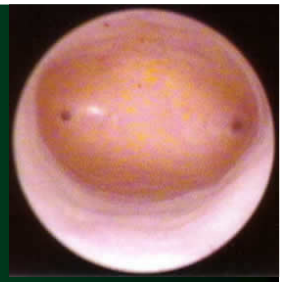

Is diagnostic hysteroscopy an effective tool to increase ART results?

Mr. Tarek El-Toukhy, MSc MD MRCOG

Consultant in Reproductive Medicine and Surgery,

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Guy's and St Thomas' NHS
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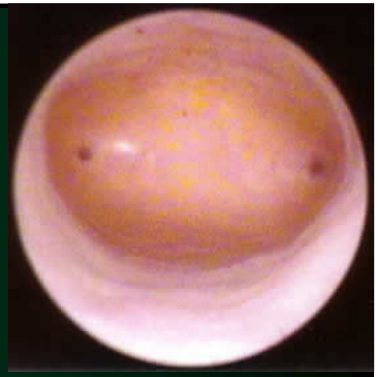
Summary



- Technical feasibility and safety
- Effectiveness in ART population
- Hysteroscopy before IVF
- TROPHY Trial

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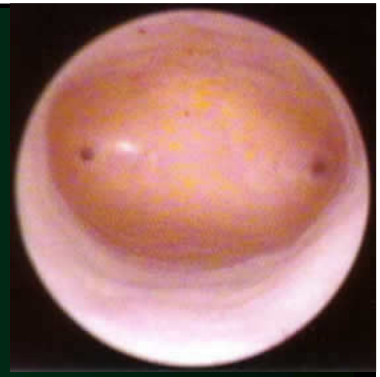
Technical feasibility



- Success rate of standard hysteroscopy:

  96% in pre- and post-menopausal population

  97% in pre-menopausal population (P=0.002)

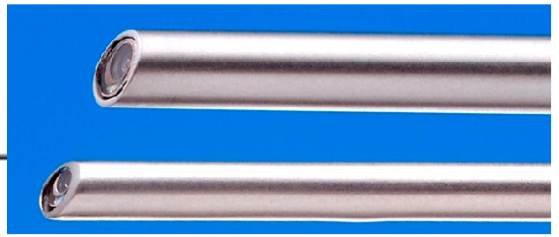
DOI: 10.1111/j.1471-0528.2007.01326.x
www.blackwellpublishing.com/bjog

Systematic review

Van Dongen et al, BJOG 2007

Human Reproduction Update 1999, Vol. 5, No. 1 pp. 73–81
© European Society of Human Reproduction and Embryology

Office mini-hysteroscopy



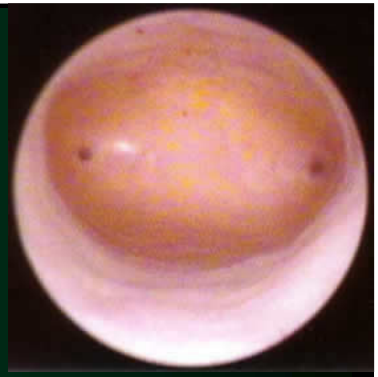
R.Campo[1], Y.Van Belle, L.Rombauts, I.Brosens and S.Gordts

Technical feasibility in 530 infertility patients

98%

Failures	No.	%
Pain	4	0.75
Internal cervical stenosis	3	0.57
Insufficient visualization	5	0.94
Complications	0	
Total	12/530	2.26

Safety



- **Standard Hysteroscopy:**
  1% (16/1399) complication rate (SR of 17 studies)

  van Dongen et al, BJOG 2007

Vaso-vagal attack in 13
False track in 2
Fundal perforation in 1

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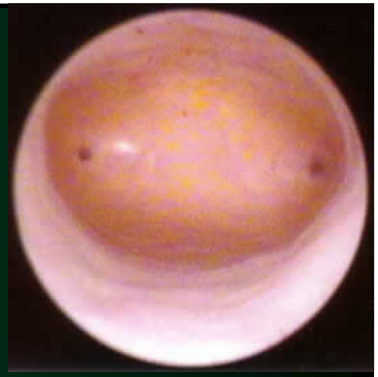
Safety



- Mini-hysteroscopy:

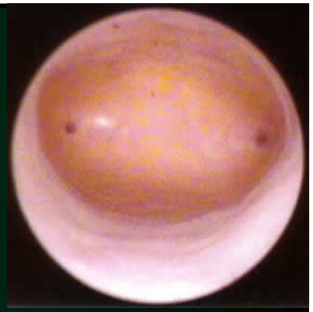
0.16%

Table IV. Complications in 4204 conventional office hysteroscopies (1982–1989)

Complications	No.	%
Fundal perforation	2	
Prolonged vagal reaction	4	
Epileptic insult	1	
Infections	0	
Total	7	0.16

R.Campo[1], Y.Van Belle, L.Rombauts, I.Brosens and S.Gordts

Human Reproduction Update 1999, Vol. 5, No. 1 pp. 73–81



Effective Tool?

- Reveal pathology
- Normal hsyteroscopy
- Effectiveness is measured by restoration of reproductive potential

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Observer agreement in the evaluation of the uterine cavity by hysteroscopy prior to *in vitro* fertilization

J.C. Kasius [1,*], F.J.M. Broekmans [1], S. Veersema [2], M.J.C. Eijkemans [3], Devroey [5], B.C.J.M. Fauser [1], and H.M. Fatemi [5]

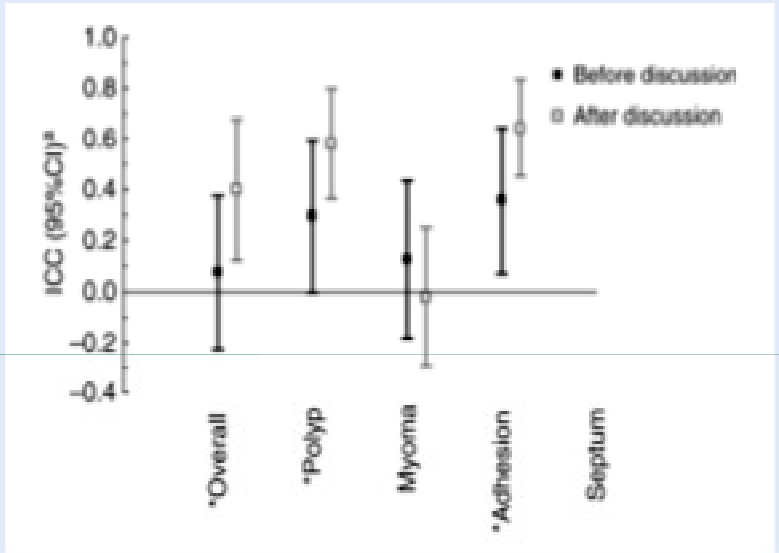

Figure 1 Level of interobserver agreement expressed as ICC[a] before and after discussion between observers. [a]ICC, intraclass correlation coefficient (equivalent of the overall weighted κ) (Fleiss and Cohen, 1973). *For diagnosing the uterine cavity to be normal or abnormal, diagnosing polyps and adhesions, the interobserver agreement significantly increased through discussion ($P < 0.01$). Impossible to compute ICC for diagnosing septa with ordinary statistics, as also used by SPSS version 15.1.

Table II Findings of the hysteroscopy performer at real-time hysteroscopy.

Findings	Prevalence	(%)
Normal cavity	94	87.9
Abnormal cavity	13[a]	12.1
Polyp	12	11.2
Myoma	1	0.9
Adhesion	0	0.0
Septa	2	1.9
Total	107[a]	100

[a]In two cases more than one abnormality was detected.

