



**The dark side of the guidelines**

**2<sup>nd</sup> Interventional Radiologist under 40 Meeting**

*Interventional Oncology*

**8-10 Maggio 2017**

*Bologna*

*Società Medica Chirurgica - Palazzo dell'Archiginnasio*



*Sessione: Apparato Genitale*

# **Embolizzazione Uterina**

**Francesco Giurazza**



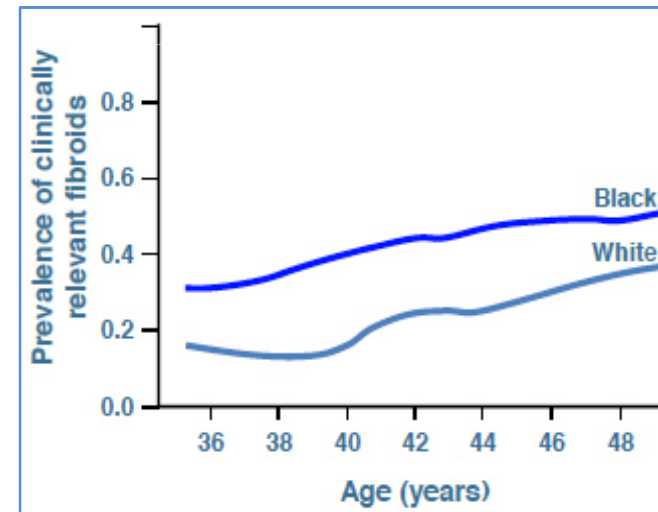
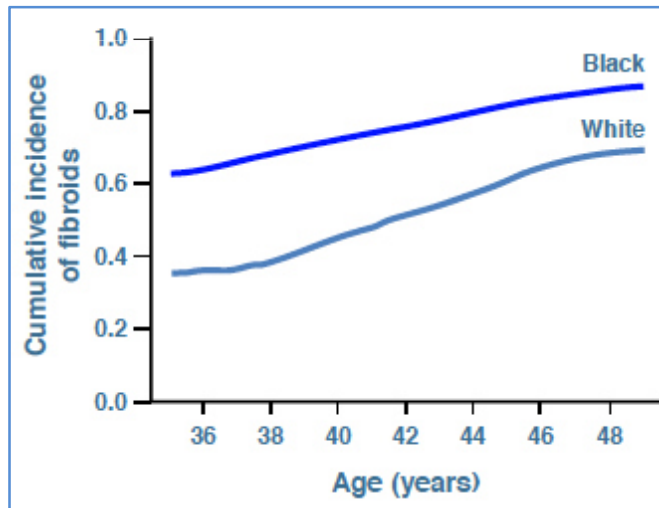
**2<sup>nd</sup> Interventional Radiologist under 40 Meeting**  
*Interventional Oncology*

