Role of Endoscopy in Gastroesophageal Reflux Disease

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Berlin, May 4, 2006
Role of Endoscopy in Gastroesophageal Reflux Disease

- **In Diagnosis**
  - Magnifying endoscopy
  - Chromoendoscopy
  - NBI, narrow band imaging

- **In Surveillance**

- **In Therapy**
Barrett-Esophagus

Methylene Blue Staining
Barrett-Eosophagus

Staining with Acetic Acid 99%
Confokal Laser Endomicroscopy

Normal Endoscopy
- ~ 30X
- No microscopic details

Zoom Endoscopy
- ~100X
- Crypts visible, but no details

Confocal Endoscopy
- ~1000X
- Cellular resolution of crypts

Kindly provided by R. Kiesslich/Mainz
Barrett-Esophagus


- CONCLUSIONS: In most patients with high-grade dysplasia or early cancer in Barrett's esophagus, subtle lesions can be identified with high-resolution endoscopy. Indigo carmine chromoendoscopy and narrow-band imaging are comparable as adjuncts to high-resolution endoscopy.
Barrett-Esophagus

• Routine use of chromoendoscopy or NBI:

• No proof of greater early detection rate of neoplasia in addition to magnifying endoscopy
Gastroesophageal Reflux Disease

Heart Burn
- 7% daily
- 14% weekly
- 44% once per month

PPI:
Successful therapy in 85-92%
Relapse after stop of PPI’s: 80% within 6 months
⇒ Costs worldwide per year > 60 billion $
Reflux Disease - “PPI - Gap”

- Allergic side effects
- Heart burn at night
- High volume reflux
- Extra esophageal manifestations
- Anxiety to take drugs
Surgical Therapy
Laparoscopic Fundoplication

- Problems of surgery: effective medical treatment available
- Indications: persistent regurgitation, unwanted side effects, denial to take drugs continuously
- Precondition: high volume, expert center, manometry
- Complications: vagus lesion, relapse, gas-bloat syndrome
GERD-Therapy without Drugs

- **Laparoscopic Fundoplication**
- **Endoscopic Therapies**

  **Gastroplication**
  (EndoCinch, ESD, Plicator)

  **Radiofrequency application**
  (Stretta, Curon Medical)

  **Injektion of an inert polymer**
  (Enteryx: no longer licensed, Gatekeeper)
“Indications” for Endoscopic Antireflux Therapy

- Impairment of quality of life due to drug therapy
- Alternative to continuous therapy with PPI
- Small axial hiatus hernia
- Important
  Symptoms & proof of reflux: endoscopy & pH-metry
  Manometry: exclusion of achalasia
EndoCinch – Endoscopic Sewing System BARD Co.

Several published studies
Patient: before EndoCinch
Endoscopic Fundoplication
Patient: 6 Weeks after EndoCinch
Patient before EndoCinch

Pat. 6 weeks after EndoCinch
EndoCinch II - Clipsystem
EndoCinch: US - Multi-Center-Study

• Prospective, multi center

• 64 patients with symptomatic reflux disease

• Post surveillance 1, 3, 6 months

**Inclusion -**

• GERD symptomatic
  > 2/weeks

• PPI/H2-Blocker con. therapy
  positive response

• pH <4 more than 4% of time

**Exclusion Criteria**

• Reflux esophagitis III/IV

• BMI > 40

• PPI refractory GERD

• Hiatal hernia > 2 cm

Filipi et al: Gastrointest Endosc 2001
Heart burn symptom score (frequency x intensity) (N=64)

Filipi et al: Gastrointest Endosc 2001
EndoCinch: US - Multi-Center-Study

Patients without Medication (< 4 Doses PPI/H₂B/month)

Filipi et al: Gastrointest Endosc 2001

(N=64)
DeMeester Symptom Score (Leipzig)

- Before EndoCinch (n=48): 21% DeMeester score
- 6 mo post-EndoCinch (n=32): 31% DeMeester score
- 12 mo Post-EndoCinch (n=11): 36% DeMeester score
24-hour pH-metry (Leipzig)

\[ n = 12 \]
\[ n = 7 \]

\[ 6 \]
\[ 1 \]
\[ 10, 20, 30 \]

\[ \text{before EndoCinch} \]
\[ \text{6 mo after EndoCinch} \]

\[ n = 22 \]
\[ p < 0.05 \]

\[ 10.1 \]
\[ 4.9 \]

\[ \% \text{time pH < 4} \]
Endocinch: Patients` Satisfaction

Would you do it again?

