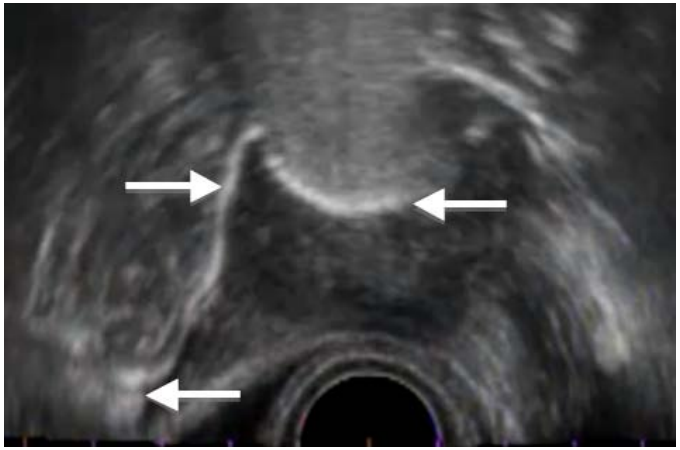
Contrast Salpingo-Sonography in evaluation of tubal patency

N. Exalto & M.H. Emanuel



ESHRE Maribor 2013

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

Gis-kit

ExEm Foam Kit

GynaecologIQ

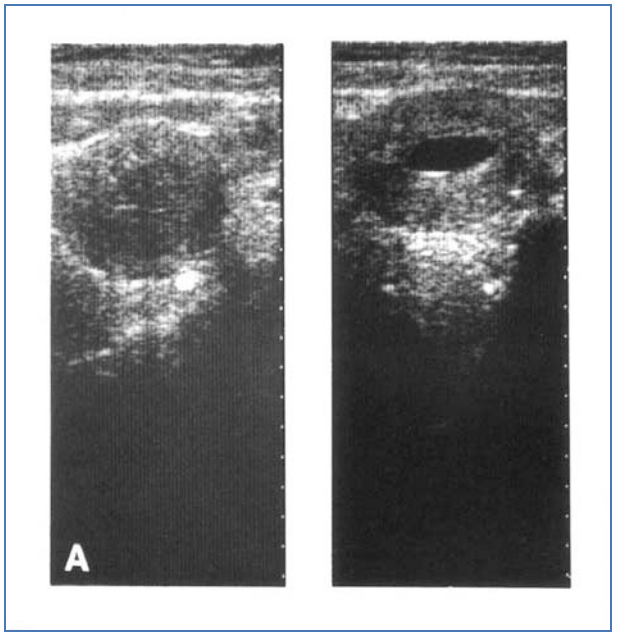
www.gynaecologiq.com

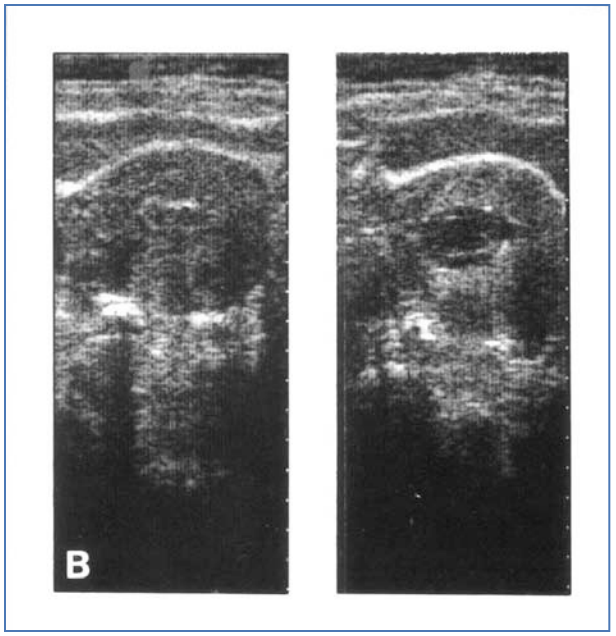
Uterine cavity distention

Hyskon (32% dextran 70)

Van Roessel J, Wamsteker K en Exalto N

Sonographic investigation of the uterus during artificial uterine cavity distention. J Clin Ultrasound 1987; 15: 439-450

