Treatment of Fecal Incontinence with Bulking Agents

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What is injection treatment?

Volume expansion in proximal anal canal
History - Pioneers


- Injectable silicone biomaterial for faecal incontinence due to internal anal sphincter dysfunction. Gut 2002
Components of Continence

- Internal sphincter
- External sphincter
- Levators + puborectal muscle
- Anal cushions
- Rectum + colon (gut motility)
Internal sphincter

- Generate 60% of RP
- Constantly active
- Autonomic innervation
- Visceral muscle
- Continuation of bowel muscular layer
External sphincter

* Represent 20% of RP
* 80% of SP
Anal cushions

Contribute 10-15% of resting pressure
Provides ultimate closure of anus
Reduced after haemorrhoidectomy
Restored by injection therapy

Levators + puborectal muscle

Contribute to continence by tonic activity in levators and Puborectal muscle and reduction of anorectal angle
Compensate for sphincter dysfunction
Enteral component

Increased incoordinated pressures might cause incontinence
Physiology

What can be expected?

No of FI episodes

Baseline
Injectables
SNS
Adequate selection?
Adequate selection?
Therapeutic ladder

- Baseline treatment
- Biofeedback
- Local sphincter surgery
- SNS
- Neosphincter
- Stoma
- Bulking
- Biofeedback
- Baseline treatment

Diagram showing a ladder with steps for different treatments and interventions.
Patient selection

- FI, not gas
- Moderate FI, not total incontinence
- Passive incontinence
- IAS defects
- Key hole defects
- Intact anal canal
Contraindications

- Anal infections
- Active IBD with proctitis
- Prolapse
  - Rectal
  - Mucosal
- Bleeding diathesis
- Anatomical problems
- Total incontinence
Questionable indications

- Urgency incontinence
- Severe incontinence
- Irradiation proctitis
- Healed IBD
- EAS defects
- Anastomoses
Technique preparations - material

- Emptied rectum
- Outpatient treatment
- Left lateral position
- Transparent proctoskope with light
- Assistent + Suction
- 4 x 1 ml Solesta
- "swabs"
Injection technique

- 5-10 mm above dentate line
- Kl 6, 9, 12, och 3.
- Visible bulge
- Retain needle in situ 10-15 sec
- 1 h observation
Technique intersphincteric injection

- UL-guided
- Perianal block
- 4 x 2 ml between IAS - EAS
Post treatment advices

- Light analgaesics
- Telephone contact after 4 weeks
- Provided
  - Insufficient effect
  - No adverse effects
  - Patient motivated
- Re treatment with 4 x 1 ml
Follow-up

- In studies
  - Symptomatic evaluation
  - Palpation
  - Rectoscopy (not before 3 months)
- Ultrasound, MRI, CT: implants usually visible
- In clinical practice
  - Tell the patient to call if unsufficient effect
Importance of migration at follow-up

- 44 implants in 15 pts
- 7 implants not visible,
- 4 implants dislocated
- No correlation remaining implants vs effect

Solesta Pilot study

- 34 pts
- 4 × 1 ml submucous inj, optional retreatment
- Evaluation at baseline, 3, 6 and 12 months
- 4 week diary, bowel questionnaire, SF 36
Results – Solesta pilot study

Change in number of incontinence episodes over time

Dis Colon Rectum. 2009 Jun;52(6):1101-6
Change in FI episodes according to baseline manometry

Figure 3: Change in number of incontinence episodes over a 4 weeks period in relation to manometry results.
NASHA Dx vs Sham

- 136 vs 70
- 6 mån blind period
- Resp 50% red FI ep.
- 52 vs 31% resp
- P=0.0089

NASHA Dx mot Sham

Incontinence free days

Change in FI episodes

FIQL

Long term follow up after NASHA Dx

ASCRS abstract annual meeting, San Antonio, June 2-6 2012
Two year follow up – Solesta Pilot Study

- FI episodes
  - Baseline: 25
  - 12 months: 10
  - 24 months: 7

- Miller score
  - Baseline: 14
  - 12 months: 11
  - 24 months: 10.5

*Tech Coloproctol.* 2012 Dec 7. [Epub ahead of print]
Two year follow up – Solesta Pilot Study

[Graph showing correlation between change in SF-36 Physical Function score and change in number of incontinence episodes]

Tech Coloproctol. 2012 Dec 7. [Epub ahead of print]
Long term efficacy of Solesta

- 83/115 enrolled completed 24 mo FU
- 68.8% reduction in FI episodes (19------8)
- Incontinence free days increased by 50% (14.6------21.7)
- Improvement in FIQL
Solesta - Intersphincteric injection

