Surgical Grand Rounds
Thermal Sealing Devices

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Overview

• Sealing device background
• Technical Considerations & Collateral Injury
• Specific areas of study
  – Hysterectomy
  – Colectomy
  – Thyroidectomy
  – Hepatobiliary
  – Hemorrhoidectomy
  – Pulmonary resection
Background

**Ligasure**
- Bipolar electrothermy
- Feedback control
- Vessels ≤ 7 mm
- Collagen, elastin reformation

**Harmonic Scalpel**
- Vibration 55 Hz
- Protein coagulation
- Vessels ≤ 3 mm
Vessel Burst Strength-1

Percentile burst strengths for 3- to 7-mm arteries (900 mmHg max).

Kennedy Surg Endo 1998
Vessel Burst Strength-2
Harold Surg Endo 2003

- Clips consistent across vessel size, unlike ligasure/harmonic
- Harmonic inferior to ligasure >3 mm

<table>
<thead>
<tr>
<th>Device</th>
<th>2 or 3-mm vessel</th>
<th>4 or 5-mm vessel</th>
<th>6 or 7-mm vessel</th>
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<tbody>
<tr>
<td>EBVS</td>
<td>128</td>
<td>601</td>
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<td>UCS</td>
<td>226</td>
<td>205</td>
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<td>PC</td>
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<td>854</td>
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<td>LC</td>
<td>757</td>
<td>593</td>
<td>628</td>
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<tr>
<td>p value</td>
<td>&lt;0.0001</td>
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Collateral Damage - Ligasure

- Ligasure tip reaches 100 C, later laparoscopic version 35 C (Campbell Surg Endo 2003)
- “Big Bites, Big Surgeon”…Big Bleed
Collateral Damage- Harmonic Scalpel
Emam Ann Surg

- Coagulation at >60 C
- At max power, >60 C 2.5 cm from tip
- Shaft heating
- No macroscopic evidence of known histologic injury

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<tr>
<th>Make</th>
<th>Level 3</th>
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<th>Level 4</th>
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<th>Level 5</th>
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<td>Ultracision</td>
<td>74.4 (20.4)</td>
<td>52.2 (12.4)</td>
<td>120.1 (36.0)</td>
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<td>136.4 (36.1)</td>
<td>95.5 (25.3)</td>
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Feb 2008, C. Lord
Surgical Grand Rounds: Thermal Sealing Devices
Hysterectomy

- Levy (OG 2003): 40 VS 53 min, 69 vs 126 c EBL favor ligasure in VH
- Hefni (BJOG 2005): 116 patients, RCCT, VH
  - 57 vs 66 min favors ligasure
  - No △ EBL
  - 0 vs 7% bleeding complications favor ligasure
- Hagen (BJOG 2005): 7/15 ligasure pts required suture ligation, trend to longer OR time with ligasure with AH
Colectomy-Ligasure-1

• Marcello Surg Endo 2006: 48 staple/clip vs 52 ligasure
  – Only prospective randomized trial comparing established technique and ligasure
  – No difference OR time
  – No difference failure right, left, or sigmoid resections
  – Significant increase in failure with total colecotomy (12 vs 1.2%) for staple/clips
Colectomy-Ligasure-2

- Campagnacci Surg Endo 2007
  - 200 retrospective pt to harmonic / ligasure
  - Significant decrease in bleeding with ligasure
  - IMA clipped in all patients
  - 2 major complications from collateral harmonic injury
Ligasure: IMA Seal Failures

FDA Reports

- 9/07: IMA bleed, lap sigmoid, EBL 2900cc
- 8/07: LAR, IMA hemorrhage 4 hours post-op
- 8/07: LAR, IMA hemorrhage post-op
- 7/07: IMA hemorrhage post-op
- 7/07: 19 unit bleed, R uterine artery
- 3/07: death from IMA hemorrhage
- 1/07: post-op IMA hemorrhage
Hemorrhoidectomy

- Vs Open hemorrhoidectomy (Palazzo BJOS 2002): 34 blinded, randomized w/ decreased OR time (5 vs 9 min), no difference in pain scale
- Vs Open hemorrhoidectomy (Franklin Dis Colon Rectum 2003): decreased OR time (6 vs 11 min) and post-op pain
- Ligasure vs harmonic (Kwok Dis Colon Rect 2004): blinded, randomized w/ decreased OR time (11 vs 18 min), pain score, analgesic req for ligasure
- Meta-Analysis (Tan Arch Surg 2007): 260 pts each, ligasure vs conventional: decreased OR time, bleeding, and POD#1 pain. Significance?
  - no difference in bleeding complications, return to work, stenosis, incontinence
Thyroidectomy

- Prospective randomized, 200 pts, ligasure vs clamp/tie (Saint Marc Arch Surg 2007)
  - No difference in complications, stay time
  - OR time ↓ 7 minutes, “which can be considered irrelevant”
Ligasure - Beyond Vessels-1

- Small Bowel (Salameh Am J Surg 2006)
  - Stapled vs ligasure: burst strength 131 vs 11-25 mmHg (p<0.001)
- Cystic Duct/Hepatic Ducts
  - Shamiyeh Surg Endo 2002; Schulze Surg Endo 2002: swine series (n=10), no leaks of CD
  - Matthews Am Surg 2001: 100% bile leak in pigs w/ ligasure and harmonic; ex vivo human CD w/ spread to 1.3 cm or low burst pressures
Ligasure - Beyond Vessels-2

• Hepatic Resection
  – Campagnacci Surg Endo 2007: ligasure vs harmonic in 24 hepectomies. No bile leaks or transfusions in ligasure group.
  – Saiura Am J Surg 2006: 60 pts RCC ligasure vs. clamp/tie. No difference in EBL, time, leak.
Ligasure - Beyond Vessels-3
Pulmonary Resection

• Tirabassi & Banever J Ped Surg 2004
  – Swine model: stapled vs ligasure
  – Equivalent burst strength

• Shigemura Ann Thorac Surg 2004
  – 12 patients for wedge resection sealed with ligasure
  – No complications
Conclusions

- Ligasure effectively seals small vessels, harmonic less so
- Studies document statistically significant but clinically less relevant differences in OR time and EBL
- Number of small, single operator/center studies investigating new applications
- Powerful thermal devices with significant risk of collateral injury compared to traditional techniques
Lung, bowel, liver, thyroid, esophagus, hemorrhoids.... Why not?