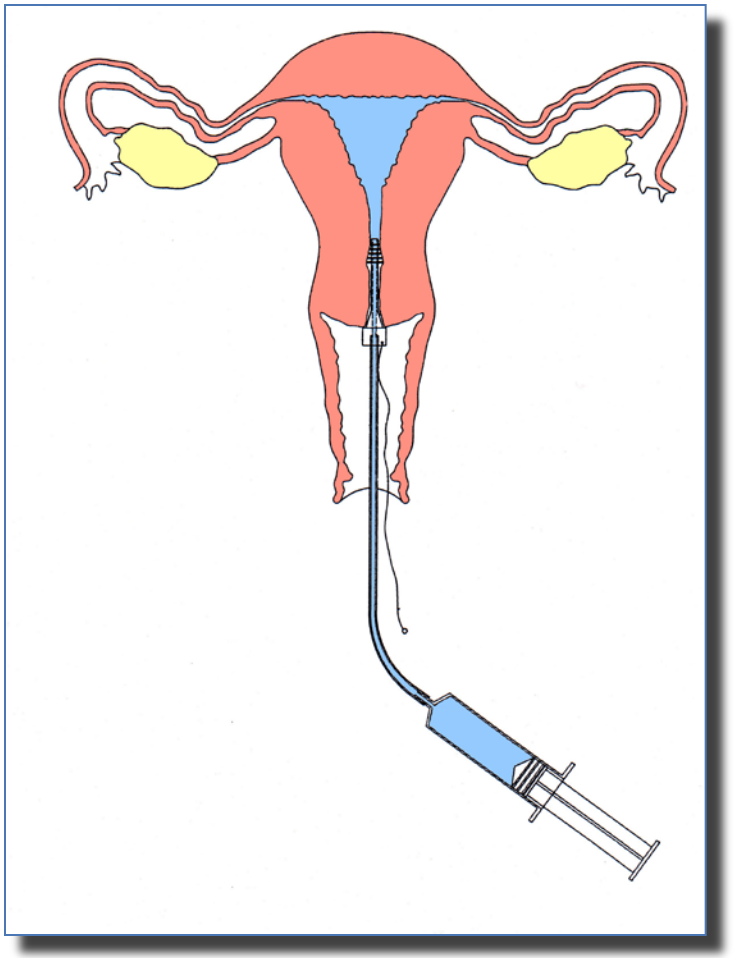




2007

- **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

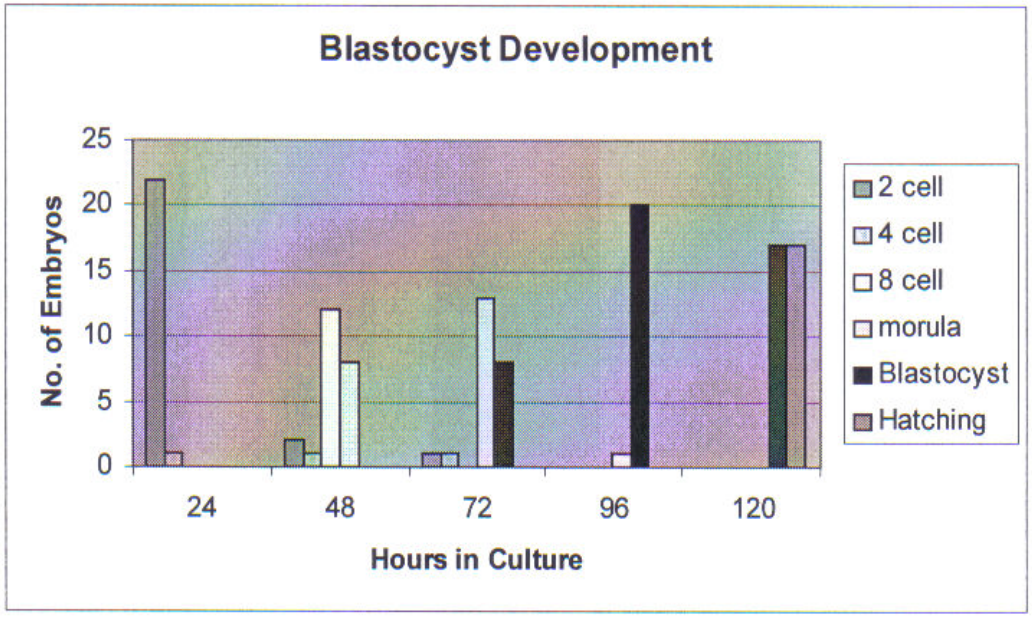
- **Safety:**

  - 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

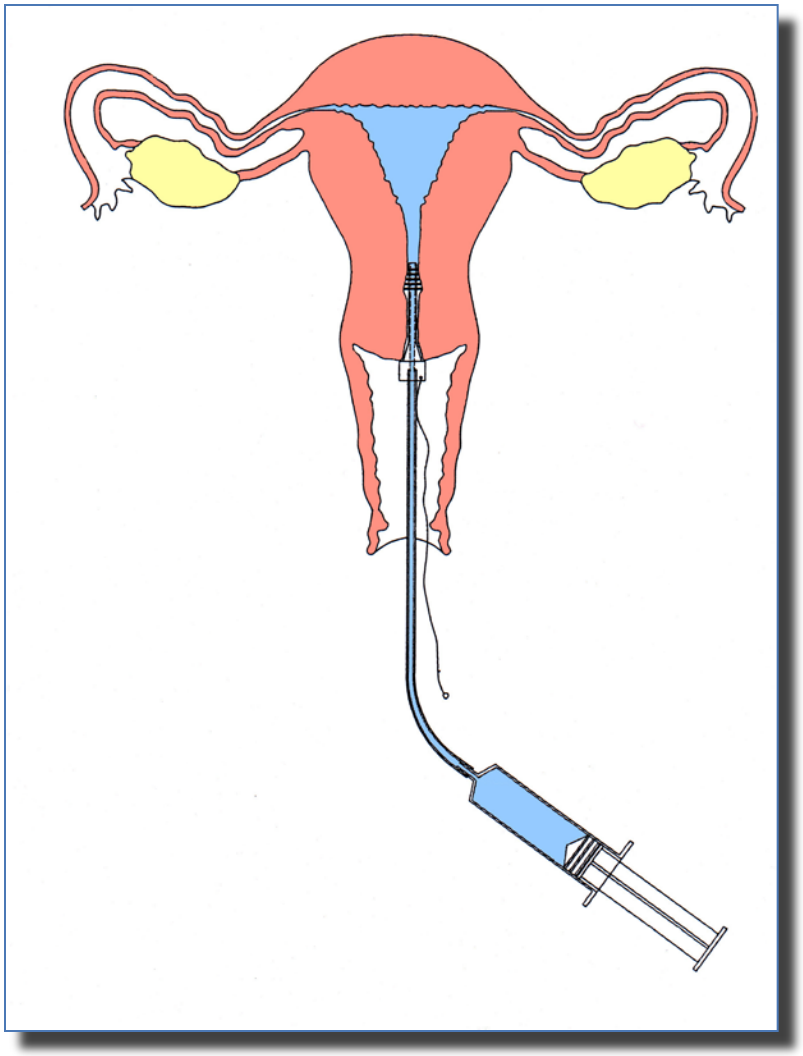
No effect on blastocyst development

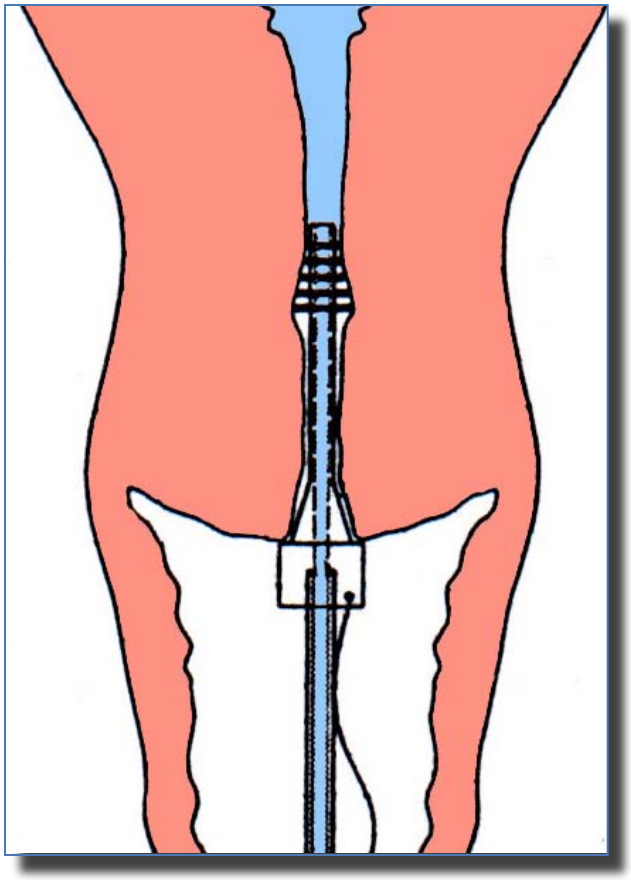
Mouse Embryo Test	Requirements for Passing	Result
Control Assay Results:	≥ 80% 1 cell to blastocyst within 120 hrs	100%
	≥ 50% blastocysts hatching within 120 hrs	95%
Test Assay Restuls:	≥ 80% 1 cell to blastocyst within 120 hrs	87%
(see graph below)	≥ 50% blastocysts hatching wihtin 120 hrs	77%