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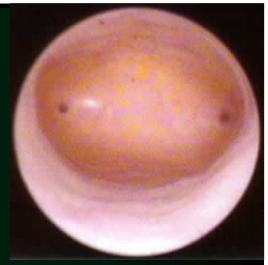

Pathology encountered

- **Prevalence in ART population 12%-45% (5000 cases)**

  (Campo et al, 1999; Hinckley and Milki, 2004; Karayalcin et al, 2010; Fatemi et al., 2010; Al-Mazny et al., 2010)

- **Commonest findings:**

  - Endometrial polyps **- Submucous fibroids**

  - Intra-uterine adhesions **- Septate uterus**

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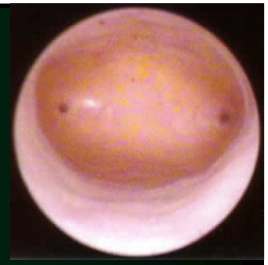


Outpatient hysteroscopy: a routine investigation before assisted reproductive techniques?

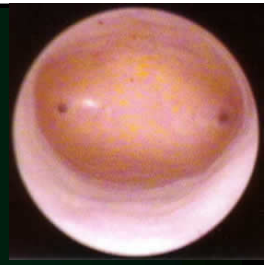
Fertility and Sterility® Vol. 95, No. 1, January 2011

TABLE 3

Hysteroscopic findings according to age distribution and previous ART failure(s).

Hysteroscopic findings	Age < 35 y (n = 67)	Age ≥ 35 y (n = 78)	No previous ART (n = 94)	Previous ART (n = 51)
Cervical stenosis	2 (3.0%)	2 (2.6%)	3 (3.2%)	1 (2.0%)
Endocervicitis	3 (4.5%)	1 (1.3%)	2 (2.1%)	2 (3.9%)
Endocervical polyp	2 (3.0%)	1 (1.3%)	3 (3.2%)	0 (0.0)
Uterine cavity hypoplasia	1 (1.5%)	1 (1.3%)	2 (2.1%)	0 (0.0)
Uterine septum	1 (1.5%)	0 (0.0)	1 (1.1%)	0 (0.0)
Intrauterine adhesions	4 (6.0%)	2 (2.6%)	2 (2.1%)	4 (7.8%)
Intrauterine foreign body	0 (0.0)	1 (1.3%)	0 (0.0)	1 (2.0%)
Endometritis	2 (3.0%)	1 (1.3%)	1 (1.1%)	2 (3.9%)
Submucous myoma	1 (1.5%)	5 (6.4%)	3 (3.2%)	3 (5.9%)
Endometrial polyp	2 (3.0%)	6 (7.7%)	3 (3.2%)	5 (9.8%)
Polypoid endometrium	1 (1.5%)	3 (3.8%)	3 (3.2%)	1 (2.0%)
Endometrial hyperplasia	0 (0.0)	4 (5.1%)	1 (1.1%)	3 (5.9%)
Blocked ostia	2 (3.0%)	0 (0.0)	1 (1.1%)	1 (2.0%)
Total findings	21 (31.3%)	27 (34.6%)[a]	25 (26.6%)	23 (45.1%)

Pathology encountered



Surgical treatment

Improve ART results

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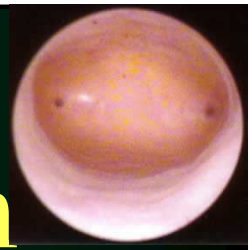
Endometrial polyps >15mm



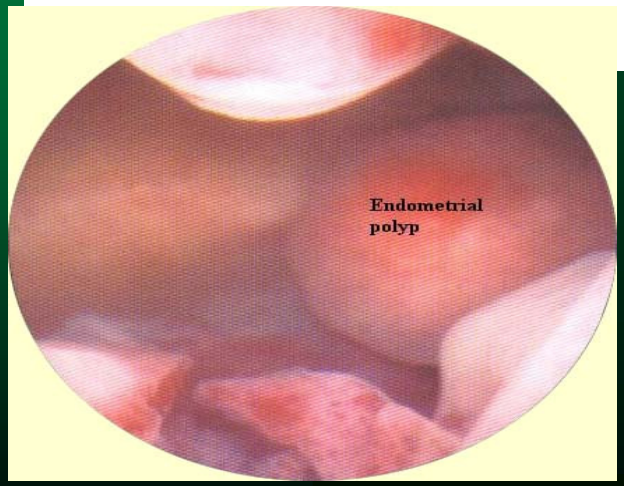
A

	Hysteroscopic polypectomy		Diagnostic hysteroscopy		Risk ratio
	Events	Total	Events	Total	M-H, Fixed, 95% CI
Perez-Medina et al. 2005	64	107	29	108	

Test for overall effect Z=4.51 (P<0.00001)

0.1 0.2 0.5 1 2 5 10

Favours no hysteroscopy Favours hysteroscopy

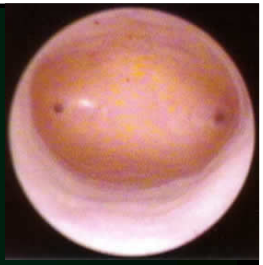


Human Reproduction Update, Vol.16, No.1 pp. 1–11, 2010

Advanced Access publication on September 10, 2009 doi:10.1093/humupd/dmp033

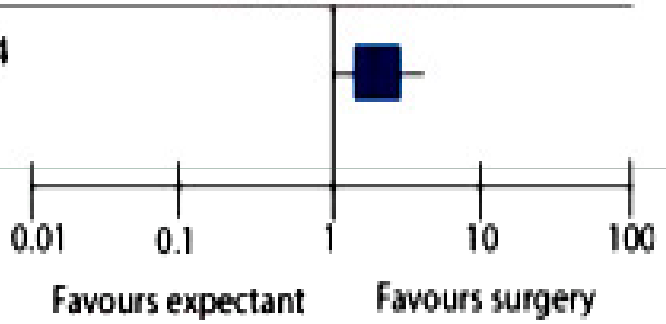
human reproduction update

Submucous fibroids <4cm



B

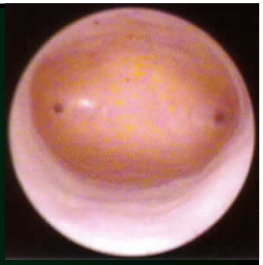
	Surgery		Expectant management		Risk ratio
	Events	Total	Events	Total	M-H, Fixed, 95% CI
Casini et al. 2005	21	52	9	24	
Test for overall effect Z=1.86 (P=0.06)					



Human Reproduction Update, Vol.16, No.1 pp. 1–11, 2010
Advanced Access publication on September 10, 2009 doi:10.1093/humupd/dmp033

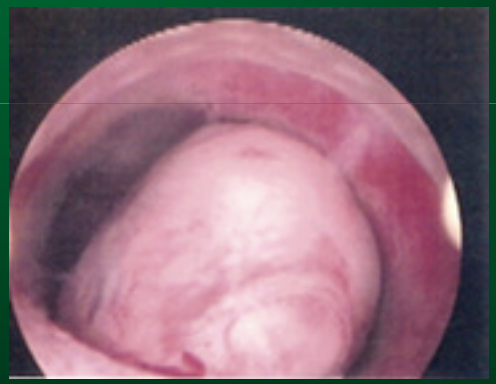
human reproduction update

Larger submucous fibroids



204 women with unexplained infertility and submucous fibroids randomised to either