20-77% delle donne in età fertile affetta

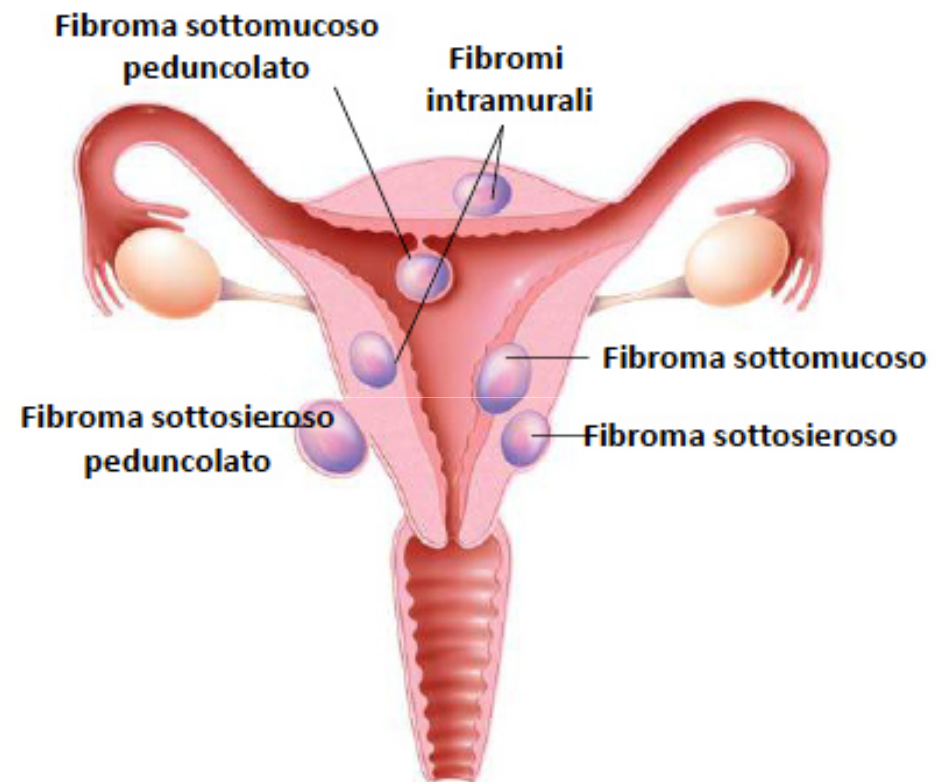
24.000.000 donne in UE

>50% sono asintomatiche

1° causa di isterectomia nel mondo



Day Baird et al. Am J Obstet Gynecol 2003;188:100-107



Viswanathan M et al, *Evidence Report/Technology Assessment* 2007, Nr 14

# THE LANCET

Volume 346, Issue 8976, 9 September 1995, Pages 671-672

THE LANCET

"In combination with the evidence derived from previous studies, results of the STS-2000 trial show that intensive glycaemic management is associated with improved clinical outcomes in intensive glycaemic control."

## Arterial embolisation for uterine myomata

J.H. Ravina (Prof) MD<sup>a</sup>, J. Ciraru-Vigneron MD<sup>a</sup>, J.M. Bouret MD<sup>a</sup>, D. Herbreteau MD<sup>b</sup>, E. Houdart MD<sup>b</sup>, A. Aymard MD<sup>b</sup>, J.J. Merland (Prof) MD<sup>b</sup>

Nel 2014 25.000 UAE/anno





## GENERAL OBSTETRICS AND GYNECOLOGY: GYNECOLOGY

### Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids (EMMY trial): Peri- and postprocedural results from a randomized controlled trial

Wouter J. K. Hehenkamp, MD,<sup>a,\*</sup> Nicole A. Volkers, MD,<sup>b</sup> Peter F. J. Donderwinkel, MD,<sup>c</sup> Sjoerd de Blok, MD, PhD,<sup>e</sup> Erwin Birnie, PhD,<sup>d</sup> Willem M. Ankum, MD, PhD,<sup>a</sup> Jim A. Reekers, MD, PhD<sup>b</sup>

*Department of Gynecology,<sup>a</sup> Department of Radiology,<sup>b</sup> Department of Public Health Epidemiology,<sup>d</sup> Academic Medical Center, Amsterdam, The Netherlands; Department of Gynecology,<sup>c</sup> Martini Hospital, Groningen, The Netherlands; Department of Gynecology,<sup>e</sup> Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands*

Received for publication February 14, 2005; revised March 23, 2005; accepted May 3, 2005

DOI: 10.1111/j.1471-0528.2011.02952.x  
www.bjog.org

## General gynaecology

### Randomised comparison of uterine artery embolisation (UAE) with surgical treatment in patients with symptomatic uterine fibroids (REST trial): 5-year results

JG Moss,<sup>a</sup> KG Cooper,<sup>b</sup> A Khaund,<sup>c</sup> LS Murray,<sup>d</sup> GD Murray,<sup>e</sup> O Wu,<sup>f</sup> LE Craig,<sup>f</sup> MA Lumsden<sup>f</sup>