MEA RESULTS: PASS

Application device





Filling slowly

Gel instillation sonohysterography: first experience with a new technique

Niek Exalto, M.D., Ph.D.,[a] Corry Stappers, C.N.P.,[a] Louisa A.M. van Raamsdonk, Pharm.D.,[b] and Mark Hans Emanuel, M.D., Ph.D.[a]

TABLE 1

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

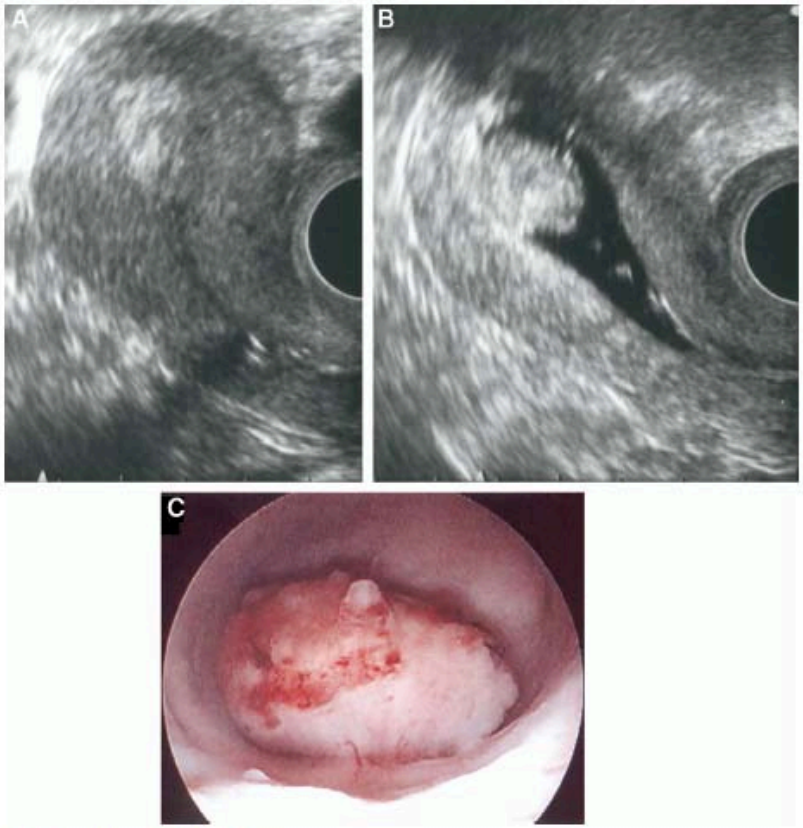
Indication	N	GIS normal (n)	GIS abnormal (n)
Abnormal uterine bleeding	52	27	25
Postmenopausal bleeding	32	11	21
Residual trophoblastic tissue	10	2	8
Habitual miscarriage/infertility	4	1	3
Evaluation myomas/polyps	5	—	5
Miscellaneous	10	8	2
Failed procedure	7	—	—
Total	120	49	64

Exalto. Gel instillation sonohysterography. Fertil Steril 2007.

G.I.S. Virtual Hysteroscopy

FIGURE 2

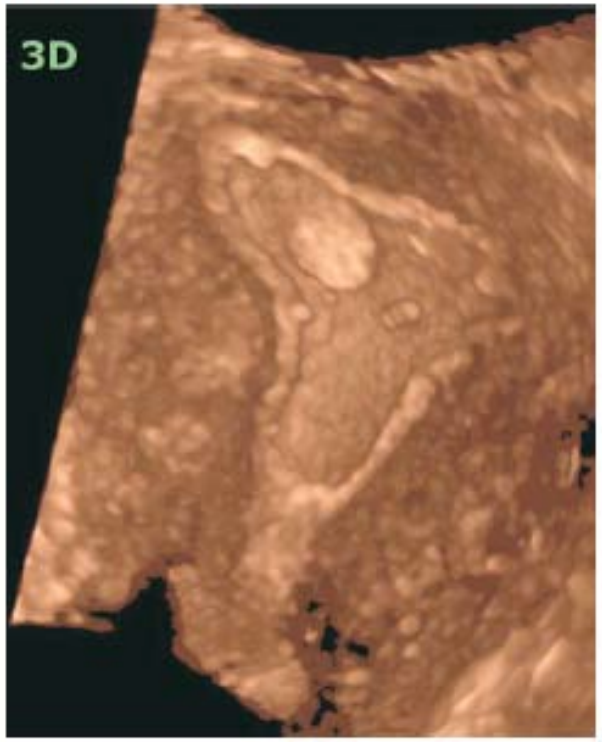
Sonographic visualization of an endometrial polyp (A) before and (B) after uterine cavity distension with gel; (C) hysteroscopic confirmation.



Exalto. Gel instillation sonohysterography. Fertil Steril 2007.

FIGURE 3

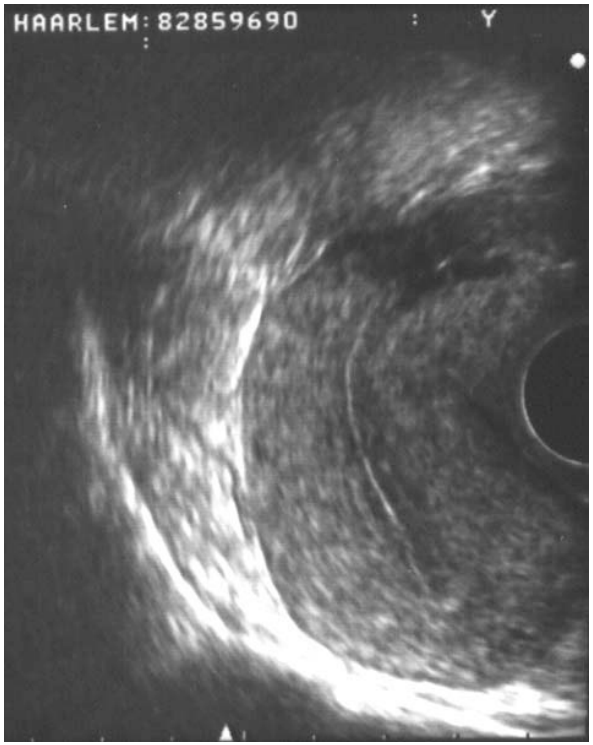
Three-dimensional (3D) gel instillation sonohysterography (GIS) reconstruction of an endometrial polyp.

