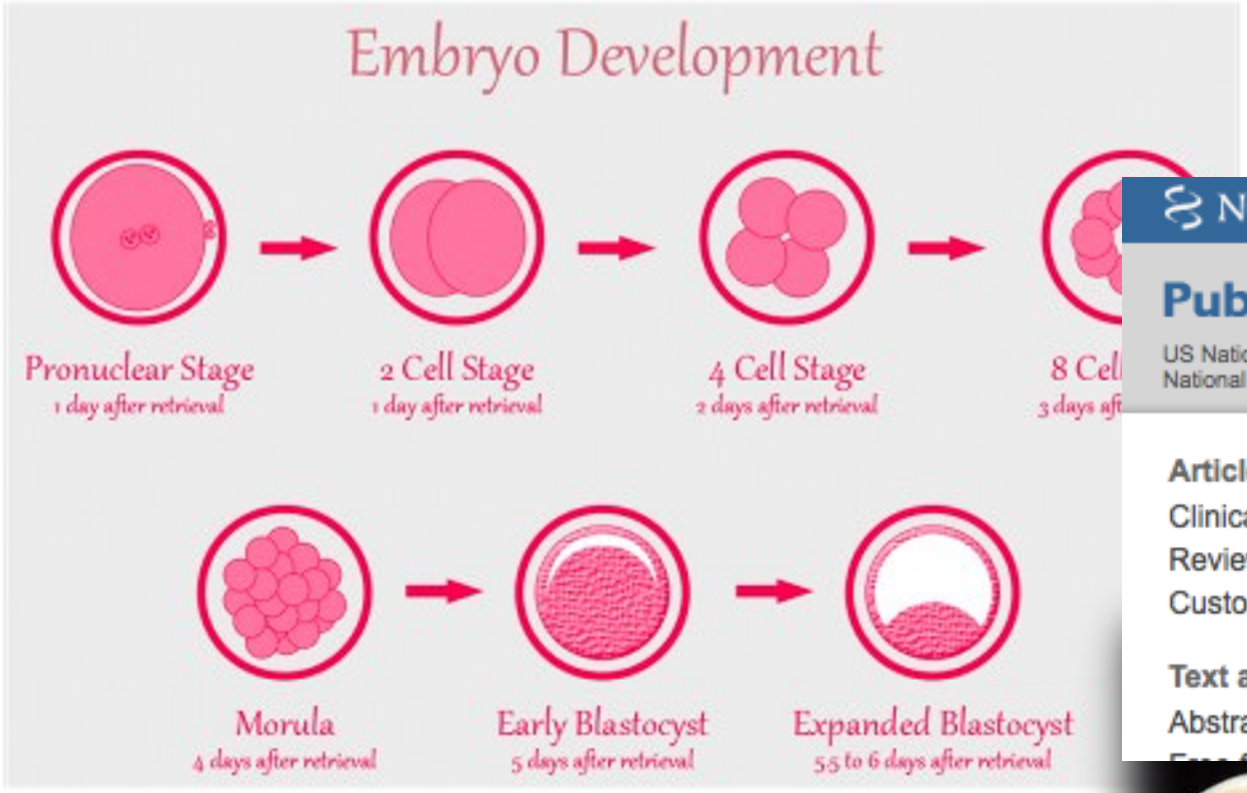
University of Study of Naples "Federico II"
Department of Obstetrics & Gynecology

What have we learnt from surgery to manage the infertile uterus?

Attilio Di Spiezio Sardo



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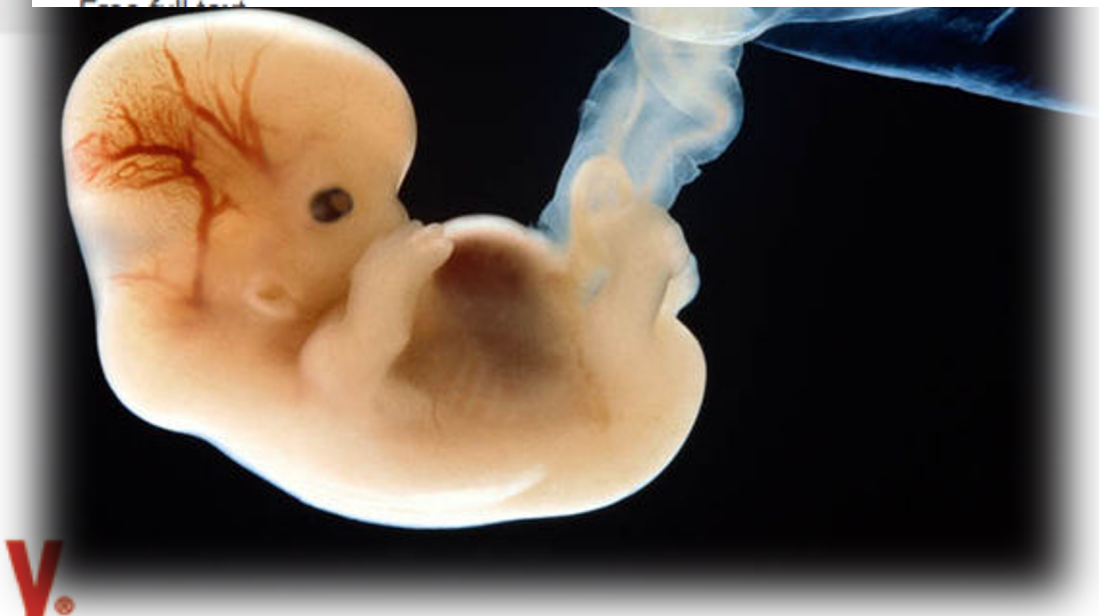

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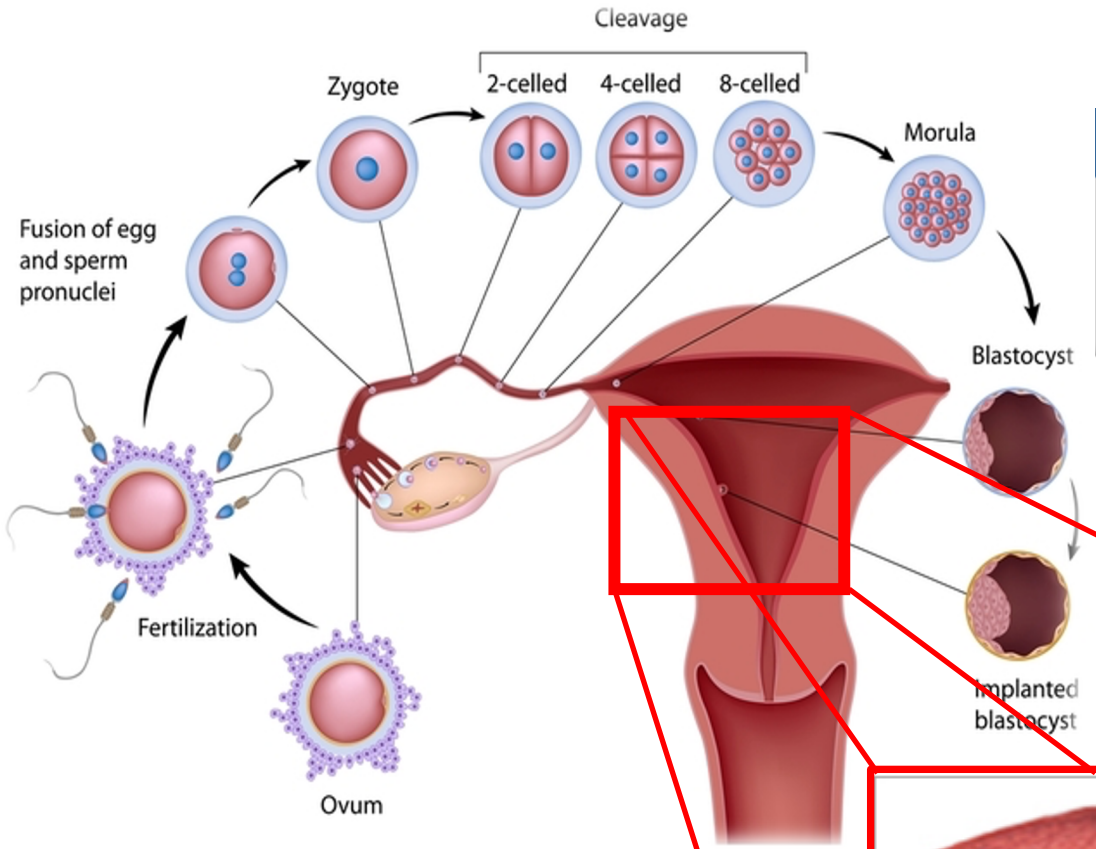

