Contrast Salpingo-Sonography in evaluation of tubal patency

N. Exalto & M.H. Emanuel
Disclosure

- N. Exalto and M.H. Emanuel:
  - invented GIS and HyFoSy
  - are owner of the patents
  - are stockholder of Gynaecologic BV
  - receive royalties of Gynaecologic BV

[Logos]

www.gynaecologiq.com
Van Roessel J, Wamsteker K en Exalto N
Gel Instillation Sonohysterography (GIS) with ExEm® Gel

An alternative for Saline Infusion Sonohysterography (SIS)

- Less leakage / pain => minimal inconvenience
- Stable filling => better image + longer investigation time
Gel: glycerol + hydroxyethylcellulose

Without other substances like

Chloorhexidine and /or lidocaïne

= Medical device # Pharmaceutical

= ExEm®-gel proper viscosity
2007

- ExEm® Gel: hydroxy-ethyl-cellulose + glycerol + purified water

- Safety:
  - Urology  urethra  catheter gel
  - Surgery  intra-abdominal adhaesion prevention
  - Ophthalmol  eyedrops  artificial tears
  - Gynecol  intra-uterine  local anaesthesia
  - Neurol  intravasc  treatment of cerebral edema

- > 30,000 GIS procedures without any serious side effects
No effect on blastocyst development

**Mouse Embryo Test**

Control Assay Results:
- \( \geq 80\% \) 1 cell to blastocyst within 120 hrs
- \( \geq 50\% \) blastocysts hatching within 120 hrs

Test Assay Results:
- \( \geq 80\% \) 1 cell to blastocyst within 120 hrs
- \( \geq 50\% \) blastocysts hatching within 120 hrs

**Requirements for Passing**

- \( \geq 80\% \) 1 cell to blastocyst within 120 hrs
- \( \geq 50\% \) blastocysts hatching within 120 hrs

**Result**

- 100%
- 95%
- 87%
- 77%

**MEA RESULTS: PASS**
Filling slowly
# Gel instillation sonohysterography: first experience with a new technique

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## Table 1

Gel instillation sonohysterography (GIS) indications and findings in 120 patients.

<table>
<thead>
<tr>
<th>Indication</th>
<th>N</th>
<th>GIS normal (n)</th>
<th>GIS abnormal (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal uterine bleeding</td>
<td>52</td>
<td>27</td>
<td>25</td>
</tr>
<tr>
<td>Postmenopausal bleeding</td>
<td>32</td>
<td>11</td>
<td>21</td>
</tr>
<tr>
<td>Residual trophoblastic tissue</td>
<td>10</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Habitual miscarriage/infertility</td>
<td>4</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Evaluation myomas/polyps</td>
<td>5</td>
<td>—</td>
<td>5</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>10</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Failed procedure</td>
<td>7</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>120</td>
<td>49</td>
<td>64</td>
</tr>
</tbody>
</table>

G.I.S. Virtual Hysteroscopy

**FIGURE 2**
Sonographic visualization of an endometrial polyp (A) before and (B) after uterine cavity distension with gel; (C) hysteroscopic confirmation.

**FIGURE 3**
Three-dimensional (3D) gel instillation sonohysterography (GIS) reconstruction of an endometrial polyp.
Position anteflexion
Position | Retroflexion
Secretory phase
Subseptate uterus
Residual placental tissue

Publications on G.I.S.
Bij de Vate et al 2010
Werbrouck et al 2011
Van Den Bosch et al 2011 a
Van Den Bosch et al 2011 b
Artefacts: air bubbles
The GIS®-kit
- Hysterosalpingo Foam Sonography (HyFoSy)
- As an alternative for Hysterosalpingo Contrast Sonography (HyCoSy) with Echovist®, saline/air, e.g. (off label)
- Gel diluted and pushed through a small opening =>
- Turbulence => local pressure drop => air dissolving => Foam
HyFoSy

- 10 ml ExEm® Gel containing 88.25% purified water mixed with
- 10 ml purified water => mixture containing 94.10% purified water =>
- Echogenicity for at least 5 minutes and sufficient fluid to pass patent tubes
- Viscosity ExEm foam 270 cPs compared to Echovist 400 cPs
- Saline mixed with air
HyFoSy

- Connect the syringe to the applicator
- Introduction of the applicator into the cervical canal
- After removal of the speculum => introduction of the US transducer
- Pushing the plunger of the syringe with light pressure by assisent
HyFoSy

- After identifying the foam in the uterine cavity =>
- Transverse plane => distension of the Fallopian tubes at both sides
- And dispersion of the foam in the peritoneal cavity
Filling slowly
First experiences with hysterosalpingo-foam sonography (HyFoSy) for office tubal patency testing

Mark Hans Emanuel¹, Michelle van Vliet¹, Maaike Weber¹, and Niek Exalto²
<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patent</td>
<td>57 / 73</td>
<td>78 % no HSG</td>
</tr>
<tr>
<td>Patent tubes both sides</td>
<td>55 / 73</td>
<td></td>
</tr>
<tr>
<td>Patent tube (one present)</td>
<td>2 / 73</td>
<td></td>
</tr>
<tr>
<td>One tube not visible</td>
<td>5 / 73</td>
<td>HSG normal 2/5</td>
</tr>
<tr>
<td>Both tubes not visible</td>
<td>5 / 73</td>
<td>HSG normal 3/5</td>
</tr>
<tr>
<td>Discordance</td>
<td>5 / 73</td>
<td>7 %</td>
</tr>
<tr>
<td>Successful procedure</td>
<td>67 / 73</td>
<td>92 %</td>
</tr>
<tr>
<td>Cervical blockage</td>
<td>5</td>
<td>HSG normal 2/5</td>
</tr>
<tr>
<td>Leakage</td>
<td>1</td>
<td>HSG normal 1/1</td>
</tr>
</tbody>
</table>

HyFoSy  n = 73
HyFoSy n = 73

- Vasovagal discomfort 5 / 73  7%
- Spontaneous pregnancy 14 / 67  20%
  - Median time (month) 3 (2 - 12)
N = 20; HyFoSy + laparoscopy and chromopertubation

All 20 HyFoSy were technically successful

1 right tube and 3 left tubes were not patent (3 proximal; 1 distal)

100% agreement between HyFoSy and Laparoscopy

Conclusion: HyFoSy is both feasible and accurate in the diagnosis of tubal patency
Conclusion

- HyFoSy with ExEm® foam is a safe alternative for HyCoSy.
- In our study HSG could be avoided in 78 % of cases.
- HyFoSy is an easy to use first step test of tubal patency.
- HyFoSy is an attractive office procedure in an ambulatory setting.
References

- **Bij de Vate AJM**, Brölman HAM, van der Slikke JW, Emanuel MH, Huirne JAF. Gel instillation sonohysterography (GIS) and saline contrast sonohysterography (SCSH): comparison of two diagnostic techniques. Ultrasound Obstet Gynecol 2010;35:486-9