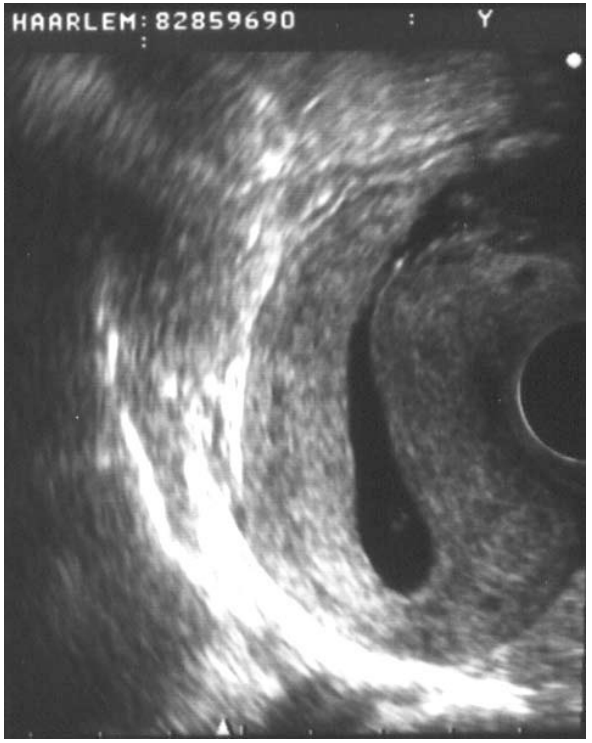


Exalto. Gel instillation sonohysterography. Fertil Steril 2007.