101 hysteroscopic myomectomy



103 diagnostic hysteroscopy

CPR 63.4%

Follow up for 1 year

CPR 28.2%

RR-2.1, 95%CI 1.5-2.9

Shokeir et al, 2010 Fertil Steril

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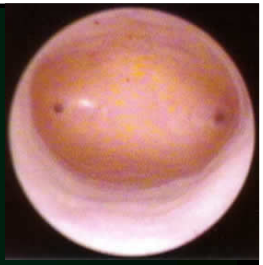
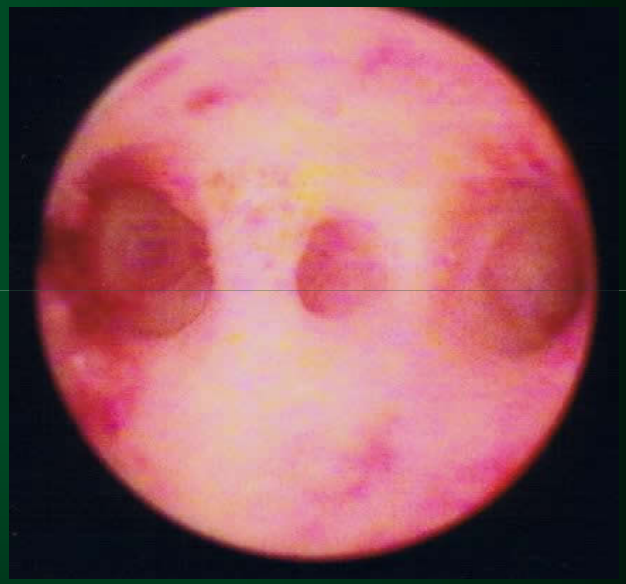
Intrauterine adhesions

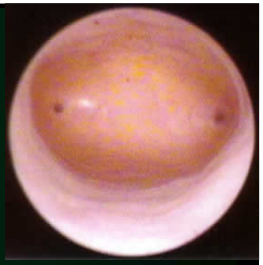


- No randomised trials



- No controlled trials
- Case series typically with N<100

Intrauterine adhesions



- Pregnancy rate ranges between 30-50%
- Live birth rates range between 10-35%
- Poor prognostic indicators:
  - Adhesions obliterating both ostia
  - Age >35 years
  - Persistence of amenorrhea
  - Reformation of adhesions at 2nd look

Thompson et al,2009; Pabuccu et al, 2008; Yu et al, 2008

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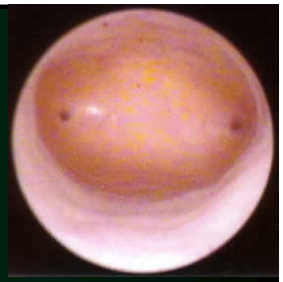
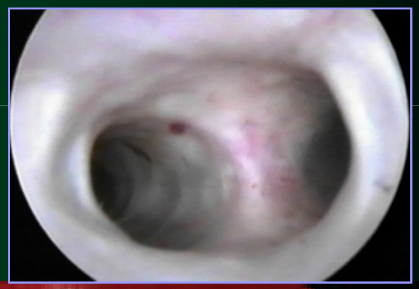
Uterine septum resection



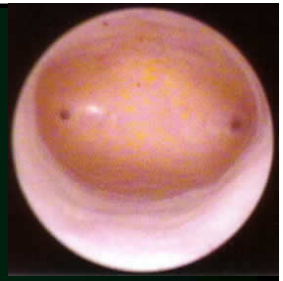
Mollo et al, 2009 Fertil Steril

- Controlled study showed higher live birth rate after septal resection (n=44) compared to controls (n=132)



34% vs 19% (P<0.01)

Hysteroscopy before IVF



Outpatient hysteroscopy and subsequent IVF cycle outcome: a systematic review and meta-analysis

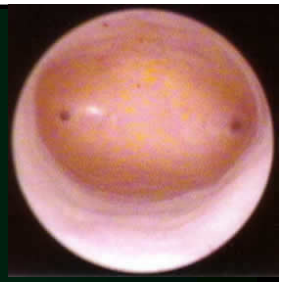
RBM Online - Vol 16. No 5. 2008 712-719

Table 2. Characteristics of the studies included in the systematic review.

Reference	*No. of participants*	*Intervention*	*No intervention*	*Outcome measure*
Demirol and Gurgan, 2004	421	210 = office 5 mm hysteroscopy	210 = no hysteroscopy	Clinical pregnancy rate, miscarriage rate
Raju *et al.*, 2006	520	265 = office 5 mm hysteroscopy	255 = no hysteroscopy	Clinical pregnancy rate, miscarriage rate, live birth rate
Mooney and Milki, 2003	94	48 = office 5 mm hysteroscopy	46 = remote hysteroscopy	Clinical pregnancy rate
Doldi *et al.*, 2005	600	300 = office 5 mm hysteroscopy	300 = no hysteroscopy	Pregnancy rate[a]
Chung *et al.*, 2006	56	28 = office hysteroscopy	28 = no hysteroscopy	Pregnancy rate[a], live birth rate, cumulative pregnancy and live birth rates

[a]The definition of pregnancy was not clear in these two studies.

Hysteroscopy before IVF



Outpatient hysteroscopy and subsequent IVF cycle outcome: a systematic review and meta-analysis

Pooling the results of five studies showed benefit from outpatient hysteroscopy in improving pregnancy rate in the subsequent IVF cycle (RR = 1.75, 95% CI 1.51–2.03)

RBMOnline - Vol 16. No 5. 2008 712-719

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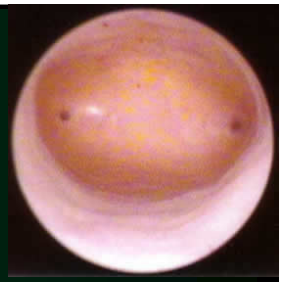
Updated Evidence



- Randomised Trials (2)
- Prospective observational data (4)

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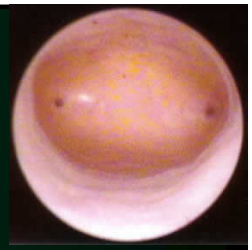
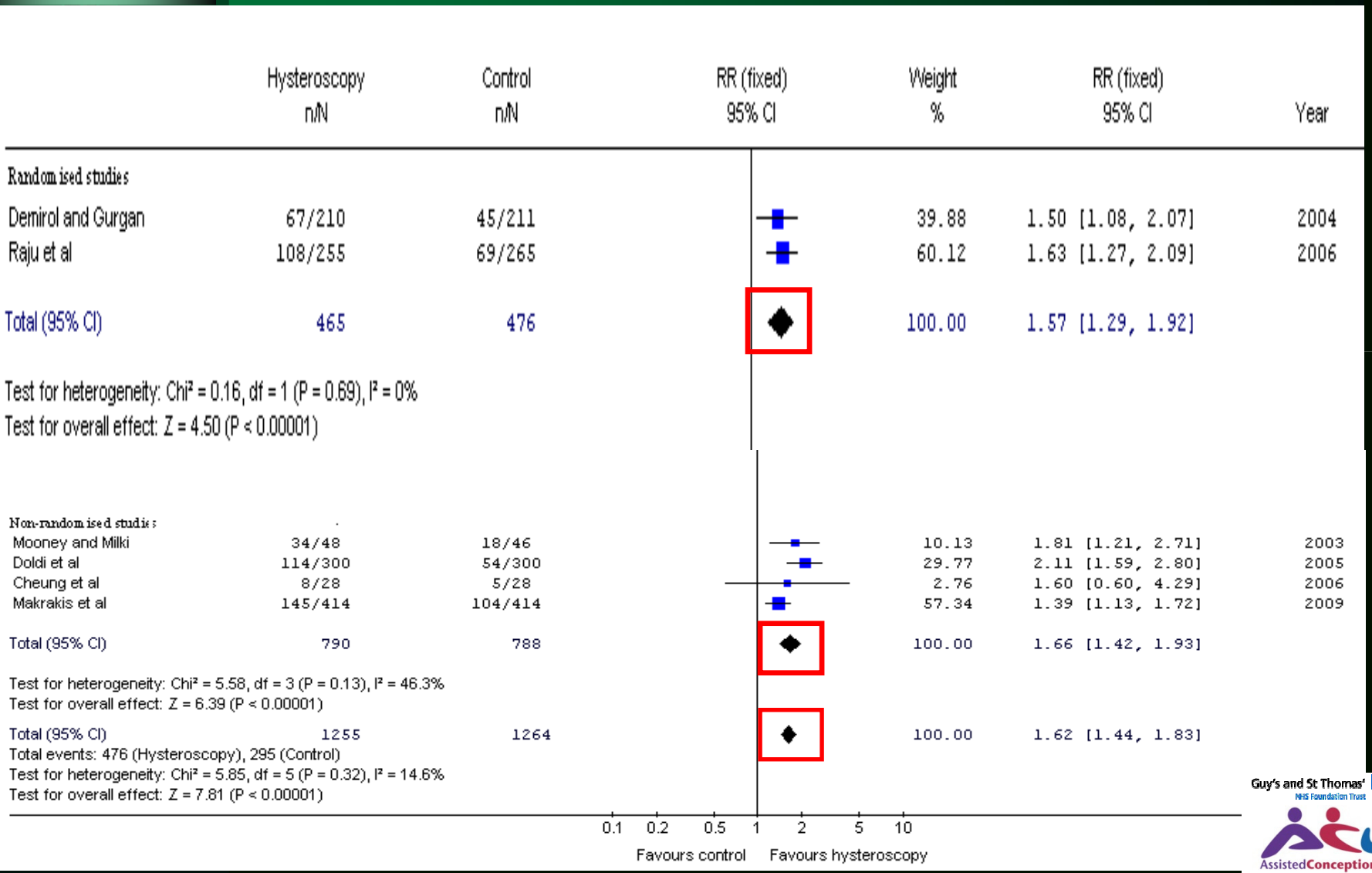
Updated Meta-analysis: CPR