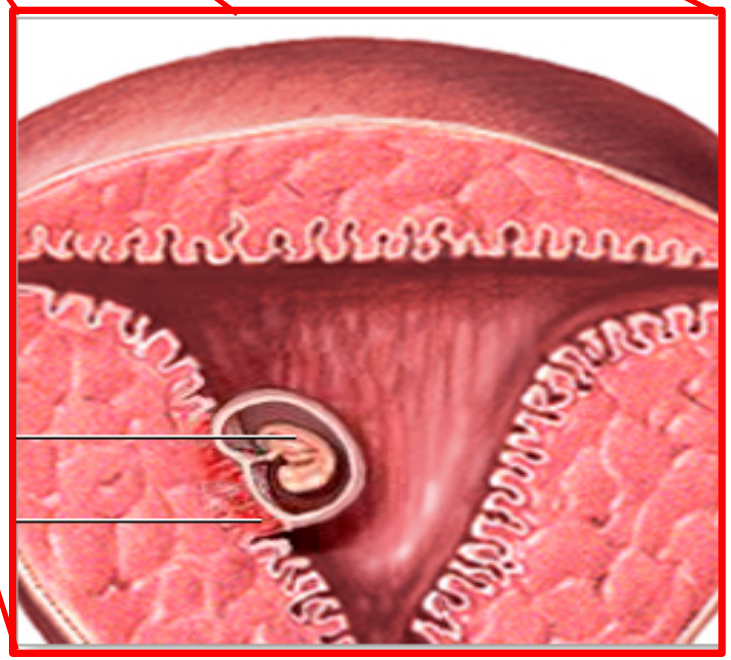

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THE LANCET

Fertility and Sterility

OXFORD ACADEMIC

human reproduction update

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Introduction:
Examining the many potential reasons why euploid blastocysts do not always result in viable pregnancies: part 1

2015

David R. Meldrum, M.D.[a,b]

[a] Reproductive Partners La Jolla, La Jolla; and [b] Division of Reproductive Endocrinology and Infertility, Department of Reproductive Medicine, University of California at San Diego, San Diego, California

Introduction:
Examining the many potential reasons why euploid blastocysts do not always result in viable pregnancies (and deliveries): part 2

2016

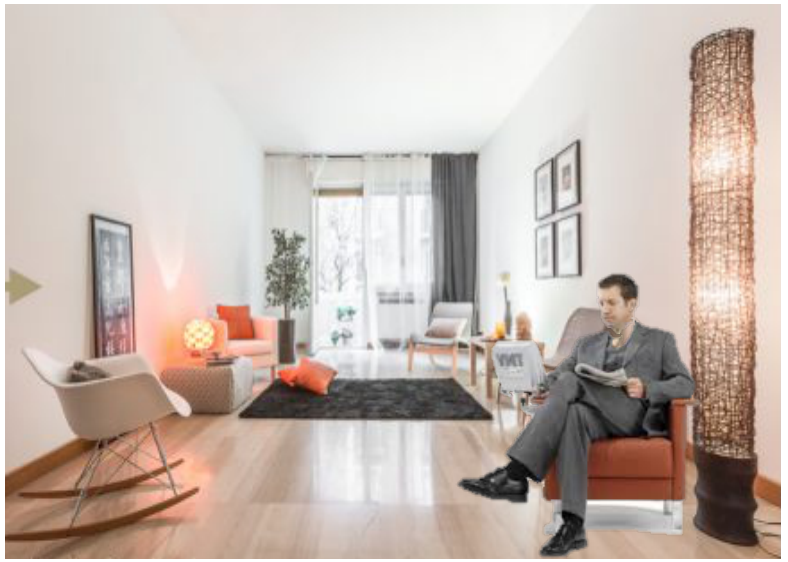
David R. Meldrum, M.D.,[a] and Dominique de Ziegler, M.D.[b]

[a] Reproductive Partners San Diego, Division of Reproductive Endocrinology and Infertility, Department of Reproductive Medicine, University of California, San Diego, California; and [b] Department of Obstetrics, Gynecology, and Reproductive Medicine, Université Paris Descartes, Paris Sorbonne Cité–Assistance Publique Hôpitaux de Paris, CHU Cochin, Paris, France

To result in a viable delivery: 1) a capable embryo must be accurately deposited and retained in an optimal location of the uterine cavity; 2) the endometrium must be receptive and synchronized to the developmental stage of the embryo; 3) the uterus must be physiologically and anatomically adequate; and 4) there should not be the presence of circulating factors capable of disrupting normal implantation and placentation, nor the absence of specific factors required for endometrial receptivity. The intri-

The **UTERUS** must be physiologically and anatomically adequate

The **ENDOMETRIUM** must be receptive and synchronized to the developmental stage of the embryo



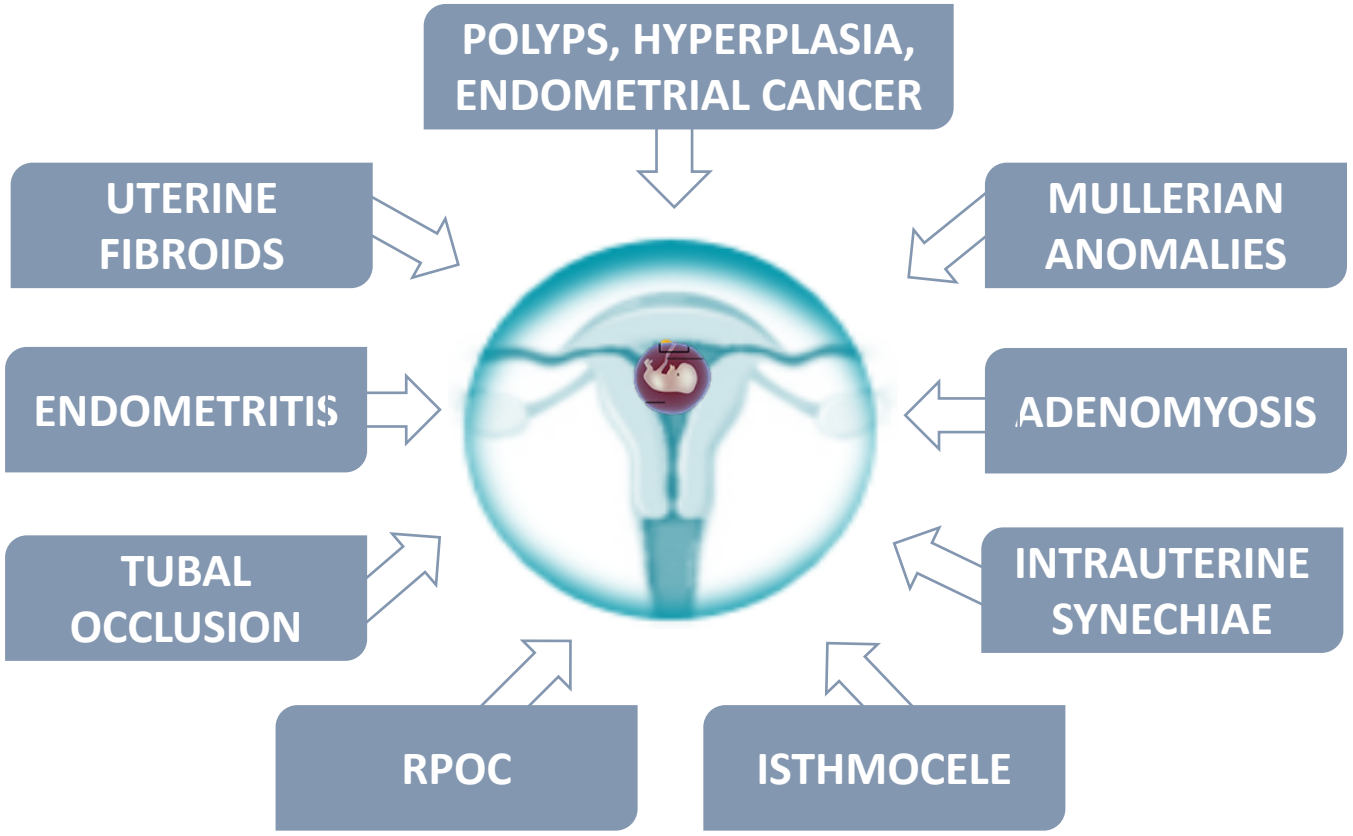
A **CAPABLE EMBRYO** must be retained in an optimal location of the uterine cavity

Meldrum D.R. et al. , Fertil Steril 2016

Uterine abnormalities are found in **40-50%** of infertile women and can be the cause of infertility in **2-3%** of women