*<sup>a</sup> North Glasgow University Hospitals, Gartnavel General Hospital, Glasgow <sup>b</sup> Department of Radiology, Aberdeen Royal Infirmary, Foresterhill, Aberdeen <sup>c</sup> Department of Obstetrics and Gynaecology, South Glasgow University Hospitals, Glasgow <sup>d</sup> Vital Statistics, Glasgow <sup>e</sup> Centre for Population Health Sciences, University of Edinburgh Medical School, Teviot Place, Edinburgh <sup>f</sup> Centre for Population and Health Sciences, University of Glasgow, Glasgow, UK  
Correspondence: Prof. JG Moss, North Glasgow University Hospitals, Gartnavel General Hospital, 1053 Great Western Road, Glasgow, G12 0YN, UK. Email jon.moss@ggc.scot.nhs.uk*

Accepted 9 February 2011. Published Online 12 April 2011.

## Prospective Data Collection of a New Procedure by a Specialty Society

### The FIBROID Registry

Obstet Gynecol. 2005 Jul;106(1):44-51.

*Evan R. Myers, MD, MPH, Scott Goodwin, MD, Wendy Landow, MPH, Matthew Mauro, MD, Eric Peterson, MD, MPH, Gaylene Pron, PhD, James B. Spies, MD, and Robert Worthington-Kirsch, MD, for the FIBROID Investigators\**



**SOGC CLINICAL PRACTICE GUIDELINE**

No. 318, February 2015 (Replaces, No. 128, May 2003)