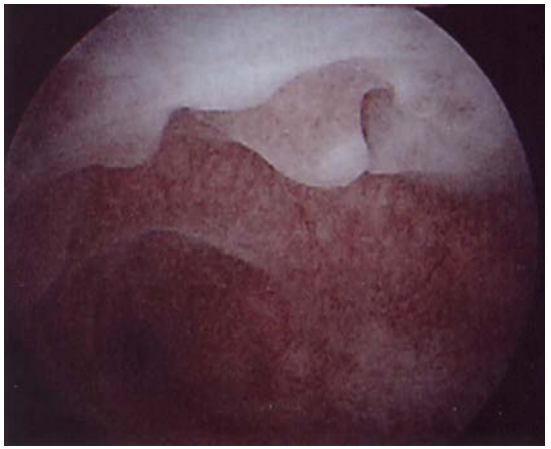
Position anteflexion

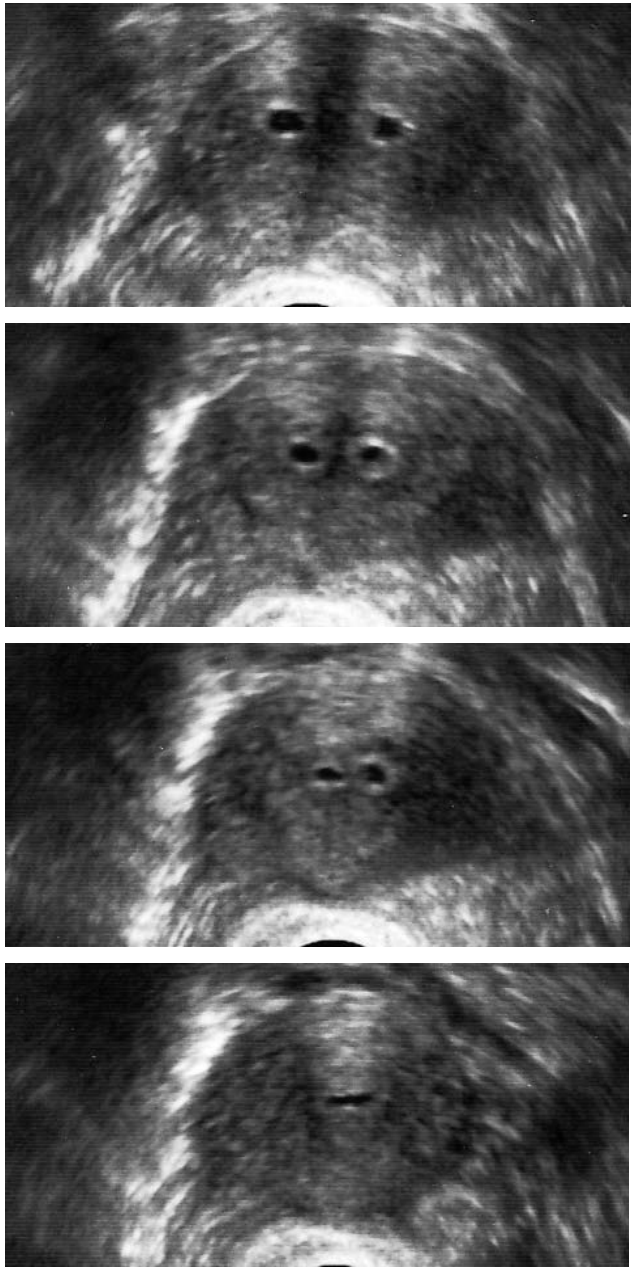
Position Retroflexion



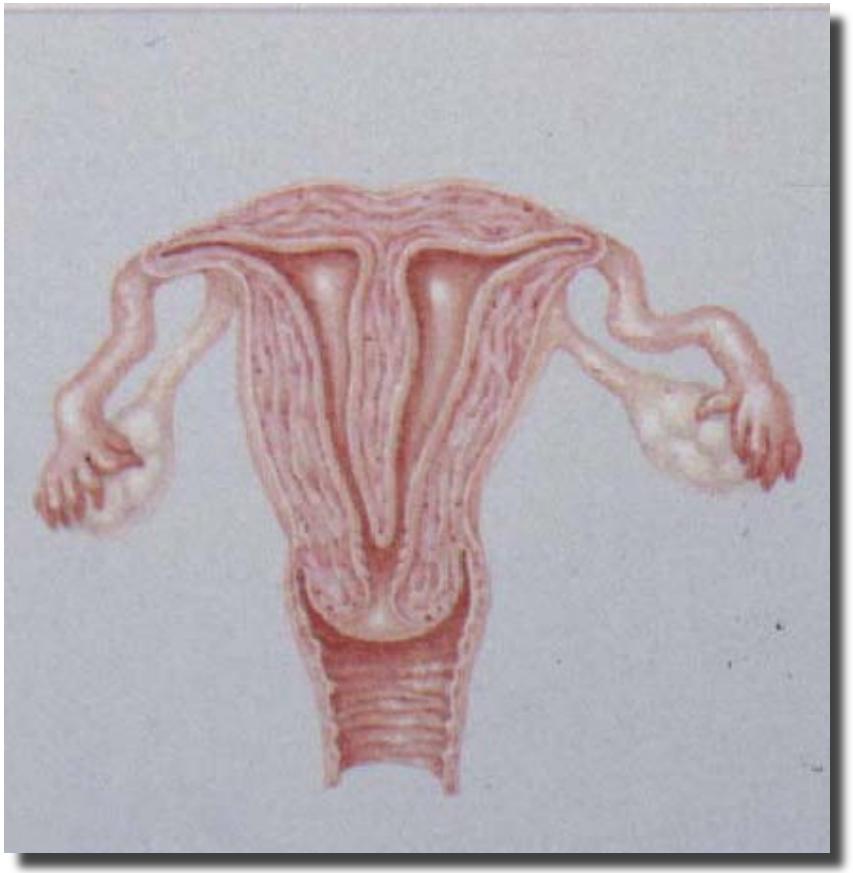


Secretory phase

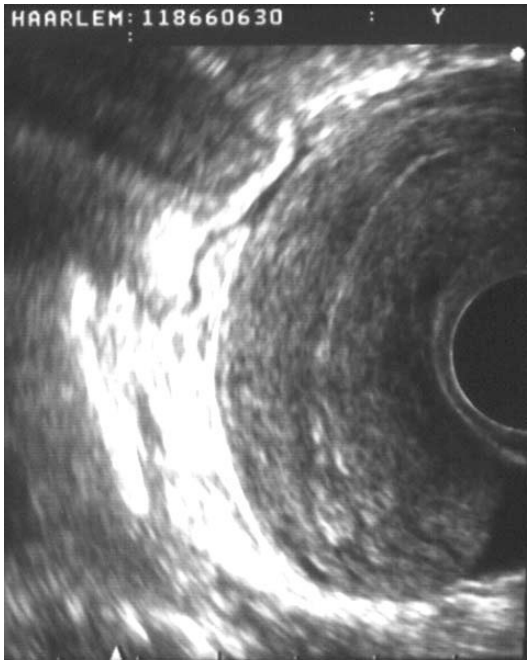


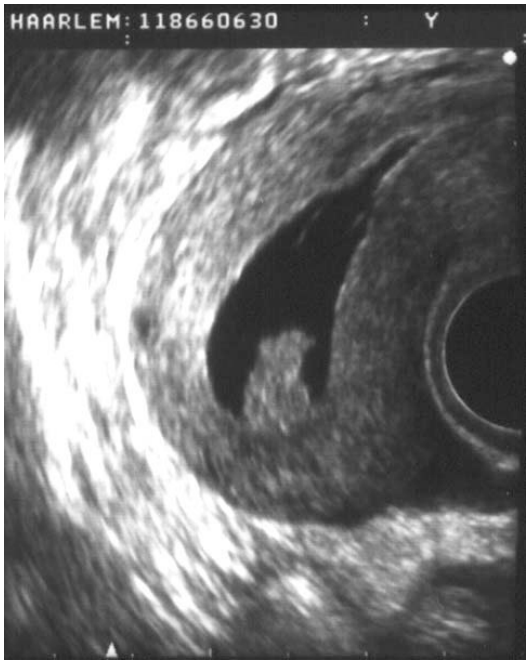


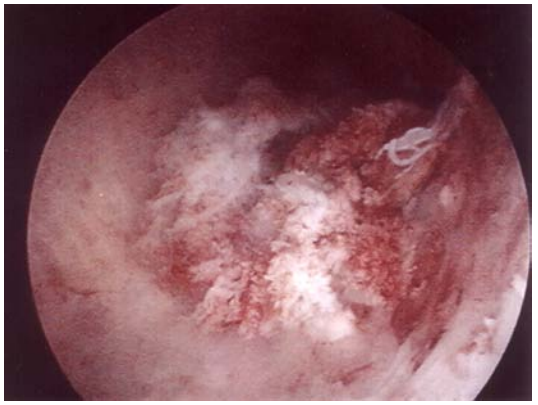