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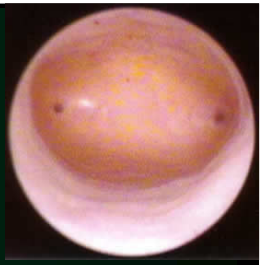
Updated Meta-analysis: LBR



Outcome: 01 Hysterodcopy and IVF-OPR/ LBR

Study or sub-category	Hysteroscopy n/N	Control n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
Raju et al	120/414	91/414		67.83	1.32 [1.04, 1.67]
Makrakis et al	72/255	44/265		32.17	1.70 [1.22, 2.37]
Total (95% CI)	669	679		100.00	1.44 [1.19, 1.75]

Total events: 192 (Hysteroscopy), 135 (Control)

Test for heterogeneity: Chi² = 1.49, df = 1 (P = 0.22), I² = 33.0%

Test for overall effect: Z = 3.73 (P = 0.0002)

0.1 0.2 0.5 1 2 5 10

Favours control Favours hysteroscopy

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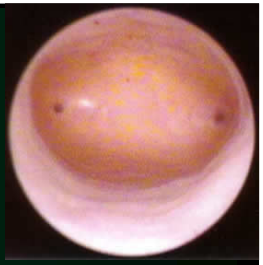
Normal hysteroscopy



Study or sub-category	Normal hysteroscopy n/N	Control n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI	Year
Mooney and Miliki	14/21	18/46		4.52	1.70 [1.06, 2.73]	2003
Demirol and Gurgan	50/154	45/211		15.21	1.52 [1.08, 2.15]	2004
Cheung et al	6/21	5/28		1.72	1.60 [0.56, 4.54]	2006
Raju et al	71/160	69/265		20.81	1.70 [1.30, 2.23]	2006
Makrakis et al	301/935	104/414		57.74	1.28 [1.06, 1.55]	2009
Total (95% CI)	1291	964		100.00	1.43 [1.25, 1.64]	

Total events: 442 (Normal hysteroscopy), 241 (Control)

Test for heterogeneity: Chi² = 3.63, df = 4 (P = 0.46), I² = 0%

Test for overall effect: Z = 5.18 (P < 0.00001)

NNT=7

0.1 0.2 0.5 1 2 5 10

Favours control Favours hysteroscopy

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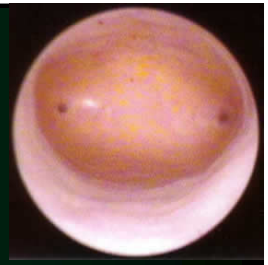
Summary of literature



- CPR/LBR could be improved by up to 50%
- Small NNT
- No complications reported
- Consistent results across all 6 studies

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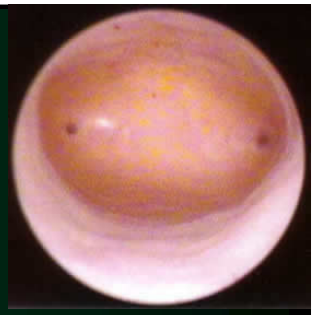
Therapeutic effect of a diagnostic test?



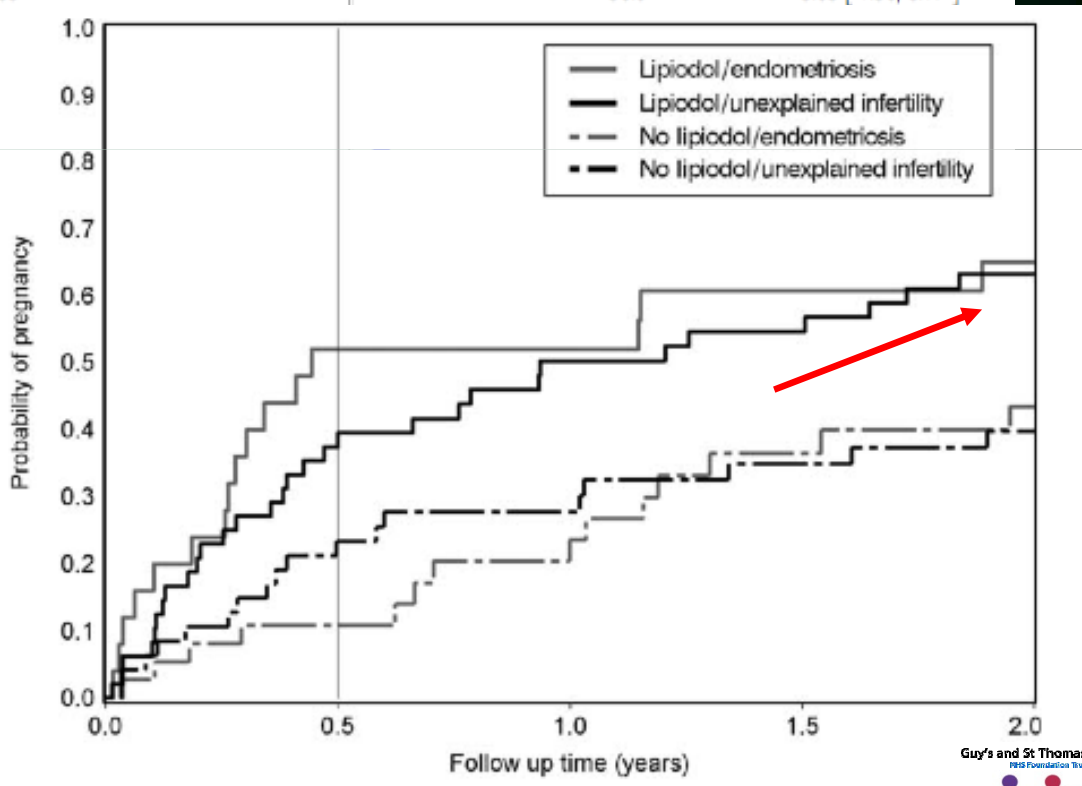
Study	OSCM n/N	No treatment n/N	Peto Odds Ratio 95% CI	Weight (%)	Peto Odds Ratio 95% CI
Johnson 2004	28/73	14/85		50.0	3.05 [1.50, 6.17]
Nugent 2002	5/17				
Ogata 1993	25/105				
Total (95% CI)	195				