**The Management of Uterine Leiomyomas**



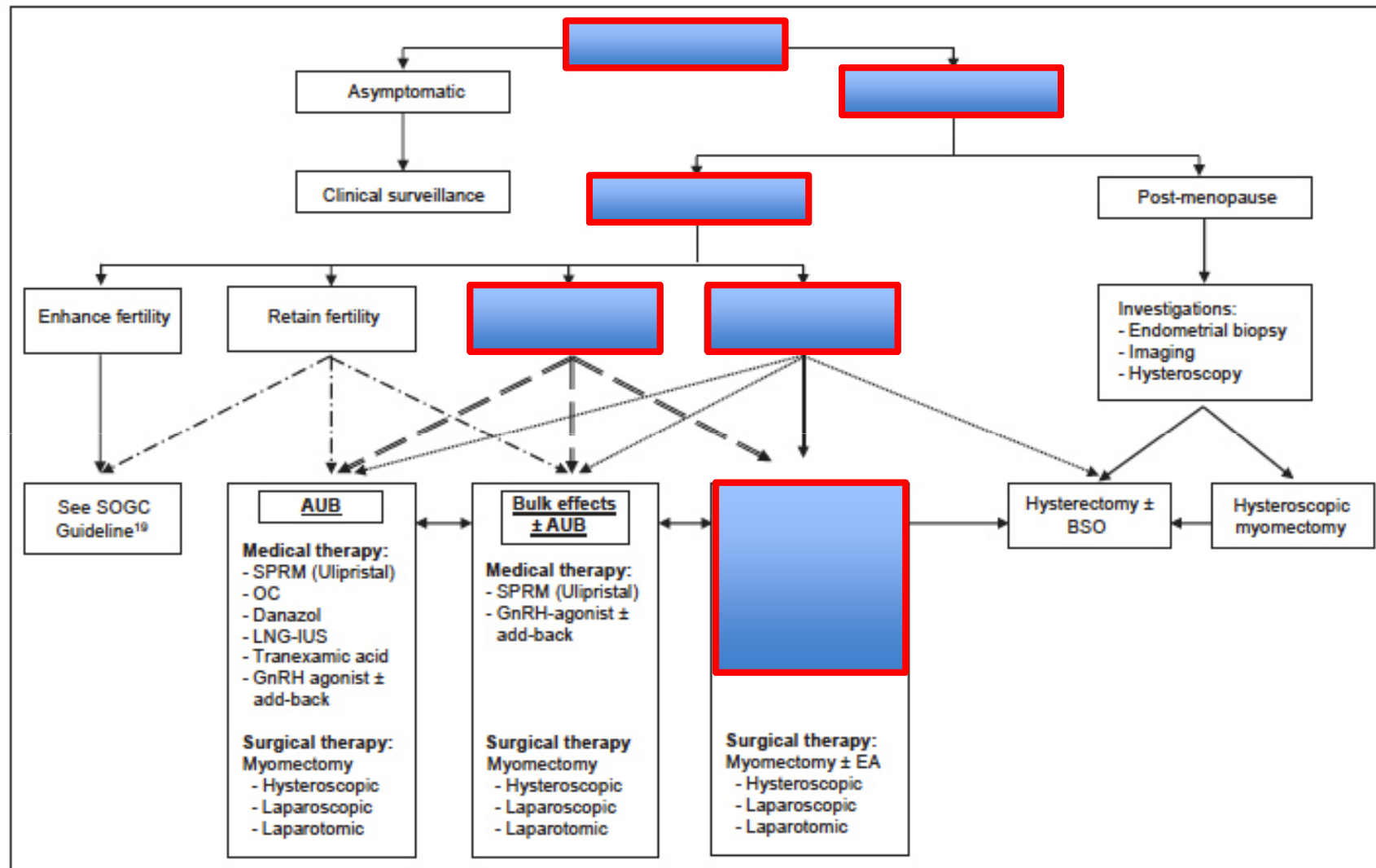
## Summary Statements

1. Uterine fibroids are common, appearing in 70% of women by age 50; the 20% to 50% that are symptomatic have considerable social and economic impact in Canada. (II-3)
2. The presence of uterine fibroids can lead to a variety of clinical challenges. (III)
3. Concern about possible complications related to fibroids in pregnancy is not an indication for myomectomy except in women who have had a previous pregnancy with complications related to these fibroids. (III)
4. Women who have fibroids detected in pregnancy may require additional maternal and fetal surveillance. (II-2)
5. Effective medical treatments for women with abnormal uterine bleeding associated with uterine fibroids include the levonorgestrel intrauterine system, (I) gonadotropin-releasing hormone analogues, (I) selective progesterone receptor modulators, (I) oral contraceptives, (II-2) progestins, (II-2) and danazol. (II-2)
6. Effective medical treatments for women with bulk symptoms associated with fibroids include selective progesterone receptor modulators and gonadotropin-releasing hormone analogues. (I)
7. Hysterectomy is the most effective treatment for symptomatic uterine fibroids. (III)
8. Myomectomy is an option for women who wish to preserve their uterus or enhance fertility, but carries the potential for further intervention. (II-2)
9. Of the conservative interventional treatments currently available, uterine artery embolization has the longest track record and has been shown to be effective in properly selected patients. (II-3)
10. Newer focused energy delivery methods are promising but lack long-term data. (III)
2. Treatment of women with uterine leiomyomas must be individualized based on symptomatology, size and location of fibroids, age, need and desire of the patient to preserve fertility or the uterus, the availability of therapy, and the experience of the therapist. (III-B)
3. In women who do not wish to preserve fertility and/or their uterus and who have been counselled regarding the alternatives and risks, hysterectomy by the least invasive approach possible may be offered as the definitive treatment for symptomatic uterine fibroids and is associated with a high level of satisfaction. (II-2A)
4. Hysteroscopic myomectomy should be considered first-line conservative surgical therapy for the management of symptomatic intracavitary fibroids. (II-3A)
5. Surgical planning for myomectomy should be based on mapping the location, size, and number of fibroids with the help of appropriate imaging. (III-A)
6. When morcellation is necessary to remove the specimen, the patient should be informed about possible risks and complications, including the fact that in rare cases fibroid(s) may contain unexpected malignancy and that laparoscopic power morcellation may spread the cancer, potentially worsening their prognosis. (III-B)
7. Anemia should be corrected prior to proceeding with elective surgery. (II-2A) Selective progesterone receptor modulators and gonadotropin-releasing hormone analogues are effective at correcting anemia and should be considered preoperatively in anemic patients. (I-A)
8. Use of vasopressin, bupivacaine and epinephrine, misoprostol, peri-cervical tourniquet, or gelatin-thrombin matrix reduce blood loss at myomectomy and should be considered. (I-A)
9. Uterine artery occlusion by embolization or surgical methods may be offered to selected women with symptomatic uterine fibroids who wish to preserve their uterus. Women choosing uterine artery occlusion for the treatment of fibroids should be counselled regarding possible risks, including the likelihood that fecundity and pregnancy may be impacted. (II-3A)