Subseptate uterus

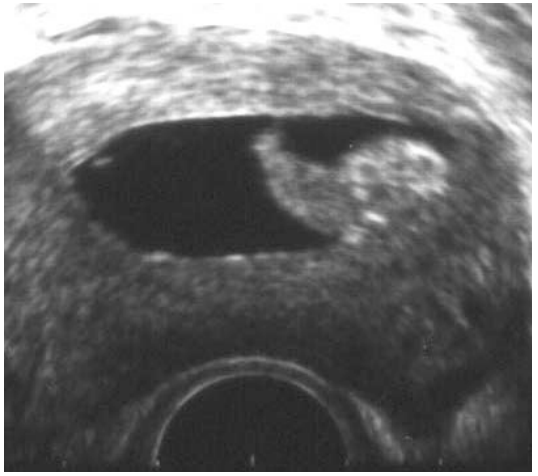


Residual placental tissue





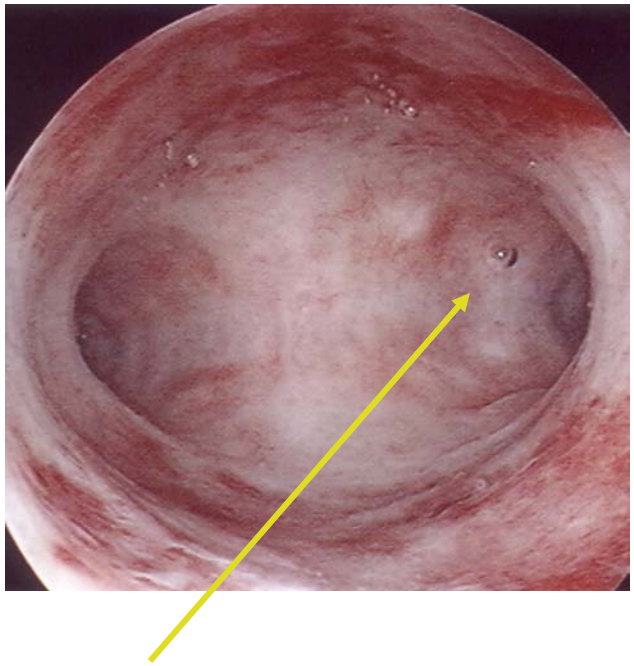




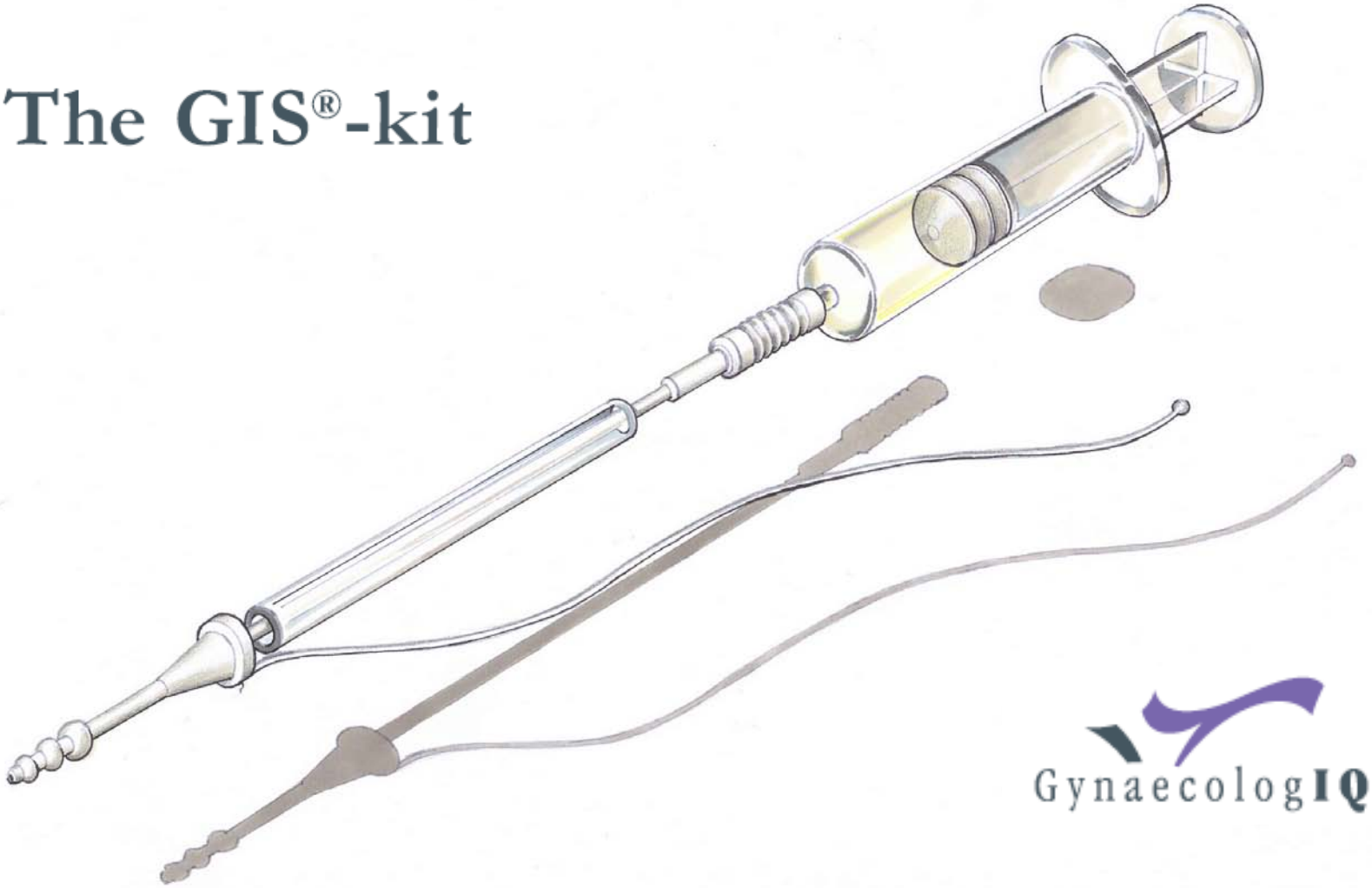
Publications on G.I.S.

Bij de Vate et al 2010
Werbrouck et al 2011
Van Den Bosch et al 2011 a
Van Den Bosch et al 2011 b

