Thermal sealing devices: valuable

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Outline

- The Past...
- Basics
- Advances in Technology
- The Devices – Ligasure, Gyrus, Harmonic scalpel, Ultracision
- Vessel sealing
- The Present...
- The Future...
Electrosurgery is more than 100 years old.

In the late 19th Century:
- Joseph Rivere

In the early 1900s
- Simon Pozzi
- Doyen

1910’s
- William Clark
History

- William Bovie:
  - Created a unit that used high-frequency current that could be used for cutting, coagulation.
  - First used at the Peter Bent Brigham Hospital in Boston on October 1, 1926 by Dr. Harvey Cushing to remove a vascular myeloma from a pt’s head.

[Image: http://www.thieme-connect.com/bilder/sns/200303/sns00163.06]
History

- Cushing used electrosurgery in more complex surgery not attempted before.
- The Liebel-Flarsheim Co.
  - Bought the patent for the Bovie Apparatus from Bovie for $1 and began production in OR’s.
Temperature Effects on Tissue

- 250°C  Tissue carbonizes from dehydration
- 100°C  Cell wall rupture
- 90°C   Tissue dessication
- 70°C   Protein denaturing
- 50°C   Enzymatic activity inactivated
- 40°C   Inflammation and edema
Basics

- **Monopolar energy:**
  - Current flows from the generator through a dispersive electrode.

- **Bipolar Energy:**
  - Circuit is completed between the tips of the instrument.
Tissue Response Generators:
- Computer controlled feedback system senses the change in resistance during the heating of tissue and automatically adjusting current and voltage.

Vessel Sealing Devices:
- Uses bipolar energy and pressure and relies on tissue response generators fuse vessel walls and creates a seal.
- High Current, Low Voltage denature the collagen and elastin in the vessel wall.
- Mechanical pressure allows the denatured protein to form a coagulum.
The Steps of RF Vessel Fusion

1. Pressure – Squeeze handle

2. Heat – Activate energy
Advances

- Ultrasonic:
  - Possess vibrating “blades” that cycle at 55,000 Hz.
  - Mechanical Energy is converted to heat that causes protein denaturation and formation of a coagulum that seals blood vessels.
Ligasure

http://www.ligasure.com
Gyrus

- Uses pulsed bipolar wave form
- Allows for cooling period between energy bursts
- Allows for cooling of jaws, less drying of tissue, less electrode sticking

[Image]

Harmonic scalpel

Ultracision

http://www.jnjgateway.com/
Bipolar Tissue Sealer – Arterial Burst Pressure

Landman, et al. 2003
Bipolar Tissue Sealer - Venous Burst Pressure

Landman, et al. 2003
Conclusion:

- Ligasure is a viable option for laparoscopic management of arteries up to 6mm, and veins up to 12mm in diameter.
Table 1. Mean ± SEM Bursting Pressures and Tensions for Canine Arterial Segments Sealed by Ultrasonic Energy (Harmonic Scalpel®; UAS) or Ligation with 3-0 Polydioxanone

<table>
<thead>
<tr>
<th>Artery Size</th>
<th>UAS</th>
<th>Suture</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medium (n=46)</td>
<td>Large (n=40)</td>
</tr>
<tr>
<td></td>
<td>(3–&lt;4.5 mm)</td>
<td>(4.5 – ≤ 6 mm)</td>
</tr>
<tr>
<td>Artery diameter (mm)</td>
<td>3.73 ± 0.06</td>
<td>5.04 ± 0.06</td>
</tr>
<tr>
<td>Bursting pressure (mm Hg)</td>
<td>318.5 ± 19.5</td>
<td>172.6 ± 18.6</td>
</tr>
<tr>
<td>Bursting tension (dyn/cm²)</td>
<td>162,858 ± 12,735</td>
<td>75,260 ± 12,112</td>
</tr>
</tbody>
</table>

Bubenik, et al. 2005
Burst Pressure

Conclusions:

- Effectively seals arteries ≤4.5mm
- Will withstand 2x normal SBP
Advantages

- **Speed:**
  - Metzelder, et al. 2006
  - Germany--Prospective Study
  - Group 1 (Feb 2003-April 2004) 10 lap transabdominal nephroureterectomy using clips/suture
  - Group 2 (April 2004-April 2005) 10 lap transabdominal nephroureterectomy using Ligasure
Advantages