Chiofalo B, 2019

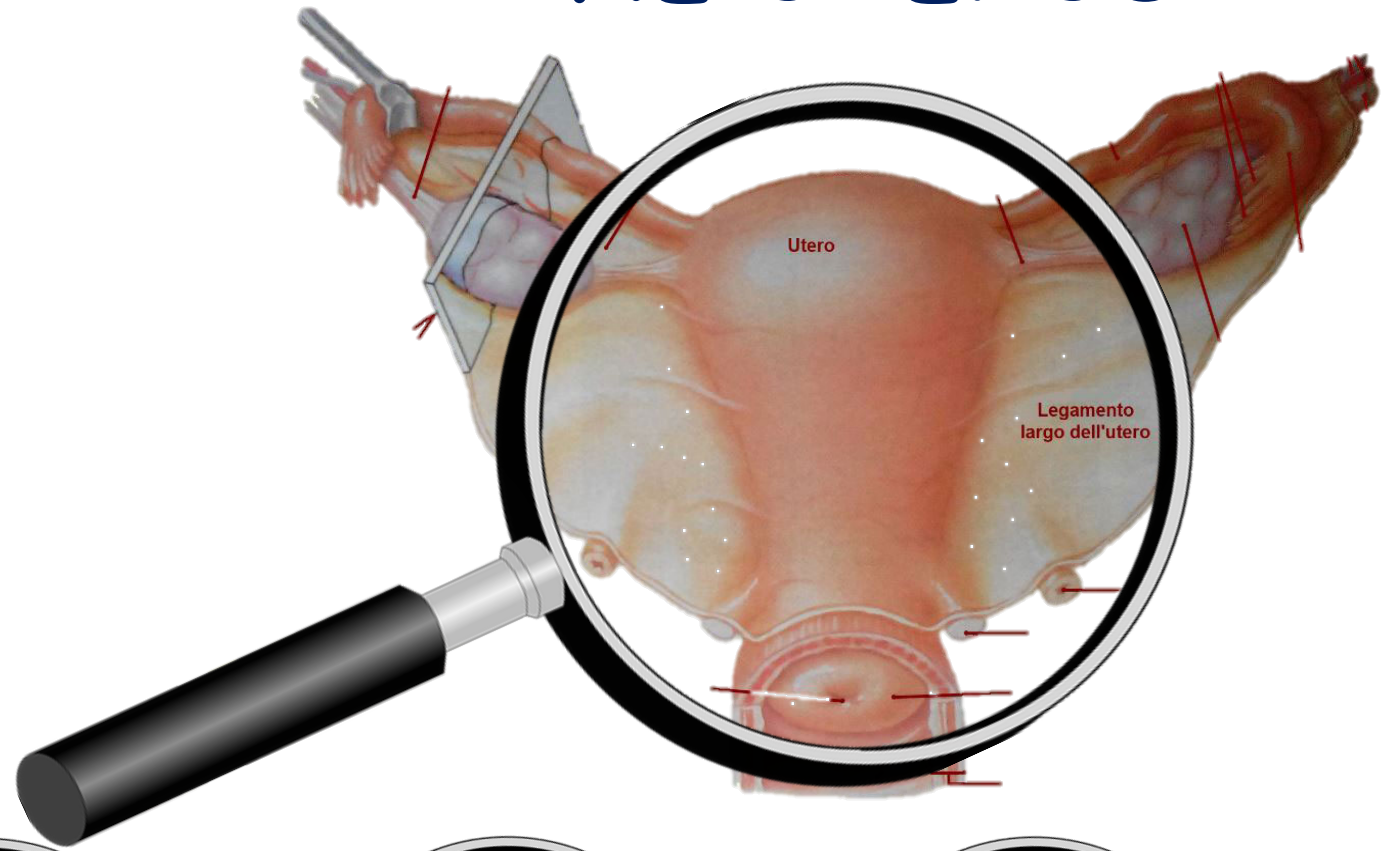
UTERINE PATHOLOGIES LIKELY TO HAVE ADVERSE EFFECT ON REPRODUCTIVE OUTCOMES



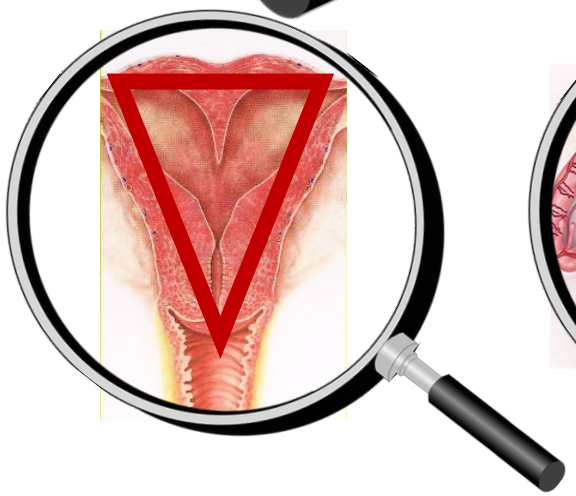
Preston PJ, 2019

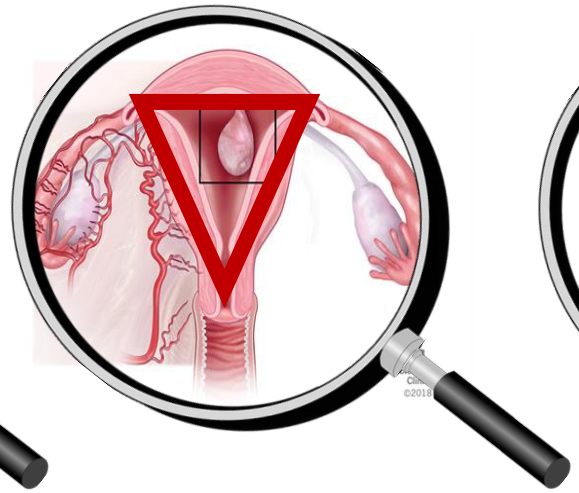
THE UTERUS

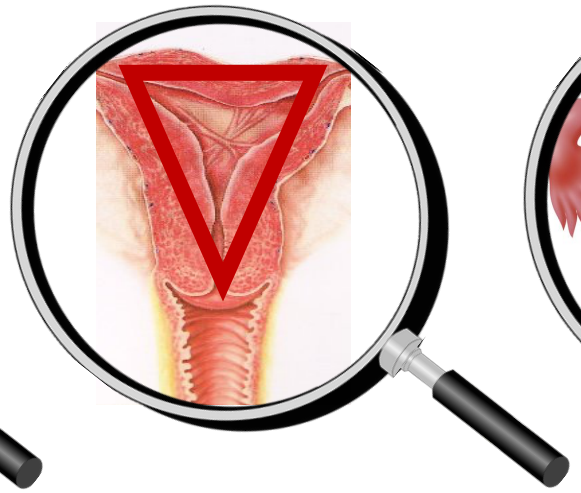
OUTSIDE



INSIDE







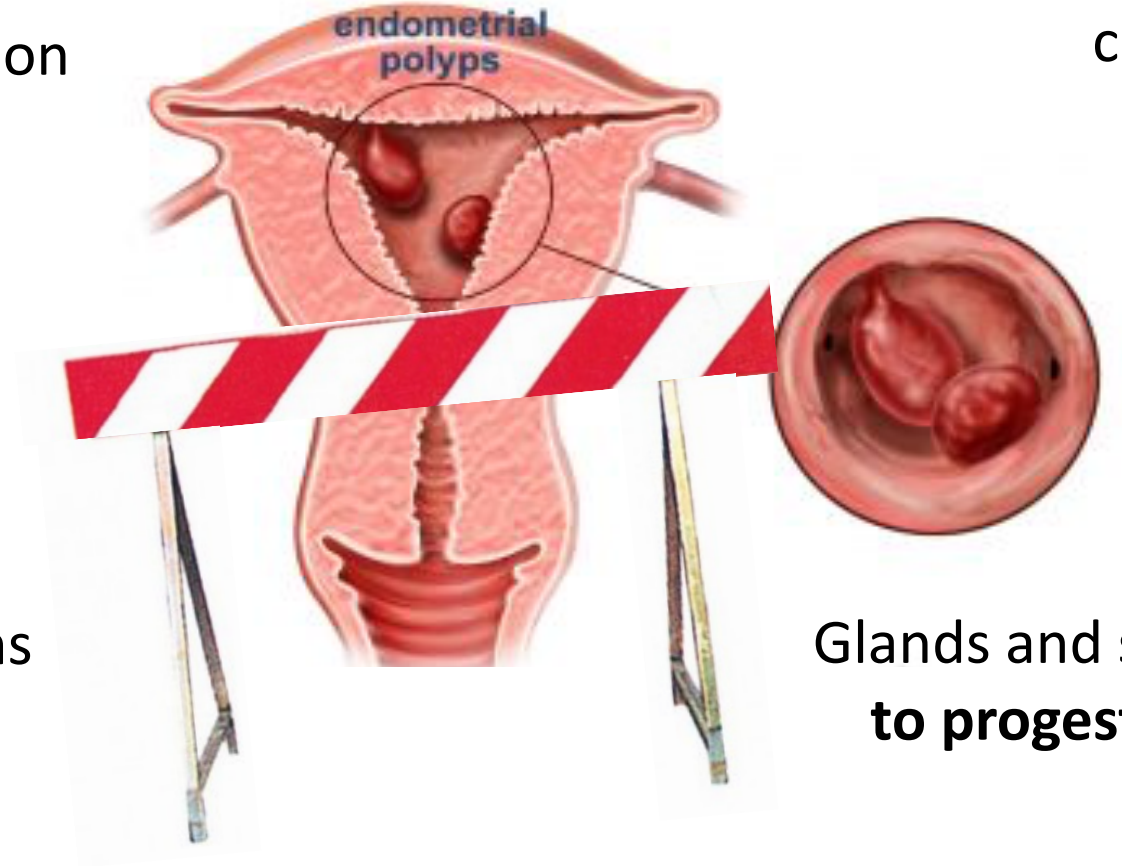
Which is the impact of the uterine pathology on fertility

Which is the reproductive outcome following treatment of the uterine pathology

Polyps & Fertility impairment

Mechanical interference
with sperm transportation

Local infiammatory
changes



Space occupying lesions

Glands and stroma **unresponsive to progesterone stimulation**

Decrease mRNA levels of **HOXA10** and **HOXA11**

(molecular markers of endometrial receptivity)