Total events: 58 (OSCM), 21 (No treatment)

Test for heterogeneity chi-square=1.39 df=2 p=0.5

Test for overall effect z=4.69 p<0.00001

HSG



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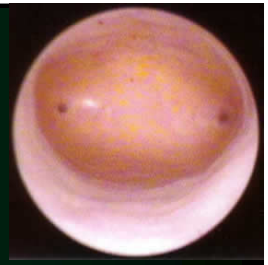
Biological explanation



- **Identification/Correction of uterine pathology**
- **Facilitate future transfers**

  (CX dil., direction and depth)

  (Groutz et al., 2007, F&S; Pabuccu et al., 2005, JMIG)
- **Endometrial injury / stimulation**

  (Barash et al, 2003; Raziel et al, 2007; Zhou et al., 2008 – all F&S)

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Cervical dilatation has a positive impact on the outcome of IVF in randomly assigned cases having two previous difficult embryo transfers

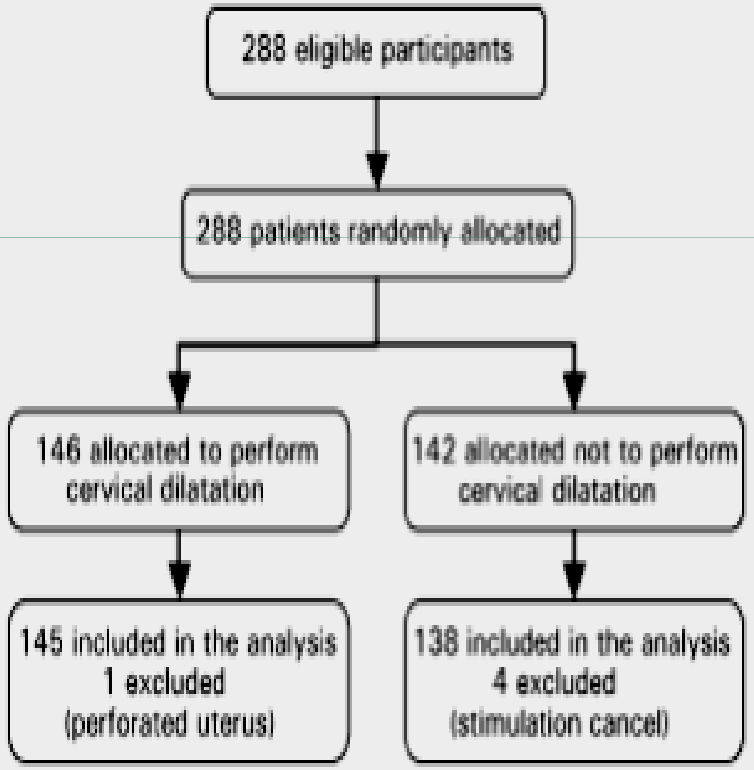
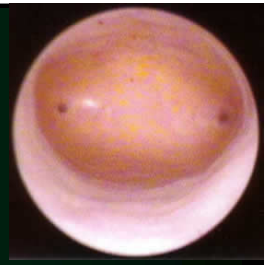


Table II. Obstetric outcome in 283 women participating in the study

	Group I: cervical dilatation (n = 145), % per transfer	Group II: no dilatation (n = 138), % per transfer	P
Clinical pregnancies	58 (40%)	33 (23.91%)	<0.01
Implantation rate	24.1%	14.9%	<0.01
1st trimester abortion	6 (4.13%)	5 (3.62%)	NS
2nd trimester abortion	2 (1.37%)	0	NS
Live deliveries, all gestations	50 (34.48%)	27 (19.56%)	<0.01
Preterm	6 (4.13%)	3 (2.17%)	NS
Term	44 (30.34%)	24 (17.39%)	<0.01

Prapas et al, 2004 HR

Endometrial injury: CPR



	Type of study	Scratch group	Control group	P-value
Barash 03	Observational	67%	30%	<0.001
Li 07	Observational	69%	14%	0.01
Raziel 07	Observational	30%	12%	0.03
Zhou 08	Observational	48%	28%	0.01
Karimzadeh 09	RCT	27%	9%	0.02
Narvekar 10	RCT	33%	14%	<0.01

OR = 2.4 (95% CI 1.9-3.1)

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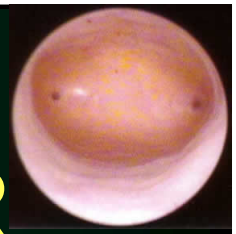
Endometrial injury: CPR



Study	Treatment n/N	Control n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI	Year
Randomised controlled trials						
Karimzadeh	13/52	4/52		36.83	3.25 [1.13, 9.31]	2009
Narvekar	16/49	7/51		63.17	2.38 [1.07, 5.28]	2010
Total (95% CI)	101	103		100.00	2.70 [1.43, 5.10]	
Test for heterogeneity: Chi² = 0.22, df = 1 (P = 0.64), I² = 0%						
Test for overall effect: Z = 3.06 (P = 0.002)						
Non-randomised controlled studies						
Barash	30/45	27/89		38.50	2.20 [1.51, 3.20]	2003
Li	24/35	5/36		10.47	4.94 [2.12, 11.48]	2004
Raziel	18/60	7/57		15.24	2.44 [1.10, 5.41]	2007
Zhou	29/60	17/61		35.79	1.73 [1.07, 2.81]	2008
Total (95% CI)	200	243		100.00	2.36 [1.80, 3.09]	
Test for heterogeneity: Chi² = 4.65, df = 3 (P = 0.20), I² = 35.5%						
Test for overall effect: Z = 6.22 (P < 0.00001)						
All studies						
Total (95% CI)	301	346		100.00	2.42 [1.88, 3.11]	
Total events: 130 (Treatment), 67 (Control)						
Test for heterogeneity: Chi² = 5.14, df = 5 (P = 0.40), I² = 2.8%						
Test for overall effect: Z = 6.92 (P < 0.00001)						

0.1 0.2 0.5 1 2 5 10

Favours control Favours treatment

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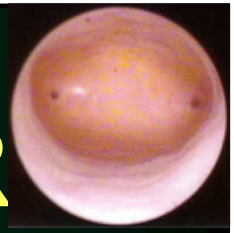
Endometrial injury: LBR



	Type of study	Scratch group	Control group	P-value
Barash 03	Observational	49%	24%	0.02
Li 07	Observational	48%	11%	0.01
Raziel 07	Observational	22%	7%	0.07
Zhou 08	Observational	42%	23%	0.01
Narvekar 10	RCT	23%	10%	0.03

OR = 3.0 (95% CI 1.9-4.6)

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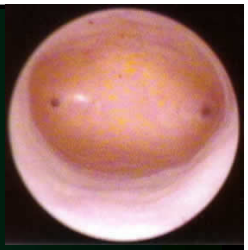
Endometrial injury: LBR



Review: Local endometrial injury and IVF outcome
Comparison: 01 Endometrial injury and IVF outcome: All studies
Outcome: 02 OPR/LBR

Study or sub-category	Treatment n/N	Control n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI	Year
Barash	22/45	21/89		33.61	2.07 [1.28, 3.34]	2003
Li	17/35	4/36		9.40	4.37 [1.63, 11.70]	2004
Raziel	13/60	5/57		12.22	2.47 [0.94, 6.49]	2007
Zhou	25/60	14/61		33.09	1.82 [1.05, 3.14]	2008
Narvekar	11/49	5/51		11.68	2.29 [0.86, 6.11]	2010
Total (95% CI)	249	294		100.00	2.28 [1.67, 3.10]	