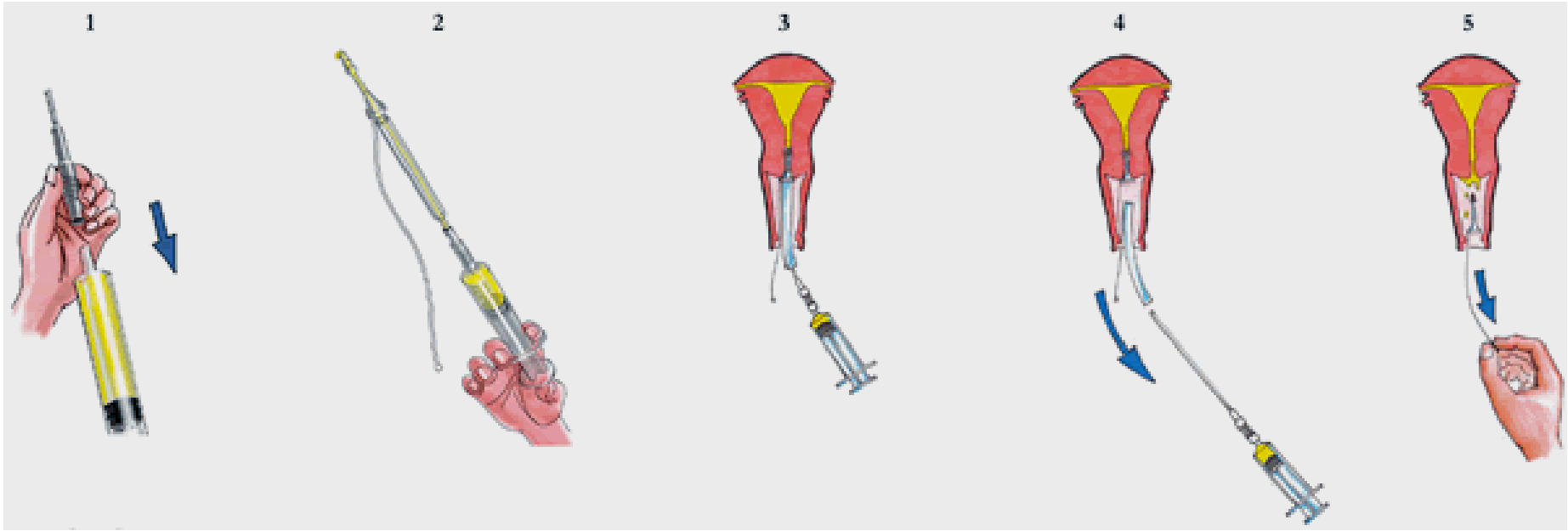
Artefacts: air bubbles



The GIS®-kit

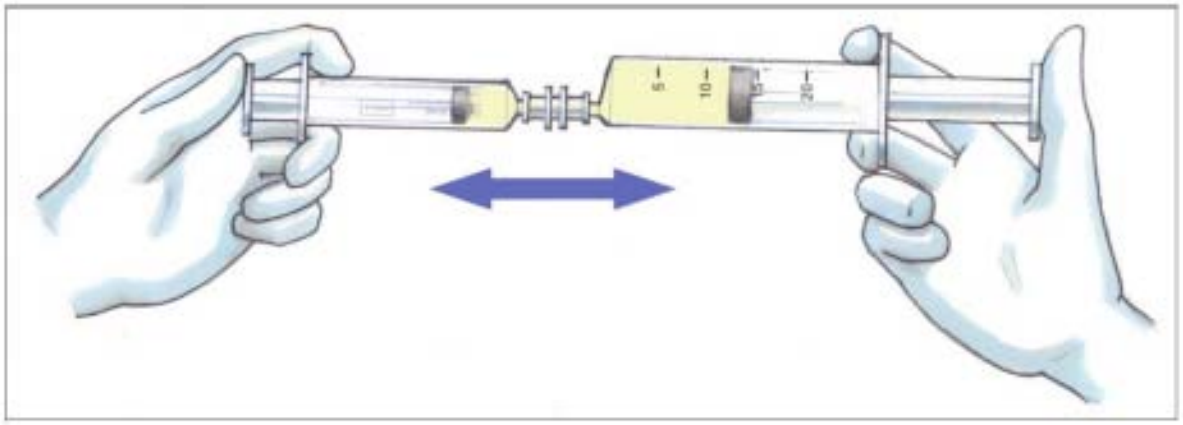


GynaecologIQ


1
2
3
4
5

2010

- **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
- Vicosity ExEm foam 270 cPs compared to Echovist 400 cPs