Metzelder, et al. 2006

Fig. 1  Mean duration of operation (min). Endoclips/suture ligation (n = 10): mean ± SEM = 167.5 min ± 16.7 min; Endo-Ligasure™ (n = 10): mean ± SEM = 108.5 min ± 12.0 min.
Advantages

- Conclusion

- Ligasure is...safe, effective and reduces operative times compared to clip application and intracorporeal suturing.
Advantages

- Marc, et al. 2007
- Prospective Randomized Study
  - Jan 1, 2004 to Nov 30, 2004 in France
  - 200 pts were randomized for total thyroidectomy using Ligasure or traditional clamp-and-tie methods.
Advantages

Marc, et al. 2007

Table 1. Results of the Study*

<table>
<thead>
<tr>
<th>Variable</th>
<th>LigaSure† (n = 100)</th>
<th>Clamp-and-Tie (n = 100)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>Not observed</td>
<td>Not observed</td>
<td>.66</td>
</tr>
<tr>
<td>Morbidity, %</td>
<td>37</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>Transient hypocalcemia</td>
<td>21</td>
<td>18</td>
<td>.72</td>
</tr>
<tr>
<td>Permanent hypocalcemia</td>
<td>1</td>
<td>2</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Transient recurrent nerve lesion</td>
<td>12</td>
<td>10</td>
<td>.82</td>
</tr>
<tr>
<td>Permanent recurrent nerve lesion</td>
<td>1</td>
<td>1</td>
<td>1.00</td>
</tr>
<tr>
<td>Cervical hematoma</td>
<td>2</td>
<td>2</td>
<td>1.00</td>
</tr>
<tr>
<td>Parathyroid gland autotransplantation, %</td>
<td>42</td>
<td>36</td>
<td>.47</td>
</tr>
<tr>
<td>Operative time, mean ± SD, min</td>
<td>41.5 ± 11.2</td>
<td>48.9 ± 6.8</td>
<td>.001</td>
</tr>
<tr>
<td>Hospital stay, mean ± SD, d</td>
<td>1.08 ± 0.3</td>
<td>1.09 ± 0.2</td>
<td>.83</td>
</tr>
</tbody>
</table>
Advantages

Conclusions:

- Mean operative time saving was 7.4 minutes—with translates to an additional 30 operations each year.
- Use of Ligasure is equally as safe and effective at vessel division and hemostasis as the clamp and tie technique, with a statistically significant...decrease in mean operative time.
Advantages

- Better Hemostasis

- Tan, et al.
  - Meta-Analysis of RCT of Ligasure vs conventional hemorrhoidectomy from 2002-2006.
  - 9 studies were used
    - 525 pts (grade III-IV hemorrhoids)
      - 266 (50.7%) used Ligasure
      - 259 (49.3%) used conventional surgery
Results:

- 9/9 studies reported statistically significant decrease in operative time in the Ligasure group.
  - 8.67 minutes, CI -15.34 to -2

- 4/9 studies reported less blood loss in the Ligasure group
  - 23.08 mL, CI -27.24 to -18.92

- No difference in reported pain on POD #1 or difference in length of stay or return to work, no statistical difference in complications.
Advantages

Ligasure hemorrhoidectomy results in a significant reduction in operative time and blood loss.
Advantages

- Marcello, et al. 2006
- Randomized Prospective Trial
  - Compared pedicle ligation during lap colectomy (vascular staplers/clips, Ligasure)
  - 100 pts randomized
    - 48 staples/clips
    - 52 Ligasure
## Advantages