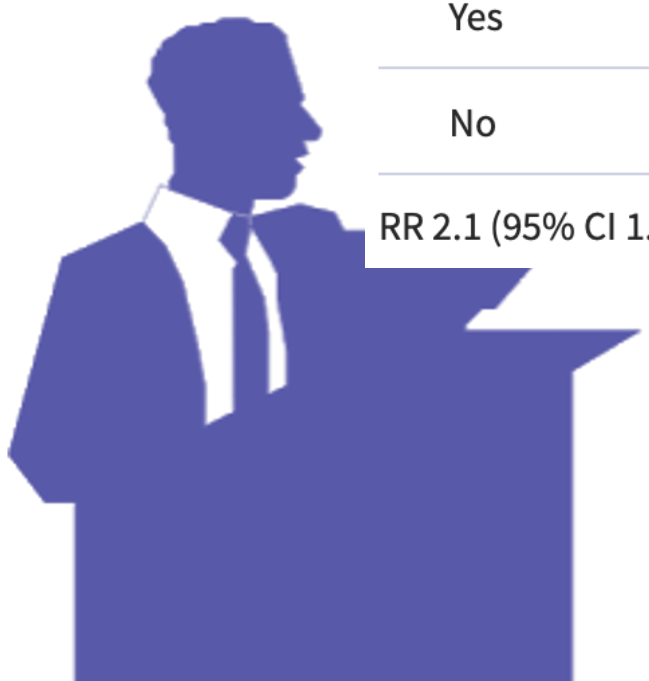
Rackow BW, 2011; *Pereira, 2015*

POLYPS AND INFERTILITY

NUMBER AND PERCENTAGE OF PREGNANCIES AFTER HYSTEROSCOPIC POLYPECTOMY

	Polypectomy		*P*-value
	Study (*n*=101)	**Control (*n*=103)**	
Pregnancy (%)			<0.001
Yes	64 (63.4)	29 (28.2)	
No	37 (36.6)	74 (71.8)	

RR 2.1 (95% CI 1.5–2.9).



Perez-Medina, 2005

Cochrane Library

Cochrane Database of Systematic Reviews

Surgical intervention versus expectant management for endometrial polyps in subfertile women (Review)

Jayaprakasan K, Polanski L, Sahu B, Thornton JG, Raine-Fenning N

Main results

Only one randomised controlled trial of endometrial polypectomy was identified for inclusion. However, a single set of data could not be extracted from this study due to internal inconsistencies of the results reported. Attempts to contact the authors to resolve the issue were unsuccessful, by phone, post and e-mail.

Authors' conclusions

Removal of endometrial polyps in subfertile women is commonly being performed in many countries with an aim to improve the reproductive outcome. We did not identify any analysable randomised trials which would allow us to reach any sound scientific conclusions on the efficacy of endometrial polypectomy in subfertile women. Well designed, methodologically sound, randomised controlled trials are urgently needed.

Hysteroscopy for treating subfertility associated with suspected major uterine cavity abnormalities (Review)

Bosteels J, Kasius J, Weyers S, Broekmans FJ, Mol BWJ, D'Hooghe TM

THE COCHRANE COLLABORATION®

Authors' conclusions

A large benefit with the hysteroscopic removal of submucous fibroids for improving the chance of clinical pregnancy in women with otherwise unexplained subfertility cannot be excluded. The hysteroscopic removal of endometrial polyps suspected on ultrasound in women prior to IUI may increase the clinical pregnancy rate. More randomised studies are needed to substantiate the effectiveness of the hysteroscopic removal of suspected endometrial polyps, submucous fibroids, uterine septum or intrauterine adhesions in women with unexplained subfertility or prior to IUI, IVF or ICSI.

SOGC CLINICAL PRACTICE GUIDELINE

No. 321, March 2015

The Management of Uterine Fibroids in Women With Otherwise Unexplained Infertility

Six systematic reviews or meta-analyses published between 2001 and 2010[15,22–26] assessed whether fibroids have an impact on fertility. On the whole, it appears that women

15. Donnez J, Jadoul P. What are the implications of myomas on fertility? A need for a debate? Hum Reprod 2002;17:1424–30.

22. Griffiths AN, D'Angelo A, Amso NN. Surgical treatment of fibroids for subfertility. Cochrane Database Syst Rev 2006;(3):CD003857 11.

23. Klatsky PC, Tran ND, Caughey AB, Fujimoto VY. Fibroids and reproductive outcomes: a systematic literature review from conception to delivery. Am J Obstet Gynecol 2008;198:357–66.

24. Pritts EA. Fibroids and infertility: a systematic review of the evidence. Obstet Gynecol Surv 2001;56:483–91.

25. Pritts EA, Parker WH, Olive DL. Fibroids and infertility: an updated systematic review of the evidence. Fertil Steril 2009;91:1215–23.

26. Somigliana E, Vercellini P, Daguati R, Pasin R, De Giorgi O, Crosignani PG. Fibroids and female reproduction: a critical analysis of the evidence. Hum Reprod Update 2007;13:465–76.

MAIN ISSUES

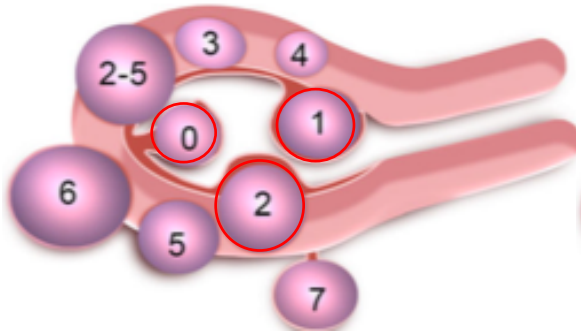
LOCATION

SIZE

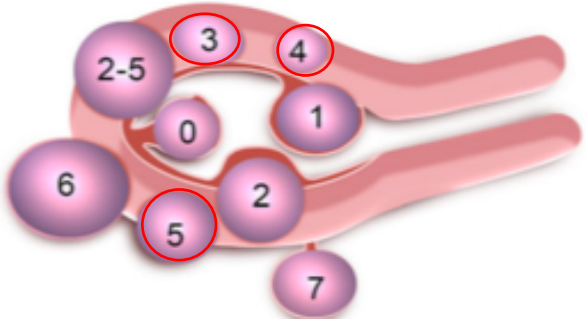
NUMBER

Reproductive prognosis

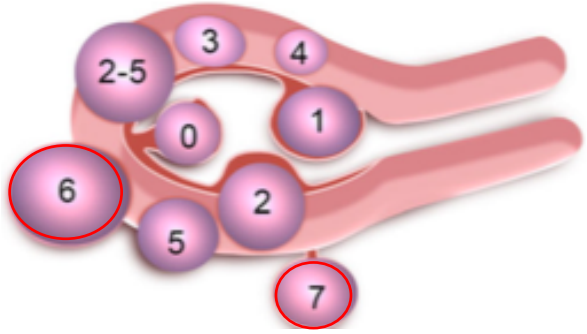
Fibroids location



Sub-mucosus



Intramural



Sub-serosal

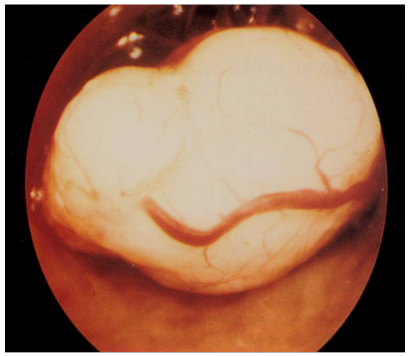
Reproductive Outcome

Somigliana, 2007, Pritts, 2009; Sunkara, 2010, Yan, 2014; Zepiridis, 2015

UTERINE FIBROIDS

Fertility and Sterility® Vol. 91, No. 4, April 2009

Fertility and Sterility



Fibroids and infertility: an updated systematic review of the evidence

Elizabeth A. Pritts, M.D.,[a] *William H. Parker, M.D.,*[b] *and David L. Olive, M.D.*[a]

- Obstacles to sperm migration
- Impairment of embryo implantation
- Obstacles to oocyte transport

FERTILITY IMPAIRMENT

Somigliana E et al. Reprod Update, 2007

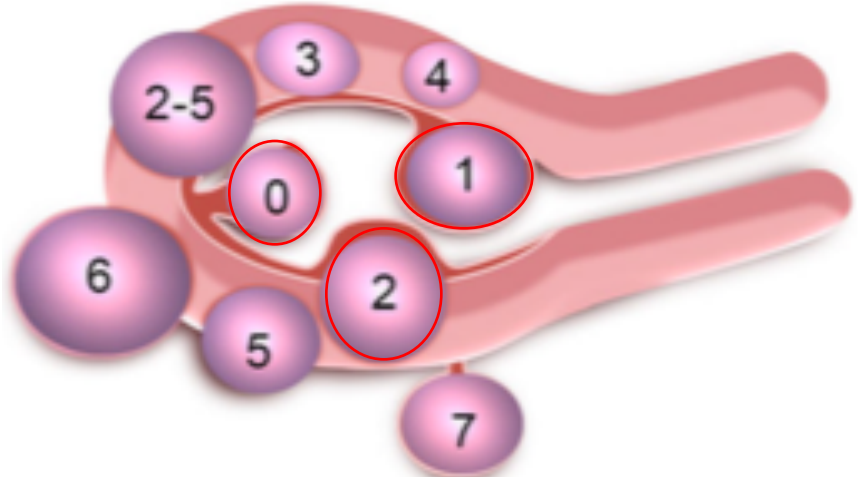
- Altered contour of the uterine cavity
- Anomalies of uterine contractility

Bettocchi S et al. Hum Reprod 2002
Buttram VC et al.Fertil Steril 1981

- Alterations in focal endometrial perfusion
- Endometrial inflammation, secretion of vasoactive substances or androgen local increase

Cicinelli E et al. Obstet Gynecol 1995
Buttram VC et al. Fertil Steril 1981

Fibroid and infertility: Sub-mucous



Maximal detrimental effect

- Infertility
- Repeated implantation failure (ART)
- Recurrent pregnancy loss

Somigliana *et al.*, Hum Reprod Update 2007, Pritts *et al.*, Fertil Steril 2009; Sunkara *et al.*, Hum Reprod 2010, Yan *et al.*, Fertil Steril 2014; Zepiridis *et al.*, Best Pract Res Clin Obstet Gynaecol 2015

Does HYSTEROSCOPIC resection of SM fibroids improve fertility or affect miscarriage rates?