Total events: 88 (Treatment), 49 (Control)
Test for heterogeneity: Chi² = 2.52, df = 4 (P = 0.64), I² = 0%
Test for overall effect: Z = 5.24 (P < 0.00001)

0.1 0.2 0.5 1 2 5 10

Favours control Favours treatment

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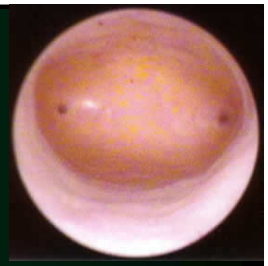
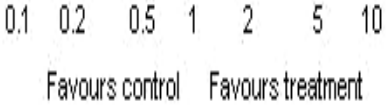
Endometrial injury: RIF



Review: Local endometrial injury and IVF outcome
Comparison: 02 Endometrial injury and IVF outcome: RIF
Outcome: 01 CPR

Study or sub-category	Treatment n/N	Control n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI	Year
Barash	30/45	27/89		50.13	2.20 [1.51, 3.20]	2003
Raziel	18/60	7/57		19.85	2.44 [1.10, 5.41]	2007
Karimzadeh	13/52	4/52		11.06	3.25 [1.13, 9.31]	2009
Narvekar	16/49	7/51		18.96	2.38 [1.07, 5.28]	2010
Total (95% CI)	206	249		100.00	2.40 [1.75, 3.28]	

Total events: 77 (Treatment), 45 (Control)
Test for heterogeneity: $Chi^2 = 0.53$, df = 3 ($P = 0.91$), $I^2 = 0\%$
Test for overall effect: $Z = 5.44$ ($P < 0.00001$)



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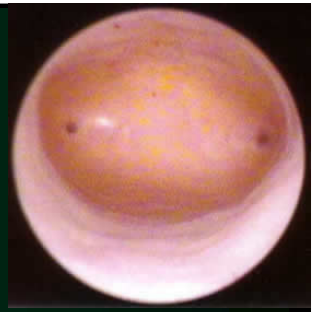
Biological explanation



- Release of cytokines and growth factors (LIF, IL-6 and 11, EGF) promoting endometrial development
- Alternation in endometrial gene expression (Laminin œ 4, Integrin œ 6, MMP1), which play key roles in implantation
- Delay endometrial maturation, thus promoting synchronisation with embryo stage

backward development

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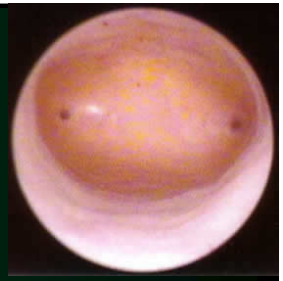
Do we need more trials?



- Small number of randomised trials available
- Methodological limitations (e.g. no blinding, no allocation concealment)
- Limited data on LBR

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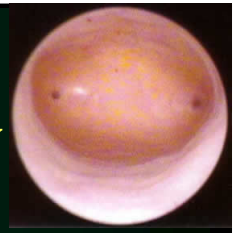
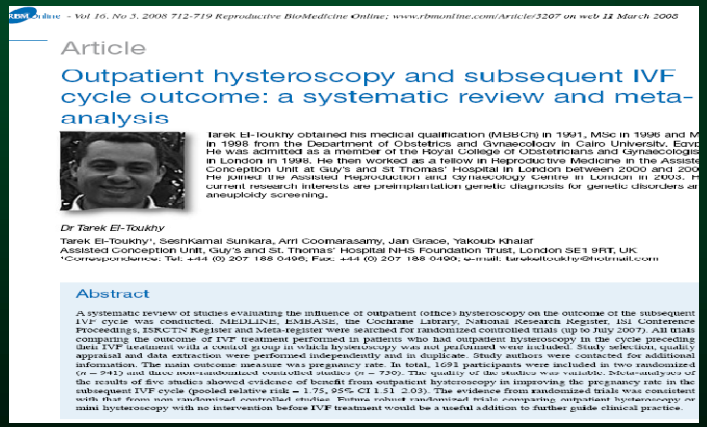
What did the systematic review recommend?



"...Future randomised trials comparing mini-hysteroscopy with no intervention before IVF treatment would be useful"



Vol 16, No 3, 2008 712-719 Reproductive BioMedicine Online; www.rbmonline.com/Article/3207 on web 12 March 2008

Article

Outpatient hysteroscopy and subsequent IVF cycle outcome: a systematic review and meta-analysis

Dr Tarek El-Toukhy

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Assisted Conception Unit, Guy's and St. Thomas' Hospital NHS Foundation Trust, London SE1 9RT, UK
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Abstract

A systematic review of studies evaluating the influence of outpatient (office) hysteroscopy on the outcome of the subsequent IVF cycle was conducted. MEDLINE, EMBASE, the Cochrane Library, National Research Register, ISI Conference Proceedings, ISRCTN Register and Meta-register were searched for randomized controlled trials (up to July 2007). All trials comparing the outcome of IVF treatment performed in patients who had outpatient hysteroscopy in the cycle preceding their IVF treatment with a control group in which hysteroscopy was not performed were included. Study selection, quality appraisal and data extraction were performed independently and in duplicate. Study authors were contacted for additional information. The main outcome measure was pregnancy rate. In total, 1691 participants were included in two randomized (n = 941) and three non-randomized controlled studies (n = 750). The quality of the studies was variable. Meta-analyses of the results of five studies showed evidence of benefit from outpatient hysteroscopy in improving the pregnancy rate in the subsequent IVF cycle (pooled relative risk = 1.75, 95% CI 1.51 2.03). The evidence from randomized trials was consistent with that from non-randomized controlled studies. Future robust randomized trials comparing outpatient hysteroscopy or mini hysteroscopy with no intervention before IVF treatment would be a useful addition to further guide clinical practice.

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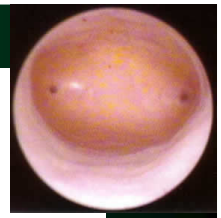
TROPHY

TRial of OutPatient HYsteroscopy

A multicentre randomised controlled study of the effects of outpatient hysteroscopy on the outcome of the subsequent IVF cycle after recurrent IVF failure.

Built with MedSciNet Clinical Trial Framework



TROPHY Trial Protocol

Trophy Collaborators meeting – ESHRE March 2009

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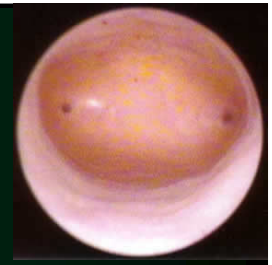
TROPHY Trial Protocol



Reproductive Health

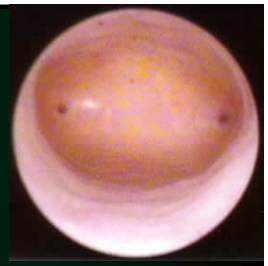
BioMed Central

Study protocol

Open Access

A multi-centre randomised controlled study of pre-IVF outpatient hysteroscopy in women with recurrent IVF implantation failure: Trial of Outpatient Hysteroscopy - [TROPHY] in IVF

Tarek El-Toukhy*[1], Rudi Campo[2], Sesh Kamal Sunkara[1], Yacoub Khalaf[1] and Arri Coomarasamy[3]



Hypothesis

Does performing an OPH prior to starting an IVF cycle improve the live birth rate in women who have experienced 2-4 failed cycles?