femView

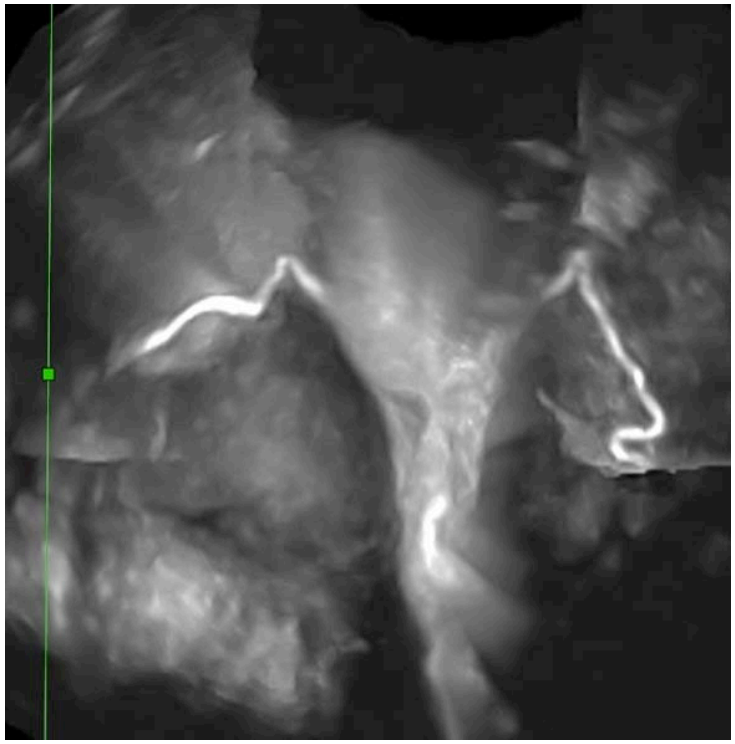
- Saline mixed with air

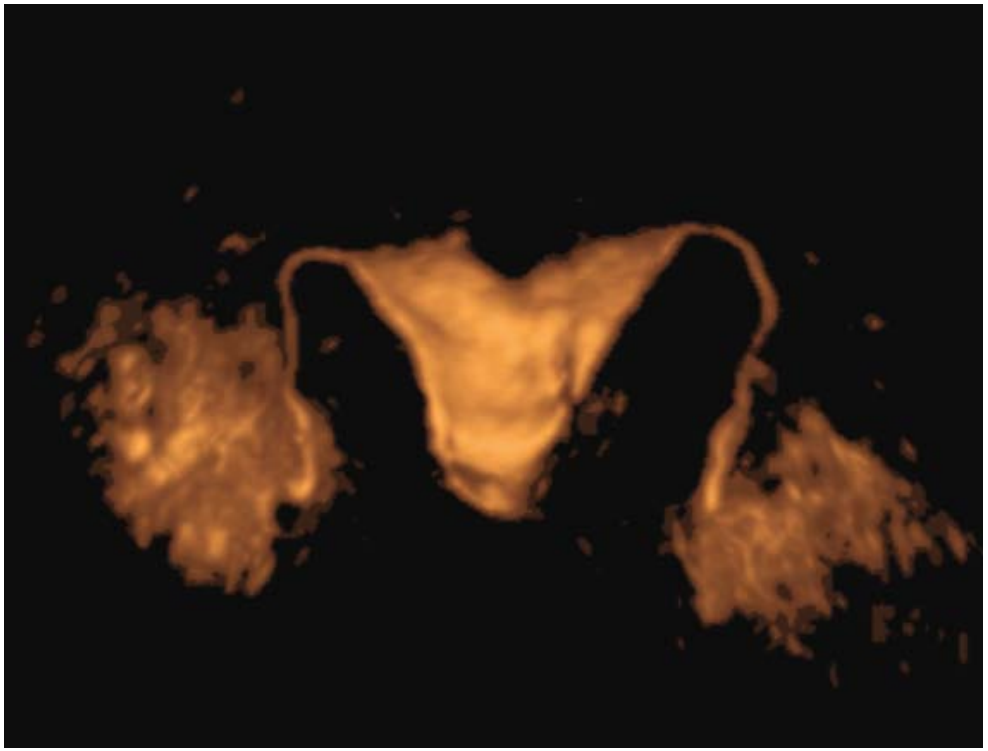
HyFoSy

- 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 assistent

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 perioneal cavity



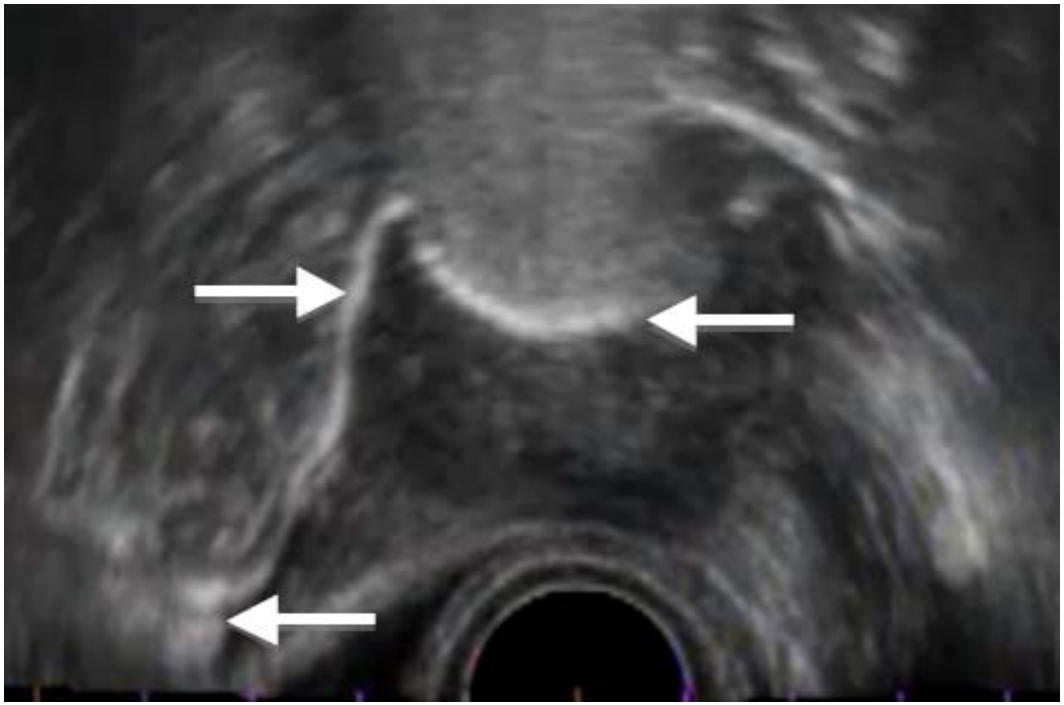


Filling slowly

human reproduction ORIGINAL ARTICLE *Gynaecology*

First experiences with hysterosalpingo-foam sonography (HyFoSy) for office tubal patency testing

Mark Hans Emanuel[1,*], Michelle van Vliet[1], Maaike Weber[1], and Niek Exalto[2]

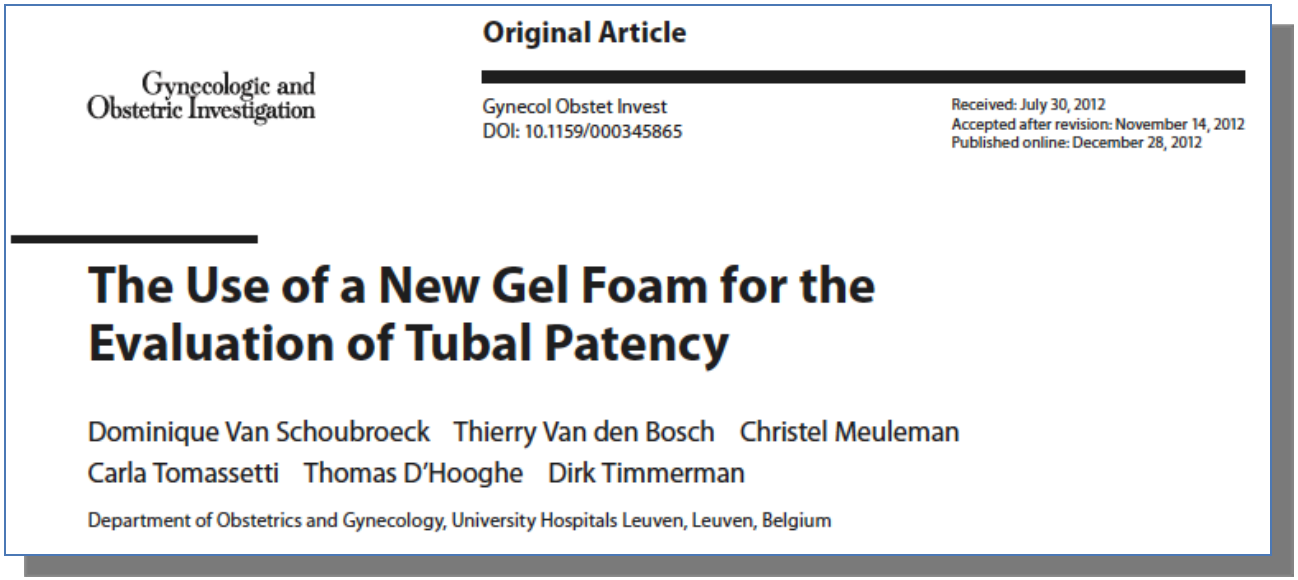


HyFoSy n = 73

Succesfull procedure	67 / 73	92 %
Cervical blockage	5	HSG normal 2/5
Leakage	1	HSG normal 1/1
Patent tubes both sides	55 / 73	
Patent tube (one present)	2 / 73	
Total patent	57 / 73	78 % no HSG
One tube not visible	5 / 73	HSG normal 2/5
Both tubes not visible	5 / 73	HSG normal 3/5
Discordance	5 / 73	7 %

HyFoSy n = 73

- Vasovagal discomfort 5 / 73 7%
- Spontaneous pregnancy 14 / 67 20%
  - Median time (month) 3 (2 - 12)



Original Article

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The Use of a New Gel Foam for the Evaluation of Tubal Patency

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- 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

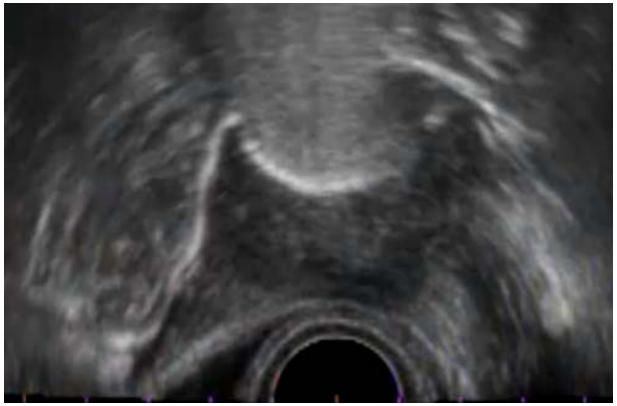
Conclusion: HyFoSy is both feasible and accurate in the diagnosis of tubal patency

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.

ExEm® gel

GIS



ExEm® foam

HyFoSy

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