Human Reproduction Update Advance Access published March 23, 2016
Human Reproduction Update, Vol.0, No.0 pp. 1–18, 2016
doi:10.1093/humupd/dmw008

human reproduction update

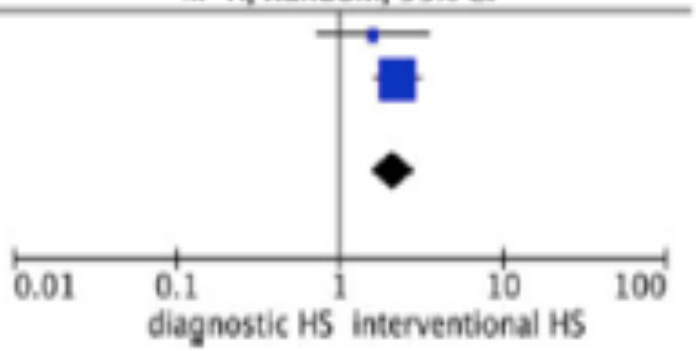
Efficacy of hysteroscopy in improving reproductive outcomes of infertile couples: a systematic review and meta-analysis

Attilio Di Spiezio Sardo[1,*], Costantino Di Carlo[2], Silvia Minozzi[3], Marialuigia Spinelli[2], Vanna Pistotti[4], Carlo Alviggi[2], Giuseppe De Placido[2], Carmine Nappi[1], and Giuseppe Bifulco[2]

PREGNANCY RATE

Study or Subgroup	interventional HS Events	Total	diagnostic HS Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Casini 2006	13	30	6	22	15.6%	1.59 [0.72, 3.52]
Pérez-Medina 2005	64	101	29	103	84.4%	2.25 [1.60, 3.17]
Total (95% CI)		**131**		**125**	**100.0%**	**2.13 [1.56, 2.92]**
Total events	77		35			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.62$, df = 1 ($P = 0.43$); $I^2 = 0\%$
Test for overall effect: $Z = 4.72$ ($P < 0.00001$)



Gynecological Endocrinology, February 2006; 22(2): 106–109

Taylor & Francis
Taylor & Francis Group

Effects of the position of fibroids on fertility

MARIA LUISA CASINI[1], FEDERICA ROSSI[2], RICCARDO AGOSTINI[2], & VITTORIO UNFER[3]

Table II. Effect of fibroid location and treatment on pregnancy rate.

Group	Treatment	No. of patients	No. of pregnancies	Pregnancy rate (%)	*p* Value
SM ($n=52$)	With surgery	30	13	43.3	<0.05
	Without surgery	22	6	27.2	
IM ($n=45$)	With surgery	23	13	56.5	NS
	Without surgery	22	9	40.9	
SS ($n=11$)	Without surgery	11	7	63.6	
IM-SS ($n=31$)	With surgery	17	6	35.3	NS
	Without surgery	14	3	21.4	
SM-IM ($n=42$)	With surgery	22	8	36.4	<0.05
	Without surgery	20	3	15.0	

SM, submucosal; IM, intramural; SS, subserosal; IM-SS, mixed intramural–subserosal; SM-IM, mixed submucosal–intramural; NS, not significant.

There was an OVERALL tendency to have a higher PR among the woman who underwent a surgical treatment for fibroid removal compared with those who were not treated.

WANTED

Master in Clinical Research
University of Rome (Italy)

Specialist in Pharmacology
University of Rome (Italy)

PhD Philosophy Doctor in Pharmacology, Pharmacognosy and Toxicology
University of Rome (Italy)

MARIA LUISA CASINI

Submucous myomas and their implications in the pregnancy rates of patients with otherwise unexplained primary infertility undergoing hysteroscopic myomectomy: a randomized matched control study

Tarek Shokeir, M.D., Muhammed El-Shafei, M.D., Hamed Yousef, M.D., Abdel-Fattah Allam, M.D., and Ehab Sadek, M.D.

Department of Obstetrics and Gynecology, Fertility Care Unit, Mansoura University Hospital, Mansoura Faculty of Medicine, Mansoura, Egypt

TABLE 2

Pregnancy rates according to the characteristics of submucous myomas.

	Pregnancy rates		
	Myomectomy	No myomectomy	
Myoma characteristic	Study (n = 101)	Control (n = 103)	*P* value
Size (mm), %			NS
<5	68.0	69.6	
5–10	56.2	53.3	
11–20	61.5	58.3	
>20	61.1	61.5	
Number, %			NS
1	44.4	40.9	
≥2	36.4	30.0	NS
Type, %			
0	57.9	33.3	<0.001
I	35.7	17.2	<0.001
II	31.3	29.0	NS
Location, %			NS
Fundal	50.0	53.8	
Lower uterine segment	41.5	42.1	

Note: NS = not significant.

Shokeir. Hysteroscopic myomectomy in unexplained infertility. Fertil Steril 2010.

Conclusion(s): Hysteroscopic myomectomy for submucous fibroids in women with unexplained primary infertility is effective in achieving a better pregnancy rate. We think that a multicenter study should be conducted before evaluating the impact of submucous myoma characteristics on fertility outcome. (Fertil Steril® 2010;94:724–9. ©2010 by American Society for Reproductive Medicine.)

ELSEVIER

THE JOURNAL OF
MINIMALLY INVASIVE
GYNECOLOGY

Special Article

AAGL Practice Report: Practice Guidelines for the Diagnosis and Management of Submucous Leiomyomas

AAGL: *ADVANCING MINIMALLY INVASIVE GYNECOLOGY WORLDWIDE*

Further evidence regarding the impact of submucous myomas on fertility can be found in studies evaluating the impact of myomectomy. It seems clear from high-quality studies that pregnancy rates are higher after myomectomy than no or "placebo" procedures [27,32]. The impact of myomectomy on fertility outcomes is discussed later in this guideline.

32. Shokeir T, El-Shafei M, Yousef H, Allam AF, Sadek E. Submucous myomas and their implications in the pregnancy rates of patients with otherwise unexplained primary infertility undergoing hysteroscopic myomectomy: a randomized matched control study. *Fertil Steril*. 2010;94:724–729 (I).

Submucous myomas and their implications in the pregnancy rates of patients with otherwise unexplained primary infertility undergoing hysteroscopic myomectomy: a randomized matched control study

Tarek Shokeir, M.D., Muhammed El-Shafei, M.D., Hamed Yousef, M.D., Abdel-Fattah Allam, M.D., and Ehab Sadek, M.D.

Department of Obstetrics and Gynecology, Fertility Care Unit, Mansoura University Hospital, Mansoura Faculty of Medicine, Mansoura, Egypt

TABLE 2

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NOTICE OF DUPLICATE PUBLICATION—RETRACTION

Submucous myomas and their implications in the pregnancy rates of patients with otherwise unexplained primary infertility undergoing hysteroscopic myomectomy: a randomized matched control study. Shokeir T, El-Shafei M, Yousef H, Allam A-F, Sadek E. Fert Steril 2010;94:724–9.

This article has been retracted at the request of the editors of *Fertility and Sterility* as it duplicates parts of a paper that had already appeared in Hum Reprod 2005;20:1632–5, doi:10.1093/humrep/deh822.

Human Reproduction Vol.20, No.6 pp. 1632–1635, 2005 doi:10.1093/humrep/deh822

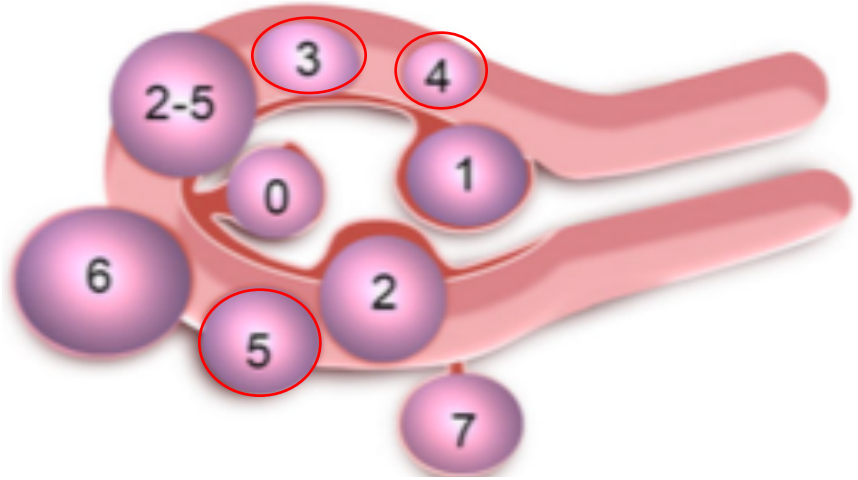
Advance Access publication March 10, 2005

Endometrial polyps and their implication in the pregnancy rates of patients undergoing intrauterine insemination: a prospective, randomized study

Tirso Pérez-Medina[1], José Bajo-Arenas, Francisco Salazar, Teresa Redondo, Luis Sanfrutos, Pilar Alvarez and Virginia Engels

Conclusion(s): Hys plained primary infertility is effective in ac uld be conducted before evaluating the imp Steril® 2010;94:724–9.

