeding in 1986
- Easy to learn and use with auditory signal
- Relatively inexpensive devices
- Ulcers with a positive Doppler signal at higher risk of rebleeding

Jensen DM. *Gastrointest Endosc* 2016;83(1):129-36; Nayor J, Saltzman JR. *Gastrointest Endosc* 2016;83(1):137-139

RCT of Doppler-guided endoscopic therapy in upper GI bleeding

- 148 patients with severe non-variceal UGI bleeding
  - Standard visually guided hemostasis
  - Doppler guided hemostasis

- **Results**
  - Rebleeding within 30 days in 20/76 (26%) standard group vs. 8/72 (11%) in Doppler group (p=0.02, NNT = 7)
  - Decreased surgery and major complications in Doppler group (p=0.05)

Jensen DM. *Gastroenterology* 2017;152(6):1310-1318
Consensus statement on the use of Doppler probes

• In patients with acutely bleeding ulcers who have undergone endoscopic therapy, the consensus group could not make a recommendation for or against using Doppler endoscopic probe (DEP) vs. no DEP to assess the need for further endoscopic therapy


Cost effectiveness of Doppler

• Decision tree evaluating the choice between Doppler endoscopic probe (DEP) and traditional endoscopic assessment (TEA) during index endoscopy for UGIB
• DEP is more efficacious (93% of patients avoiding rebleeding vs 79% for TEA)
• DEP is less expensive: $8500 vs $9100 for TEA
• DEP is an economically dominant strategy to TEA

Barkun AN. *Clin Gastroenterol Hepatol* 2019;17(12):2463
COVID-19 Impact on UGIB

- Less admissions for UGIB (40% ↓)
- Sicker patients (↓ hgb, more transfusions)
- Less upper endoscopies done (likely to minimize aerosol generating procedures)
- More capsule endoscopies and CTA
- Outcomes similar (mortality)

Schmiderer A. Endoscopy 2020 May 14
Kim J. Gastroenterology 2020 May 6

Take home points

- Resuscitate your patients adequately and risk stratify patients
- Perform endoscopy within 24 hours
- IV PPI drip x 72 hours if endoscopic therapy done
- Standard endoscopic therapies are cautery and hemoclips
- Monopolar cautery is a promising alternative
- OTSCs effective therapy with large vessels and for rebleeding
- Hemostatic spray is useful to treat active GI bleeding
- Doppler probes may decrease rebleeding rates
- Be aware of changes in management and new UGIB guidelines
Questions?

Moderator:
Kenneth R. DeVault, MD, FACG

Speaker:
John R. Saltzman, MD, FACG

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Ashwani K. Singal, MD, MS, FACG & Jessica L. Mellinger, MD
August 6, 2020 at Noon EDT

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Kenneth R. DeVault, MD, FACG
August 13, 2020 at Noon EDT

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