## Recommendations

1. Women with asymptomatic fibroids should be reassured that there is no evidence to substantiate major concern about malignancy and that hysterectomy is not indicated. (III-D)

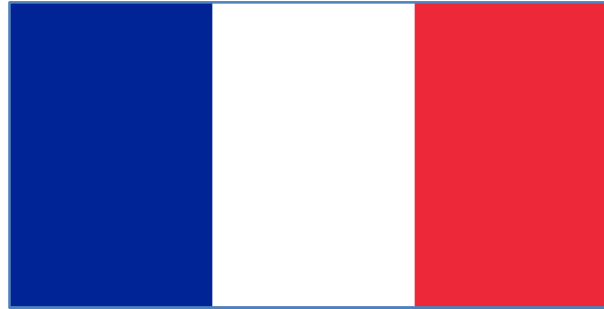
## The dark side of the guidelines



## Recommendation

9. Uterine artery occlusion by embolization or surgical methods may be offered to selected women with symptomatic uterine fibroids who wish to preserve their uterus. Women choosing uterine artery occlusion for the treatment of fibroids should be counselled regarding possible risks, including the likelihood that fecundity and pregnancy outcomes. (II-3A)





European Journal of Obstetrics & Gynecology and Reproductive Biology 165 (2012) 156–164



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## European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: [www.elsevier.com/locate/ejogrb](http://www.elsevier.com/locate/ejogrb)



### Review

## Therapeutic management of uterine fibroid tumors: updated French guidelines

Henri Marret<sup>a,\*</sup>, Xavier Fritel<sup>b</sup>, Lobna Ouldamer<sup>a</sup>, Sofiane Bendifallah<sup>c</sup>, Jean-Luc Brun<sup>d</sup>,  
Isabelle De Jesus<sup>e</sup>, Jean Derrien<sup>f</sup>, Géraldine Giraudet<sup>g</sup>, Vanessa Kahn<sup>h</sup>, Martin Koskas<sup>i</sup>,  
Guillaume Legendre<sup>j</sup>, Jean Philippe Lucot<sup>g</sup>, Julien Niro<sup>k</sup>, Pierre Panel<sup>k</sup>, Jean-Pierre Pelage<sup>l</sup>,  
Hervé Fernandez<sup>c</sup>

For perimenopausal women who have been informed of the alternatives and the risks, hysterectomy is the most effective treatment for symptomatic fibroids and is associated with a high rate of patient satisfaction. When possible, the vaginal or laparoscopic routes should be preferred to laparotomy for hysterectomies for fibroids considered typical on imaging. Because uterine artery embolization is an effective treatment with low long-term morbidity, it is an option for symptomatic fibroids in women who do not want to become pregnant, and a validated alternative to myomectomy and hysterectomy that be offered to patients.

It is therefore possible to conclude that uterine artery embolization is an effective treatment with a low morbidity rate and thus a treatment option for symptomatic fibroids in women who do not want to become pregnant .

In the first place, generally, not enough data are available to enable a guideline to be based on the number or size of fibroids that it is possible to embolize. On the other hand, neither a single submucosal intracavitary fibroid (types 0 and 1) nor a single subserosal pedunculated fibroid (grade C) should be treated by embolization because of the risk of complications.

Uterine artery embolization with non-spherical PVA particles or with tris-acryl microspheres larger than 500  $\mu\text{m}$  provides efficacious short-term treatment of heavy menstrual bleeding, compression symptoms and pelvic pain in 90% of cases (LE1).