- 84% would do it again
- 16% would not do it again

Would you recommend the procedure to friends? N = 43

- 79% would recommend
- 21% would not recommend
## EndoCinch - Effect on Symptoms

<table>
<thead>
<tr>
<th>Study</th>
<th>n=</th>
<th>Mean F/U (mos)</th>
<th>HSS</th>
<th>RFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filipi (2001)</td>
<td>64(47)</td>
<td>6</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Park (2001)</td>
<td>142</td>
<td>3</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Patel (2001)</td>
<td>55</td>
<td>3.7</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Mahmood (2001)</td>
<td>20(11)</td>
<td>3</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Maple (2001)</td>
<td>23(21)</td>
<td>6.7</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Abdu-Rebyeh (2002)</td>
<td>16(14) &lt; 3</td>
<td>yes</td>
<td>----</td>
<td></td>
</tr>
<tr>
<td>Liu (2002)</td>
<td>19(17)</td>
<td>&lt; 6</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Caca (2002)</td>
<td>54(43)</td>
<td>6</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Chen (2002)</td>
<td>183(42)</td>
<td>12</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Arts (2002)</td>
<td>20</td>
<td>3</td>
<td>yes</td>
<td>----</td>
</tr>
</tbody>
</table>
Endocinch


• CONCLUSION: Endoscopic gastroplication (EndoCinch) is a safe and minimally invasive endoscopic treatment for GORD with reasonable short term results. In contrast, long term outcome is disappointing, probably due to suture loss in the majority of patients.
Endocinch: predictors of outcome?


- Three variables were significantly predictive for successful endoscopic anti-reflux treatment at the multivariate level: presence of typical symptoms (P=0.01), complete symptom relief with acid suppressive therapy (P=0.01), and normal lower esophageal sphincter pressure (P = 0.04).
ESD: Flexible Endoscopic Sewing Device
Wilson-Cook Medical

- No studies in GERD
- Animal studies regarding sewing technique
- First trials in humans
- FDA approval: „soft tissue apposition“
- In Europe not licensed
ESD


- CONCLUSIONS: Endoluminal gastroplication using the ESD is an easy and safe, but unfortunately ineffective procedure for endoscopic GERD treatment. Endoluminal gastroplication techniques clearly need refinements before these therapies can evolve as a treatment option for GERD patients.
PLICATOR  NDO Surgical
CONCLUSIONS: Endoscopic full-thickness plication is feasible, safe and, in this pilot study, appeared to reduce symptoms and medication use associated with GERD.
12 published studies
Stretta – Quality of Life: (GERD-HRQL)

Triadafilopoulos et al: Gastrointest Endosc 2002

N=94
### Stretta – Sham-Control-Study

<table>
<thead>
<tr>
<th>6 Months</th>
<th>Sham (n=30)</th>
<th>Stretta (n=34)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heartburn</td>
<td>-0.6</td>
<td>-1.6</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>GERD-HRQL</td>
<td>-3</td>
<td>-13</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>SF-36</td>
<td>+1</td>
<td>+7</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Stop of PPI therapy</td>
<td>-29%</td>
<td>-46%</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

- 20 pats Cross-over: GERD-HRQL $-2 \rightarrow -11$
- Ø Change in pH-metry or manometry
  - but: pH-change in responder-subgroup

**Corley et al: Gastroenterology 2003**
Injection of Biocompatible Polymers

Enteryx™ – Ethylene-Vinyl-Ethanol:
Enteric Medical / Boston Scientific

fatal complications
no longer in use
Implantation of Polyacrylnitrol
Gatekeeper - Medtronic®

Medizinische Klinik & Poliklinik II
Universität Leipzig
JM May 2006
Peptic Esophageal Stenosis
Peptic Esophageal Stenosis after bouginage
Endoscopic Antireflux Therapy

Summary

- Endoscopic anti reflux therapy at the beginning of a new aerea
- Techniques at present only partially successful
- No clear cut long term results
- No prospective randomized comparative data
- Limited indications → detailed post surveillance mandatory
Summary
Barrett-Esophagus

• Routine use of chromoendoscopy or NBI:

• No proof of greater early detection rate of neoplasia in addition to magnifying endoscopy