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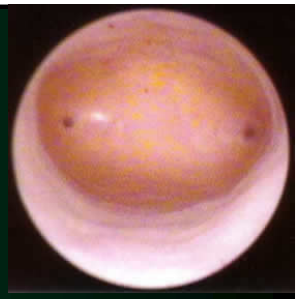
Population



- Women under 38, BMI ≤ 35
- Failed two-four failed IVF/ET cycles
- Normal TVS of cavity

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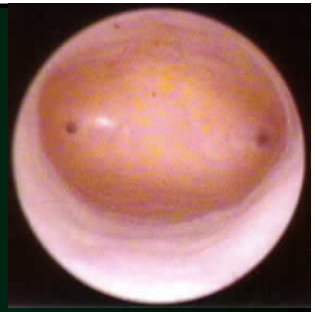
Exclusion criteria



- Age 38 or above
- Less than 2 or more than 4 failed cycles
- Fibroids distorting the cavity or untreated hydrosalpinges
- BMI>35
- Recent hysteroscopy (within 2 months)

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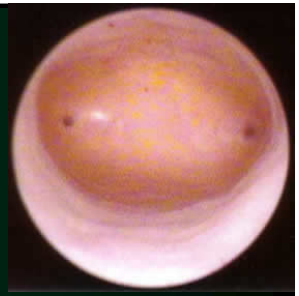
Intervention



- Saline OPH (2.9-5mm) - Trophy Scope
- Cycle before IVF
- Any standard IVF protocol
- Any type of FSH/HMG for stimulation

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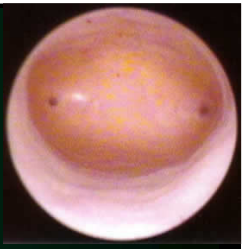
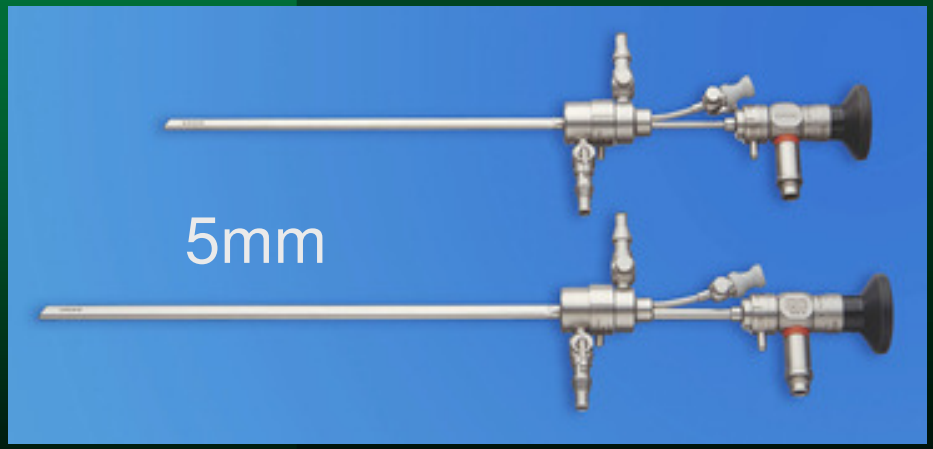
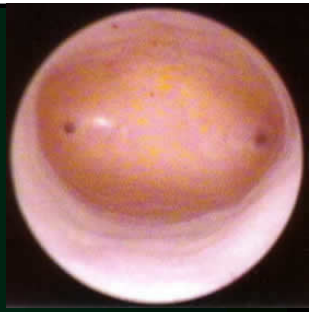
TROPHY scope (Storz)
Campo Compact Hysteroscopes





Telepack

Control group



- No hysteroscopy
- Any standard IVF protocol
- Any type of FSH/HMG for COS

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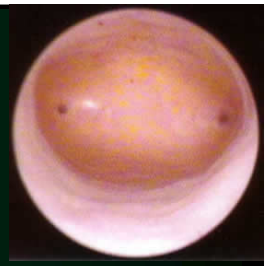
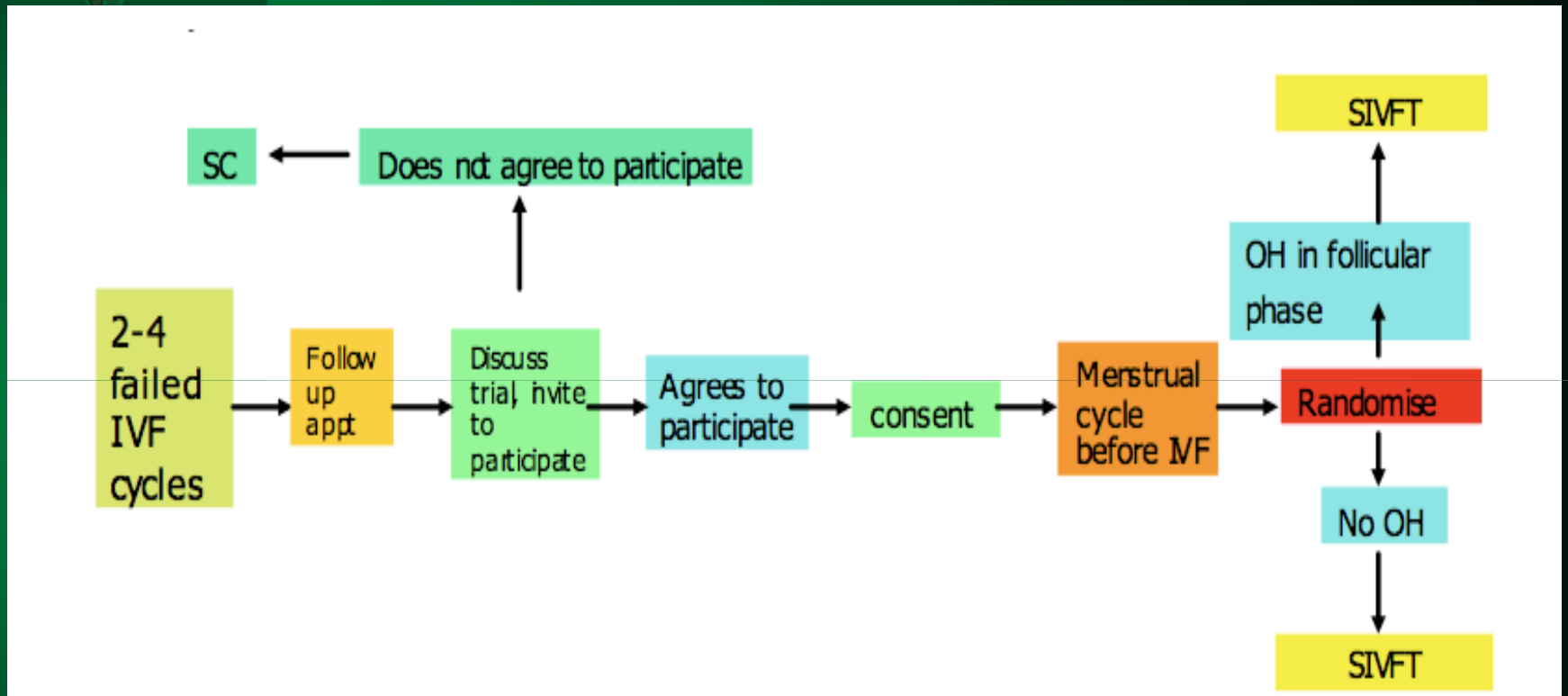
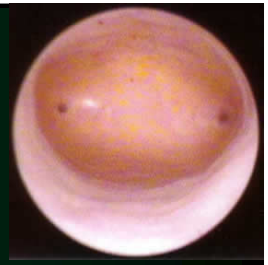
Participant flow in the study





SC=standard care, Appt=appointment, OH= outpatient hysteroscopy, SIVFT=standard IVF treatment

Outcome measures (ITT)



- **Primary:**
  - LBR/cycle started

- **Secondary:**
  - PR , CPR and IR
  - OPH findings
  - Adverse effects (including miscarriage rate)
  - Health Economic Evaluation

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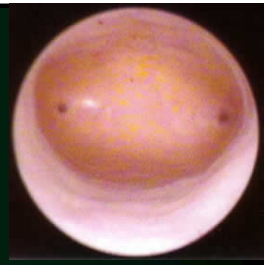
Sample size calculation