Fibroid and infertility: intramural (3-5)

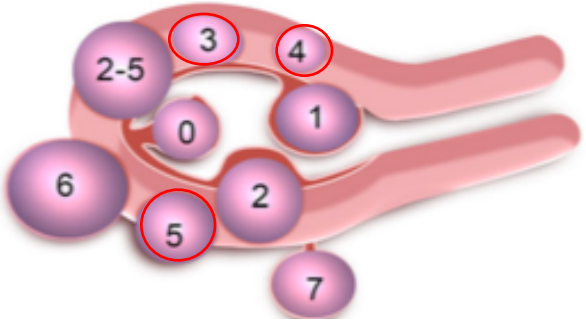


Negative effect depending on

- size (> 3-4 cm may be deleterious)
- number

Somigliana *et al.*, Hum Reprod Update 2007, Pritts *et al.*, Fertil Steril 2009; Sunkara *et al.*, Hum Reprod 2010, Yan *et al.*, Fertil Steril 2014; Zepiridis *et al.*, Best Pract Res Clin Obstet Gynaecol 2015

Does myomectomy of IM fibroids improve fertility or affect miscarriage rates?



UTERINE FIBROIDS

Fibroids and infertility: an updated systematic review of the evidence

Elizabeth A. Pritts, M.D.,[a] *William H. Parker, M.D.,*[b] *and David L. Olive, M.D.*[a]

[a] Wisconsin Fertility Institute, Middleton, Wisconsin; and [b] Department of Obstetrics and Gynecology, University of California, Los Angeles, California

Effect of myomectomy on fertility: intramural fibroids (fibroids in situ controls).

Outcome	Number of studies/ substudies	Relative risk	95% confidence interval	Significance
Clinical pregnancy rate	2	3.765	0.470–30.136	Not significant
Implantation rate	0	—	—	—
Ongoing pregnancy/live birth rate	1	1.671	0.750–3.723	Not significant
Spontaneous abortion rate	1	0.758	0.296–1.943	Not significant
Preterm delivery rate	0	—	—	—

Pritts. Fibroids and infertility. Fertil Steril 2009.

human reproduction update

2012

ART and uterine pathology: how relevant is the maternal side for implantation?

Daniela Galliano[1,*], José Bellver[2], César Díaz-García[3], Carlos Simón[2,4] and Antonio Pellicer[2,3,4]

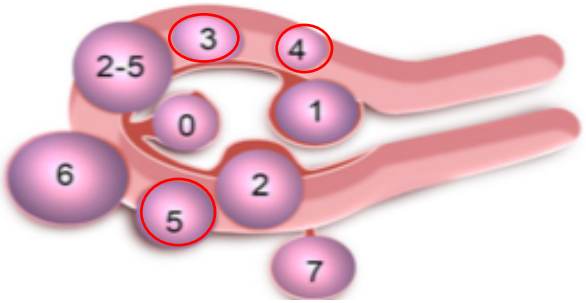


Table I Grading of Recommendations Assessment, Development and Evaluation (GRADE) scores on evidence available regarding the different causes of uterine infertility and their treatments.

Uterine structure	Quality of evidence regarding different uterine pathologies and their impact on live birth rate after ART		Quality of evidence and grade of recommendation of uterine treatments aimed at improving live birth rates after ART		Additional recommendation for ART cycle
Endometrium			**Evidence**	**Recommendation**	
	Endometrial appearance	⊕	Sildenafil: ⊕	▲?	See also 'Vascularization' below
			Pentoxyphylline+Vit E: ⊕	▲?	
			Estradiol: ⊕	▲?	
			G-CSF: ⊕	▼▼	
	Polyps	⊕	Polypectomy: ⊕	▲?	
	Asherman/atrophy	⊕	Adhesiolysis: ⊕	▲?	
			Adhesion prevention: Expectant management ⊕	▲?	
			Medical curettage: ⊕	▲?	
			Adhesion barriers: ⊕⊕⊕/⊕⊕	▲?	
			IUD: ⊕	▲?	
			Foley: ⊕	▲?	
			Amnion: ⊕⊕	▲?	
			Estradiol: ⊕	▲?	
			Antibiotics: ⊕	▲?	
	Infections	⊕	Antibiotic treatment: ⊕	▲?	
Myometrium			**Evidence**	**Recommendation**	
	Intramural fibroids	⊕	Myomectomy: ⊕	▲?	SET if endometrial cavity affected during myomectomy
			Hormonal treatments: ⊕	▲?	
			UAE: ⊕	▼▼	
			MRgFUS: ⊕	▼▼	
			RF: ⊕	▼▼	
	Adenomyosis	⊕	GnRH analogs: ⊕	▲?	
			Surgical management: ⊕	▼▼	
	Hyperperistaltism	⊕	Cervical closing: ⊕	▲?	
			Progesterone: ⊕	▲?	

GRADE Score for strength of recommendations:
▲▲ Strong recommendation for using an intervention.
▲? Weak recommendation for using an intervention.
▼? Weak recommendation against using an intervention.
▼▼ Strong recommendation against using an intervention.

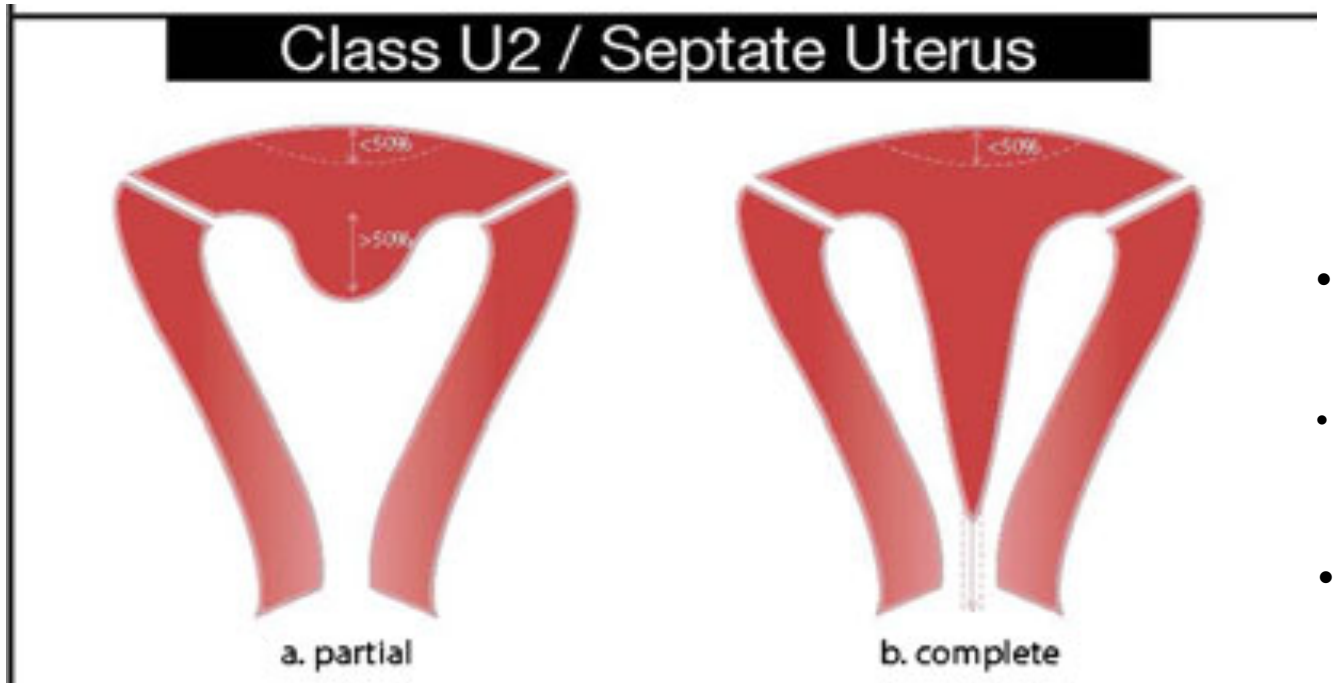
Best Pract Res Clin Obstet Gynaecol. 2016 Jul;34:66-73. doi: 10.1016/j.bpobgyn.2015.12.001. Epub 2015

Infertility and uterine fibroids.

Zepiridis LI[1], Grimbizis GF[1], Tarlatzis BC[2].