16 patients, (1 man, mean age 64, 45-80)
FI episodes through diary and CCFIS

ASCRS abstract annual meeting, San Antonio, June 2-6 2012
Side effects

- Solesta pilot study: 3 pts (9%) urgency, fever, diarrhea
- Randomised study: 2 (1.5%) abscesses (1 prostatic and 1 perirectal)
- All adverse events resolved
Permacol as submucous implant

- 100 pts, 70 women, mean age 61 (36-82)
- 56 reported improvement
- CCFIS 14----8
- Repeat injection in 38, 3:rd injection in 15
- Older age predictor of success

Permacol as submucous implant

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<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Median age, y (range)</td>
<td>61 (36–82)</td>
</tr>
<tr>
<td>Sex (M:F)</td>
<td>30:70</td>
</tr>
<tr>
<td>Median squeeze pressures</td>
<td>54.7 (21.1–112.2)</td>
</tr>
<tr>
<td>Median resting pressures</td>
<td>40.4 (18.1–89.9)</td>
</tr>
<tr>
<td>Normal physiology profiles</td>
<td>22</td>
</tr>
<tr>
<td>Sphincter morphology</td>
<td></td>
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<tr>
<td>IAS defects</td>
<td>24</td>
</tr>
<tr>
<td>IAS thin</td>
<td>14</td>
</tr>
<tr>
<td>EAS defects</td>
<td>12</td>
</tr>
<tr>
<td>EAS thin</td>
<td>7</td>
</tr>
<tr>
<td>Both defects</td>
<td>6</td>
</tr>
<tr>
<td>Delayed PNMTL</td>
<td>60</td>
</tr>
<tr>
<td>Types of fecal incontinence</td>
<td></td>
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<tr>
<td>Idiopathic</td>
<td>70%</td>
</tr>
<tr>
<td>Traumatic</td>
<td>15%</td>
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<tr>
<td>Neuropathic</td>
<td>10%</td>
</tr>
<tr>
<td>Mixed</td>
<td>5%</td>
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<tr>
<td>Repeat injections</td>
<td></td>
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<tr>
<td>First repeat</td>
<td>38%</td>
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<tr>
<td>Second repeat</td>
<td>15%</td>
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IAS = internal anal sphincter; EAS = external anal sphincter; PNMTL, pudendal nerve motor nerve latency.

Permacol as submucous implant

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline score</th>
<th>6 wk</th>
<th>6 mo</th>
<th>12 mo</th>
<th>24 mo</th>
<th>36 mo</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCFIS scores (range)</td>
<td>14 (9–18)</td>
<td>6 (5–14)</td>
<td>8 (6–14)</td>
<td>12 (10–16)</td>
<td>8 (6–12)</td>
<td>8 (6–12)</td>
<td>0.01</td>
</tr>
<tr>
<td>Subjective Improvement</td>
<td>NA</td>
<td>80%</td>
<td>74%</td>
<td>60%</td>
<td>74%</td>
<td>68%</td>
<td>–</td>
</tr>
<tr>
<td>Repeat injections (range)</td>
<td>16 (12–8)</td>
<td>–</td>
<td>10 (8–14)</td>
<td>14 (10–14)</td>
<td>10 (8–12)</td>
<td>10 (8–12)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

The p value compares baseline versus 36 months results.
CCFIS = Cleveland Clinic Florida Incontinence Score; NA = not applicable.

The Gatekeeper

British Journal of Surgery 2011; 98: 1644–1652
The Gatekeeper

- FI episodes 7·1/week to 1·4, 1·0 and 0·4 at 1-month, 3-month and last follow-up \( (P = 0·002) \).
- **CCFIS 12·7 to 4·1, 3·9 and 5·1** \( (P < 0·001) \)
- No morbidity
- *British Journal of Surgery 2011; 98: 1644–1652*
Potential adverse events

- Abscesses < 3%
- Pain about 5%
- Outlet obstruction unusual
- Positive effect sometimes delayed 3-6 mo
Cochrane review

- PTQ superior to Durasphere
- US superior to digital guidance in intersphincteric injection
- PTQ not superior to placebo
- Solesta superior to sham concerning
  - FI episodes
  - incontinence free days

Summary and conclusions

- Simple, minimal invasive treatment
- 50% reduction in FI episodes
- Stable effect up to 3 years
- Potential to improve QoL
Summary and conclusions

- Few side effects
- Valuable complement to established treatments
- Indicated after baseline treatment or to optimise after more invasive procedures