- For a DS alpha of 5%
- For a power of 80%
- In order to increase live birth rate from 25% to 35%, need 360 + 360 = 720 women
- 5% drop out rate = 38

758 (379 in each arm) across 8 European centres

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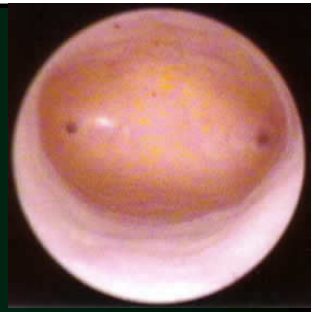
Funding



- Participating centres
- ESHRE and EAGE (logistic support)
- Karl Storz = OPH instruments and training in each of the participating 8 centres
- Tristel = sterilisation

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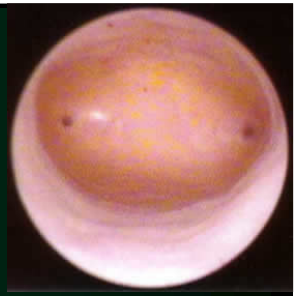
Analysis



- Comparative analysis (within study, with patients outside study)
- Minimisation
  - Age <31, 31-37years
  - BMI <30, 30-34
  - Number of previous failed cycles
    - 2
    - 3-4
  - FSH level
    - <10
    - 10 or more
- Adjustments and sensitivity analysis
  - Logistic regression (hysteroscopy findings: normal, abnormal, control for centre effect)

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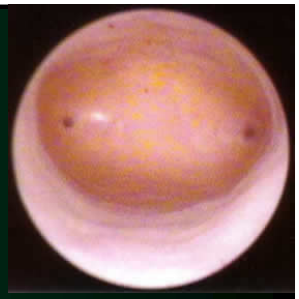
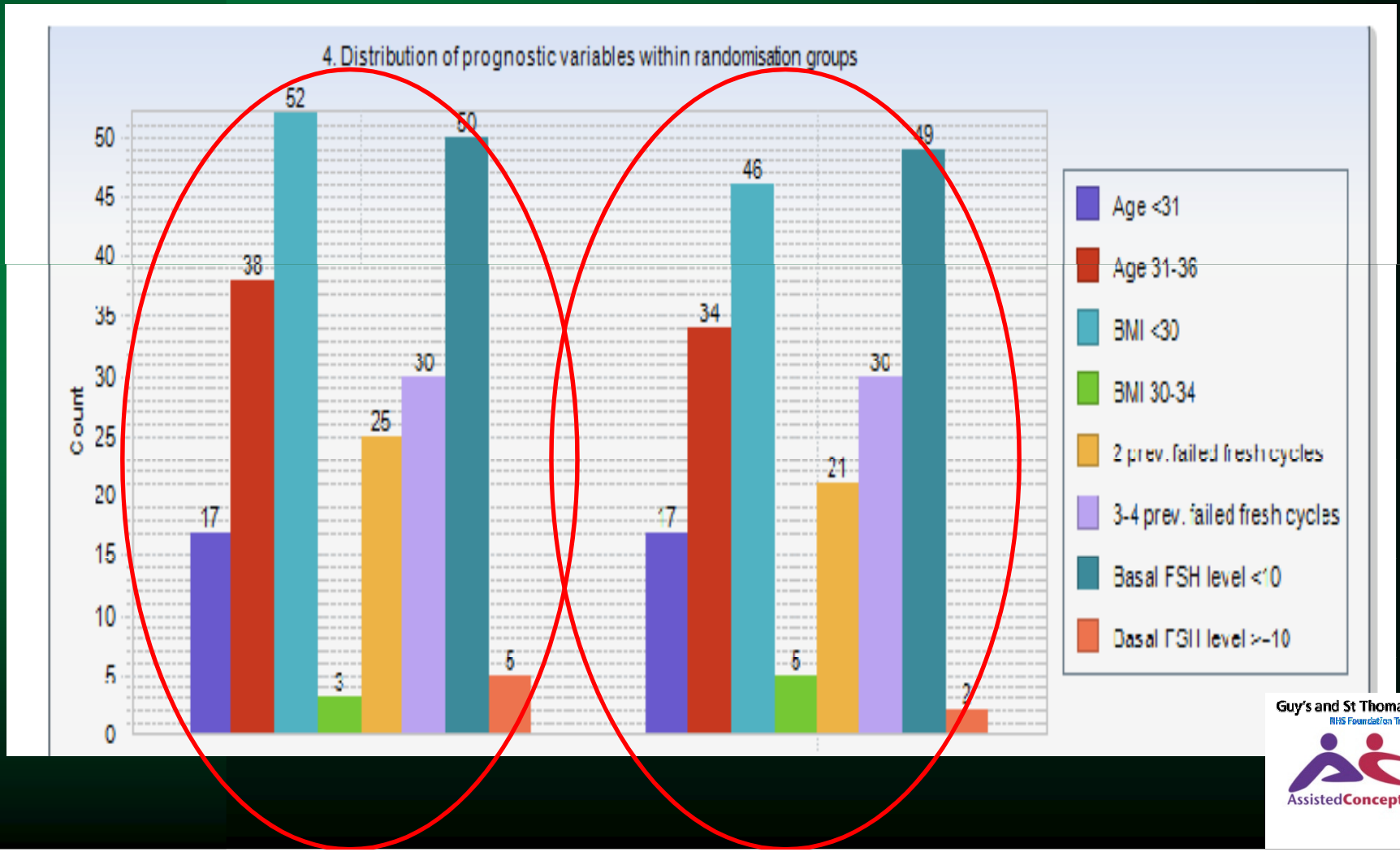
Prognostic variables





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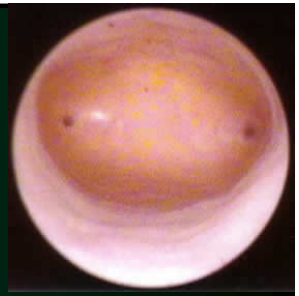
Targets and timelines



- 450 cases by end of 2011
- Complete study by mid 2012
- Publication of LB results in 2013

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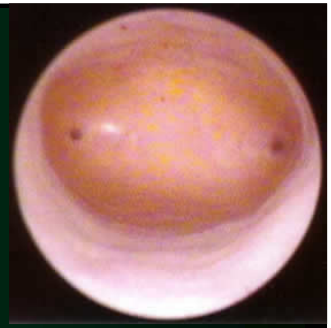
Conclusions



- Hysteroscopy is a safe and effective diagnostic and therapeutic tool in ART patients
- Treatment of intra-uterine pathology can improve ART outcome (Level I-III)
- Diagnostic Hysteroscopy before IVF is likely to improve outcome in subsequent IVF cycle (Level I)

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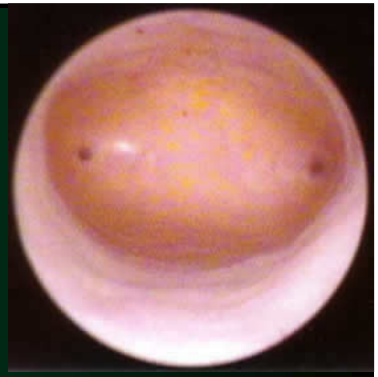
The future…



- On-going randomised trials will shed more light on the role of routine out-patient hysteroscopy before IVF

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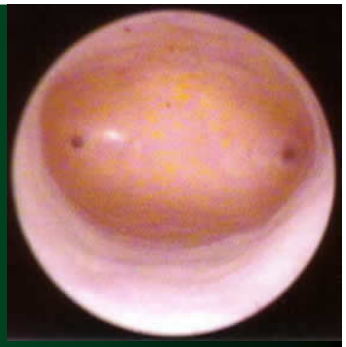
Our Team



Thank You

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