TYPE	INDICATION FOR SURGICAL TREATMENT			CURRENT RECOMMENDATIONS
	Impact on reproductive potential	Effectiveness of surgical intervention	Additional indications	
SUBMUCOSAL	Significant impairment	Significant impairment	Abnormal uterine bleeding	Excision : hysteroscopic
INTRAMURAL >4 CM	Significant impairment	Improvement (need further evidence)	Potential pregnancy complications symptoms	Excision : preferably laparoscopic
INTRAMURAL < 4 CM	unclear	unclear	unclear	Expectant management
SUBSEROSAL	Non significant	Non significant	Potential complications	Expectant management

SEPTATE UTERUS AND INFERTILITY



- Miscarriages in the I and II trimesters *
  (Raga, 1997)
- Preterm labor and intrauterine growth retardation
  (Homer, 2000)
- Infertility (?) **
  (Fedele,1993; Pabuccu, 2004)

* increase in intrauterine pressure and a decrease in the volume of the uterine cavity

** structural and ultrastructural endometrial changes and changes in the vascularization at the site of implantation

eshre
Science Moving People Moving Science

ESGE
European Society for Gynaecological Endoscopy

When do we have to treat?

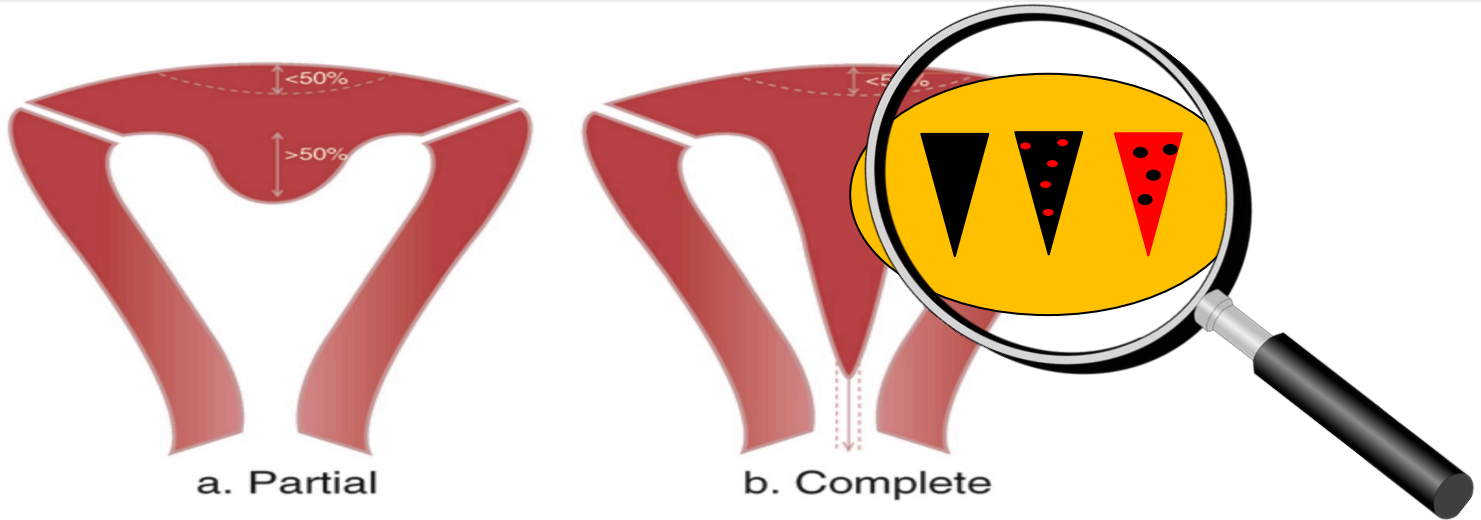
"NOT all the septa are the SAME"

The pathophysiology of septate uterus

BJOG

GF Grimbizis

Department of Obstetrics and Gynaecology, Medical Faculty, Aristotle University of Thessaloniki, Thessaloniki, Greece



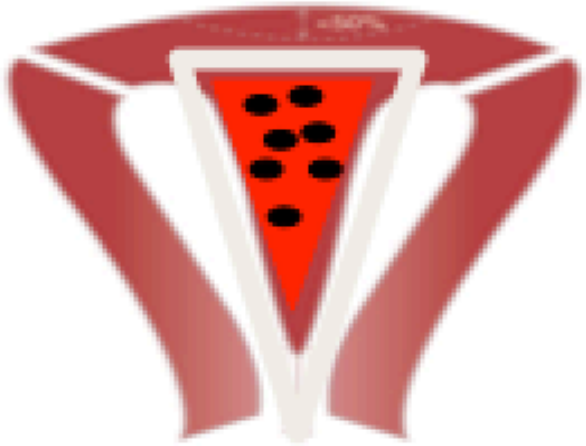
A “PURE” re-absorption defect with normal fusion

Fibrous and Less vascularized

SUBFERTILITY
changes in the overlying endometrium

A “MIXED” re-absorption and obscure fusion defect

More muscular and vascularized



RECURRENT MISCARRIAGES
PRE-TERM BIRTH
Abnormal pattern of muscular architecture and uterine motility

Ultrasound Obstet Gynecol 2011; 38: 371–382
Published online in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/uog.10056

Reproductive outcomes in women with congenital uterine anomalies: a systematic review

Y. Y. CHAN*, K. JAYAPRAKASAN†, A. TAN‡, J. G. THORNTON†, A. COOMARASAMY‡ and N. J. RAINE-FENNING†

**Department of Obstetrics and Gynaecology, Nottingham University Hospitals NHS Trust, Nottingham, UK; †Division of Human Development, School of Clinical Sciences, University of Nottingham, Nottingham, UK; ‡Academic Unit of Obstetrics and Gynaecology, Birmingham Women's Hospital, Birmingham, UK*

Nouri *et al. Reproductive Biology and Endocrinology* 2010, 8:52
http://www.rbej.com/content/8/1/52

REPRODUCTIVE BIOLOGY AND ENDOCRINOLOGY

REVIEW Open Access

Reproductive outcome after hysteroscopic septoplasty in patients with septate uterus - a retrospective cohort study and systematic review of the literature

Kazem Nouri[1], Johannes Ott[1], Johannes C Huber[1], Eva-Maria Fischer[1], Lucija Stögbauer[1] and Clemens B Tempfer*[2]

a. Partial b. Complete

FERTILITY AND STERILITY®
VOL. 73, NO. 1, JANUARY 2000

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MODERN TRENDS

Edward E. Wallach, M.D.
Associate Editor

The septate uterus: a review of management and reproductive outcome

Hayden A. Homer, M.B.B.S., Tin-Chiu Li, M.B.B.S., Ph.D., and Ian D. Cooke, M.B.B.S.

Reproductive Medicine and Surgery Unit, Department of Obstetrics and Gynaecology, Jessop Hospital for Women, Sheffield, Yorkshire, United Kingdom

FERTILITY AND STERILITY®
VOL. 81, NO. 6, JUNE 2004

Published by Elsevier Inc.
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Reproductive outcome after hysteroscopic metroplasty in women with septate uterus and otherwise unexplained infertility

Recai Pabuçcu, M.D.,[a] and Victor Gomel, M.D.[b]

Ankara, Turkey, and Vancouver, British Columbia, Canada

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of hysteroscopic metroplasty of a uterine septum for primary infertility or recurrent miscarriage

Guidance	Recommendations
Clinical guidelines	**Fertility: assessment and treatment for people with fertility problems. NICE guideline CG156 (2013).** There are no recommendations related to hysteroscopic metroplasty in the NICE guideline. The full guideline has the following statement: 'Uterine septum is a congenital anomaly of the female reproductive tract. The incidence is not increased among women with infertility compared with other women (2–3%). It is more common in women who have had recurrent pregnancy loss or preterm birth. Hysteroscopic metroplasty has not been shown to increase pregnancy rates in women with infertility who have a septate uterus. [Evidence level 2b–3]'

Cochrane Library

Cochrane Database of Systematic Reviews

Septum resection for women of reproductive age with a septate uterus (Review)

Rikken JFW, Kowalik CR, Emanuel MH, Mol BWJ, Van der Veen F, van Wely M, Goddijn M

Summary of main results

Consistent with the first issue of the review in 2011, we did not find any RCTs comparing hysteroscopic septum resection with expectant management in women of reproductive age with a uterus in this update.

Ongoing studies

We found two ongoing trials in our search of the WHO ICTRP: the TRUST study, NTR1676, and the Pilot randomised controlled trial of hysteroscopic septal resection (ISRCTN28960271). Results of neither trial have been published.

Voor vragen over inclusie of randomisatie kunt u contact opnemen met Judith Rikken (contactgegevens klik hier)

Study information

TRUST
The Randomised Uterine Septum Transsection Trial

Background
The prevalence of recurrent miscarriage in women with a septate uterus is increased. At present the finding of a septate uterus in women with recurrent miscarriage is not an indication for surgical correction of the septum. The role of hysteroscopic metroplasty in women affected by subfertility is being debated as well.
It is not known whether a septum should be removed in women with subfertility and/or recurrent miscarriage to improve reproductive outcome.

Objective
This study will answer the question whether surgical intervention (hysteroscopic metroplasty) in women with subfertility and/or recurrent miscarriage and a septate uterus will improve their reproductive outcome

Study design
A multi centre randomised controlled trial.

Study population
68 women with recurrent miscarriage (two or more) before 20 weeks of gestational age and/or subfertility with a septate uterus.

Intervention
Random allocation to hysteroscopic metroplasty or no intervention.