<table>
<thead>
<tr>
<th>Overall</th>
<th>LIG (n = 52)</th>
<th>S/C (n = 48)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures: n (%)</td>
<td></td>
<td></td>
<td>0.88</td>
</tr>
<tr>
<td>Right colectomy</td>
<td>17 (33)</td>
<td>17 (35)</td>
<td></td>
</tr>
<tr>
<td>Left/sigmoid colectomy</td>
<td>22 (42)</td>
<td>21 (44)</td>
<td></td>
</tr>
<tr>
<td>Total colectomy</td>
<td>13 (25)</td>
<td>10 (21)</td>
<td></td>
</tr>
<tr>
<td>TAC</td>
<td>5</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>TPC</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>IPAA</td>
<td>5</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Hand-assisted laparoscopy: n (%)</td>
<td>35 (67)</td>
<td>34 (71)</td>
<td>0.70</td>
</tr>
<tr>
<td>Operative time (min)(^b)</td>
<td>179 ± 62 (92–363)</td>
<td>190 ± 70 (86–383)</td>
<td>0.44</td>
</tr>
<tr>
<td>Adjusted operative time(^b) (min)(^a)</td>
<td>177 ± 62 (92–363)</td>
<td>186 ± 70 (86–383)</td>
<td>0.46</td>
</tr>
<tr>
<td>Conversions</td>
<td>0</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>Total EBL (ml)(^b)</td>
<td>217 ± 167 (50–800)</td>
<td>231 ± 166 (50–1,000)</td>
<td>0.33</td>
</tr>
<tr>
<td>Vessels ligated/case(^a)</td>
<td>3.3 ± 2.0 (1–7)</td>
<td>3.2 ± 2.1 (1–9)</td>
<td>0.78</td>
</tr>
<tr>
<td>Ligation failures: n (%)</td>
<td>5/169 (3)</td>
<td>14/152 (9.2)</td>
<td>0.02</td>
</tr>
<tr>
<td>Failure EBL(^c)</td>
<td>100 (25–800)</td>
<td>50 (20–50)</td>
<td>0.054</td>
</tr>
</tbody>
</table>

### Right colectomy

<table>
<thead>
<tr>
<th>(n = 17)</th>
<th>(n = 17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand-assisted laparoscopy: n (%)</td>
<td>1 (6)</td>
</tr>
<tr>
<td>Operative time (min)(^b)</td>
<td>139 ± 37 (92–227)</td>
</tr>
<tr>
<td>Adjusted operative time(^b) (min)(^a)</td>
<td>136 ± 37 (92–227)</td>
</tr>
<tr>
<td>Vessels ligated/case(^a)</td>
<td>2.2 ± 1.0 (1–4)</td>
</tr>
<tr>
<td>Ligation failures n (%)</td>
<td>1/37 (2.7)</td>
</tr>
</tbody>
</table>

### Left/sigmoid colectomy

<table>
<thead>
<tr>
<th>(n = 22)</th>
<th>(n = 21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand-assisted laparoscopy: n (%)</td>
<td>22 (100)</td>
</tr>
<tr>
<td>Operative time (min)(^b)</td>
<td>160 ± 23 (123–226)</td>
</tr>
<tr>
<td>Adjusted operative time(^b) (min)(^a)</td>
<td>159 ± 24 (123–226)</td>
</tr>
<tr>
<td>Vessels ligated/case(^a)</td>
<td>2.2 ± 0.6 (1–3)</td>
</tr>
<tr>
<td>Ligation failures: n (%)</td>
<td>3/48 (6.3)</td>
</tr>
</tbody>
</table>

### Total colectomy

<table>
<thead>
<tr>
<th>(n = 13)</th>
<th>(n = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand assisted laparoscopy: n (%)</td>
<td>12 (92)</td>
</tr>
<tr>
<td>Operative time (min)(^b)</td>
<td>264 ± 56 (165–363)</td>
</tr>
<tr>
<td>Adjusted operative time(^b) (min)(^a)</td>
<td>261 ± 55 (165–363)</td>
</tr>
<tr>
<td>Vessels ligated/case(^a)</td>
<td>6.5 ± 0.5 (6–7)</td>
</tr>
<tr>
<td>Ligation failures: n (%)</td>
<td>1/84 (1.2)</td>
</tr>
</tbody>
</table>

LIG, LigaSure Atlas group; S/C, staple/clips group; TAC, total abdominal colectomy/ileoanesotomy or ileorectal anastomosis; TPC, total proctocolectomy/ileoanesotomy; IPAA, total proctocolectomy with ileal pouch anal anastomosis; EBL, estimated blood loss

\(^a\) Values listed as mean ± standard deviation (range)

\(^b\) Operative times were adjusted for concomitant procedures

\(^c\) Values listed as median (range)

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Marcello, et al. 2006
### Advantages