## ACR Appropriateness Criteria<sup>®</sup> on Treatment of Uterine Leiomyomas

Charles T. Burke, MD<sup>a</sup>, Brian S. Funaki, MD<sup>b</sup>, Charles E. Ray, Jr, MD<sup>c</sup>,  
Thomas B. Kinney, MD<sup>d</sup>, Jon K. Kostelic, MD<sup>e</sup>, Andrew Loesberg, MD<sup>f</sup>,  
Jonathan M. Lorenz, MD<sup>g</sup>, Steven F. Millward, MD<sup>h</sup>, Albert A. Nemcek, Jr, MD<sup>i</sup>,  
Charles A. Owens, MD<sup>j</sup>, Howard Shaw, MD<sup>k,l</sup>, James E. Silberzweig, MD<sup>m</sup>,  
George Vatakencherry, MD<sup>n</sup>

*J Am Coll Radiol 2011;8:228-234*







## **STANDARDS OF PRACTICE**

# **Quality Improvement Guidelines for Uterine Artery Embolization for Symptomatic Leiomyomata**

Sean R. Dariushnia, MD, Boris Nikolic, MD, MBA, LeAnn S. Stokes, MD, and James B. Spies, MD, MPH,  
for the Society of Interventional Radiology Standards of Practice Committee

*J Vasc Interv Radiol 2014; 25:1737–1747*



### Indications

Patient selection for UAE requires consideration of presenting symptoms, clinical history, physical examination, size number and location of the leiomyomata or other uterine conditions, patient interest in future fertility, and patient preferences. Although each patient's circumstances must be taken into consideration when recommending therapy, practical guidelines can be adopted that allow for an appropriate standard of care to ensure proper patient selection.

UAE is indicated for the treatment of uterine leiomyomata that are causing significant symptoms, occasionally a single symptom, but more commonly a combination of symptoms. The most common of these are:

1. Heavy or prolonged menstrual bleeding;
2. Severe menstrual cramping;
3. Pelvic pressure, discomfort, excessive bloating or fullness, particularly perimenstrual, or bothersome abdominal wall distortion caused by the enlarged uterus;
4. Pelvic pain related to identified leiomyomas, including dyspareunia;
5. Urinary urgency, frequency, nocturia, or retention related to the enlarged leiomyomatous uterus; and
6. Hydronephrosis caused by the enlarged uterus.



Therefore, in the absence of definitive data demonstrating a clear superiority of one treatment over another, and the current literature showing durable improvement in the large majority of patients treated with embolization, uterine embolization should be considered an appropriate option for patients with symptomatic adenomyosis.

Indeed, the early anecdotal concerns regarding the safety and effectiveness of uterine embolization with pedunculated leiomyomas with a narrow attachment has not been borne out in subsequent larger investigations, and symptomatic and safety outcomes are similar to those in patients without this type of leiomyoma. Therefore, this type of leiomyoma should not be considered a contraindication to uterine embolization.

*There is very low-level evidence suggesting that myomectomy may be associated with better fertility outcomes than UAE, but more research is needed.*

Interventional radiologists should inform patients about the risks associated with UAE, including the possibility of a missed diagnosis of cancer and a delay in definitive treatment. A realistic estimate of the frequency of missed malignancy based on the two aforementioned reports should be included in the information provided to patients.

## The dark side of the guidelines

Autore	Anno di pubblicazione	Periodo di Revisione	N. Pazienti	Sarcomi Uterini N (%)	Leiomiomasarcomi N (%)
Leibsohn et al.	1990	1983-1988	1429		
Reiter et al.	1992	1986-1989	104		
Parker et al.	1994	1988-1992	1332		
Takamizawa et al.	1999	1983 - 1997	923		
Sinha et al.	2008	1998-2005	505		
Kamikabeya et al.	2010	1987-2008	1364		
Rowland et al.	2011	2006-2011	1115		
Leung et al.	2012	1996-2005	1297		
Seidman et al.	2012	2005-2010	1091		
<b>Totale</b>			<b>9160</b>		

## Contraindications

The absolute contraindications to UAE are viable pregnancy; active (untreated) infection; and suspected uterine, cervical, or adnexal malignancy (unless the procedure is being performed for palliation or as an adjunct to surgery). The relative contraindications to UAE include coagulopathy, severe contrast medium allergy, and renal impairment, all of which can often be ameliorated. Some of these conditions also substantially increase the risk associated with surgery, and UAE may offer a safer option than surgery in some of these circumstances. Therefore, an individualized decision as to the safest choice of therapy should be reached in consultation with the patient and her gynecologist.