News

TRUST
The Randomised Uterine Septum Transsection Trial

August 3th 2017
The 54th patient is included via the Radboud university in Nijmegen! Only 14 to go

TRUST

Inclusies sinds 2009

June 19th 2015

Thee TRUST goes international: soon the Oslo University Hospital (Norway), LIFE Leuven (Belgium) and the Avicenna research institute Teheran (Iran) will be participating. And mean

October 26th 2015

More international centers have agreed to participate in the TRUST trial: Guy's hospital (London, UK), Birmingham women's hospital (Birmingham, UK), East Kent hospital (Kent, UK) and UCLH (London, UK). We are busy arranging all the paperwork.

January 24th 2016

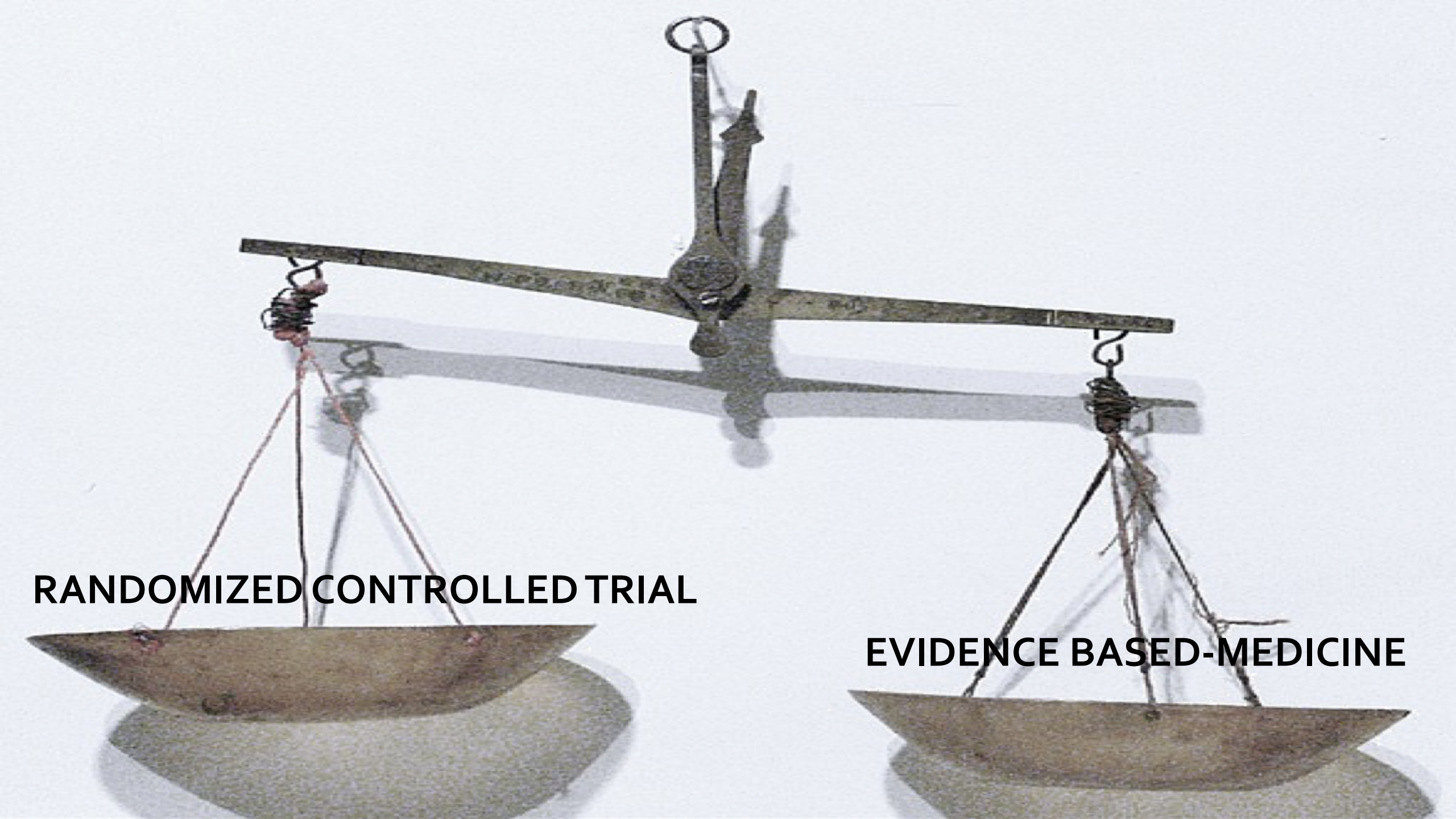
We welcome the University of Illinois (Chicago, USA) as new participating center!

February 17th 2016

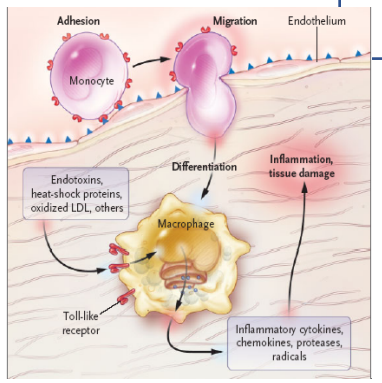
The METC of the AMC has approved the Catharina hospital as new participating center. Let's wait for the first inclusion in Eindhoven!

November 21st 2016

We have obtained ethical approval in the Avicenna hospital in Teheran, Iran!


RANDOMIZED CONTROLLED TRIAL
EVIDENCE BASED-MEDICINE

ISTHMOCELE AND INFERTILITY



Inflammatory process + Presence of blood at the cervix

Alterated cervical mucus

NO PASSAGE of spermatozoa

Blood reflux

Endometritis

NO IMPLANTATION of the embryo

SECONDARY INFERTILITY

2019

Prevalence of Infertility Among Patients With Isthmocele and Fertility Outcome After Isthmocele Surgical Treatment: A Retrospective Study

Stefano Calzolari, MD,[1] Giovanni Sisti, MD,[2] Dora Pavone, MD,[2] Eleonora Ciocia, RM,[1] Natalia Bianchini, RM,[1] Mauro Cozzolino, MD[3]

Table 1. Demographic and Isthmocele Characteristics of the Study Population (n=35)

Variable	Group A – Fertile Patients (Became Pregnant Within 12 Months After Diagnosis of Isthmocele) n=19	Group B – Infertile Patients (Did Not Become Pregnant Within 12 Months After Diagnosis of Isthmocele) n=16	*P* Value
Age, years, mean (range)	35.5 (33-38)	36.5 (35-38)	0.1170
Body mass index, kg/m^2, mean (range)	21.8 (21.5-24.1)	23.2 (22.4-26.2)	0.0001
Isthmocele grade			0.0421
1	12 (63.2)	4 (25.0)	
2	7 (36.8)	10 (62.5)	
3	0	2 (12.5)	
Isthmocele type			0.2809
Superior	14 (73.7)	10 (62.5)	
Middle	5 (26.3)	4 (25.0)	
Inferior	0	2 (12.5)	
Number of c-sections			0.0205
1	19 (100)	12 (75.0)	
2		4 (25.0)	
Cervical dilatation at last c-section			0.7014
<4 cm	15 (78.9)	11 (68.8)	
≥4 cm	4 (21.1)	5 (31.3)	
Presented fetal part at last c-section			0.3707
Vertex	9 (47.4)	10 (62.5)	
Breech	10 (52.6)	6 (37.5)	
Surgical time, minutes, mean (range)	24 (15-32)	23.5 (15-36)	1

Continuous variables were compared by Mann-Whitney *U* test and categorical data compared by chi-square test.
Data are reported as n (%) unless otherwise indicated.

Table 2. Analysis of Fertility Outcome After Isthmocele Hysteroscopic Treatment (n=16)

Variable	Group B1 – Became Pregnant n=9	Group B2 – Did Not Become Pregnant n=7	*P* Value
Age, years, mean (range)	34.5 (33-36)	36.5 (35-38)	0.0151
Body mass index, kg/m^2, mean (range)	22.7 (21.8-23.7)	23.2 (22.4-24.1)	0.1335
Isthmocele grade			0.0361
1	7 (77.8)	1 (14.3)	
2	2 (22.2)	5 (71.4)	
3	0	1 (14.3)	
Isthmocele type			0.4869
Superior	7 (77.8)	5 (71.4)	
Middle	2 (22.2)	1 (14.3)	
Inferior	0	1 (14.3)	
Number of c-sections			0.2416
1	9 (100)	6 (85.7)	
2	0	1 (14.3)	
Cervical dilatation at last c-section			0.0293
<4 cm	9 (100)	4 (57.1)	
≥4 cm	0	3 (42.9)	
Presented fetal part at last c-section			0.0907
Vertex	4 (44.4)	6 (85.7)	
Breech	5 (55.6)	1 (14.3)	
Surgical time, minutes, mean (range)	23.1 (15-32)	23.5 (15-36)	1

Continuous variables were compared by Mann-Whitney *U* test and categorical data compared by chi-square test.
Data are reported as n (%) unless otherwise indicated.

56.3% OF INFERTILE PATIENTS BECAME PREGNANT AFTER THE OPERATION

To conclude …

The UTERUS must be physiologically and anatomically adequate

Meldrum D.R. et al. , Fertil Steril 2016

"The womb is the field of generation; and if this field be corrupted it is in vain to expect any fruit, though it be ever so well sow"

Aristotele
383 a.C. – 322 a.C