Table 4. Cost of vascular pedicle ligation

<table>
<thead>
<tr>
<th>Cost of devices (February 2003)</th>
<th>LigaSure Atlas</th>
<th>Clip applicer (large)</th>
<th>Endoscopic stapler</th>
<th>Each stapler reload</th>
<th>S/C*</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$317</td>
<td>$105</td>
<td>$269</td>
<td>$87</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of pedicle ligation/case</td>
<td>LIG</td>
<td>$400 ± 112</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total group</td>
<td>$317</td>
<td>$375</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(105–672)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right colectomy</td>
<td>$317</td>
<td>$348 ± 95</td>
<td>$375</td>
<td></td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(105–548)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left/sigmoid colectomy</td>
<td>$317</td>
<td>$362 ± 52</td>
<td>$375</td>
<td></td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(270–462)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total colectomy</td>
<td>$317</td>
<td>$565 ± 67</td>
<td>$567</td>
<td></td>
<td>0.002</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(462–672)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

LIG, LigaSure Atlas group; S/C, staple/dips group
* Values listed in the S/C group as mean ± standard deviation and median (range)

Marcello, et al. 2006
Advantages

Cost per case was less in the Ligasure group:

- $317 vs 400
- Cost difference greatest in the total colectomy group because cases usually required 1 stapler, 1 staple reload, and 2 clip appliers for the division of 6-9 major vessels.
Advantages

Conclusions:

- Ligasure proved to be more cost effective during laparoscopic colectomy, especially total colectomy, and may allow the surgeon more versatility in its application.
Advantages

- Speed
- Hemostasis
- Cost
Smulders, et al.

- Used a prototype Ligasure Anastomotic Device (LAD) to create 8 total anastomoses in pigs (4 pigs, 2 anastomoses each).
- POD #7 animals taken back to the OR to look for signs of peritonitis/anastomotic leak.
- Each anastomosis was examined histologically.
- Conclusion: “confirm the feasibility to create...intestinal anastomoses using Ligasure technology”.
Santini, et al.

Clinical Phase:

- June 2003-May 2004 used Ligasure on 36 pts undergoing lung surgery.
  - 16 thoracotomies
    - 19 wedge resections
    - 2 segmentectomies
    - 2 fissure separations
  - 20 VATS
    - 13 wedge resections
    - 5 bullectomies
    - 2 adherence dissections
The future...¹³

Results:

- Mean operating time 77 minutes
- No complications
- Mean post-op stay 7.3 days
The future...  

Conclusions:

- Use of Ligasure in lung surgery appears feasible and easy. It provides satisfactory hemostasis and air-leak prevention; results are comparable to those of stapling devices, but this system seems to have a better benefit/cost ratio. Larger series are needed to confirm these data.

- Compared to staplers, this system allows a better tailoring of nonanatomical lung resection margins, thus saving functional lung tissue and avoids the use of multiple reloadable cartridges, thus reducing cost.
The future…

- Eroglu, et al. Turkey.
  - Prospective Trial involving 60 pts (30 in each group) comparing use of Ligasure and traditional clamping methods used in Ivor Lewis Esophagectomy
The future...  

**Table 2. Perioperative Outcomes**

<table>
<thead>
<tr>
<th></th>
<th>LigaSure*</th>
<th>Conventional*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 30)</td>
<td>(n = 30)</td>
</tr>
<tr>
<td>Operating time (mins)</td>
<td>260 ± 35</td>
<td>307 ± 35</td>
</tr>
<tr>
<td>Perioperative blood loss (mL)</td>
<td>390 ± 256</td>
<td>533 ± 211</td>
</tr>
<tr>
<td>Postoperative drained (mL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal</td>
<td>40 ± 61</td>
<td>70 ± 86</td>
</tr>
<tr>
<td>Thorax</td>
<td>540 ± 359</td>
<td>690 ± 646</td>
</tr>
<tr>
<td>Postoperative complication</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Hospital stay (y)</td>
<td>13.3 ± 2.9</td>
<td>14.4 ± 4.4</td>
</tr>
<tr>
<td>Hospital mortality</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

* LigaSure Vessel Sealing System (Valleylab, Boulder, CO)  

** Values are mean plus standard deviation.
Conclusion:

- [Ligasure showed] a reduction in intraoperative and postoperative blood loss, and a shortening of operation duration.
- We believe that the use of [Ligasure] in esophageal surgery will become even more widespread in the future.
Thank you!

Questions...
References