## The dark side of the guidelines



CIRSE

Embolizzazione dei fibromi uterini

Informazioni per il Paziente

**Radiologia Interventistica:  
l'alternativa alla chirurgia**

Organizzazione  
Ufficio centrale CIRSE  
[www.cirse.org](http://www.cirse.org)

Illustrazioni mediche  
Emilie Delattre  
[emide@givolla.fr](mailto:emide@givolla.fr)  
In cooperazione con  
Marc R. Sapoval

Grafica  
LOOP.ENTERPRISES media  
[www.loop-enterprises.com](http://www.loop-enterprises.com)

Traduzione Italiana  
Dott. Walter Lauriola  
[walterlauriola@yahoo.it](mailto:walterlauriola@yahoo.it)

In collaborazione con la  
Sezione di Radiologia Vascolare e Interventistica della  
Società Italiana di Radiologia Medica -SIRM-



[www.cirse.org](http://www.cirse.org)  
[www.uterinefibroids.eu](http://www.uterinefibroids.eu)  
Cardiovascular and Interventional Radiological Society of Europe  
[www.radiointerventistica.org](http://www.radiointerventistica.org)  
Radiologia Vascolare e Interventistica

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Cardiovascular and Interventional  
Radiological Society of Europe  
2011



Cardiovasc Intervent Radiol (2015) 38:536–542  
DOI 10.1007/s00270-014-1031-x

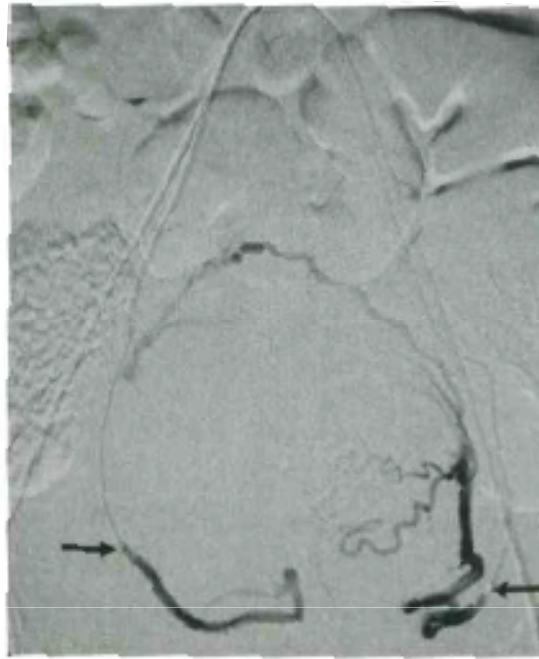


CrossMark

CIRSE STANDARDS OF PRACTICE GUIDELINES

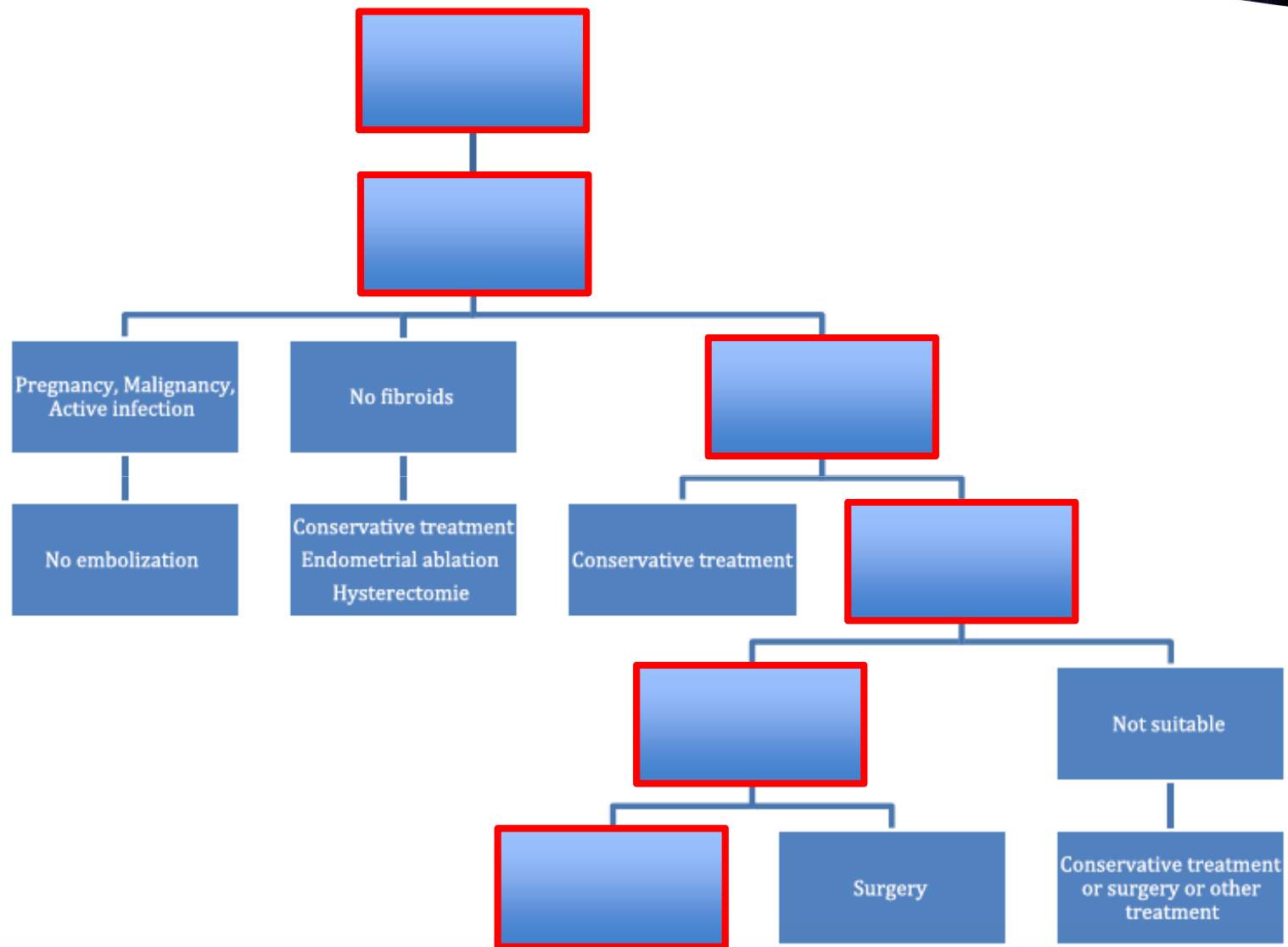
## Uterine Artery Embolization for Symptomatic Leiomyomata

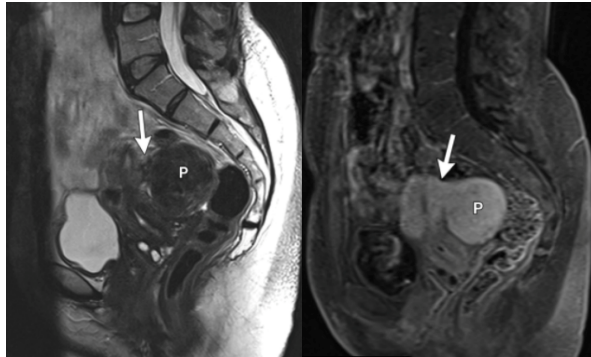
Hans van Overhagen • Jim A. Reekers



**Successo Tecnico:** occlusione/marcata riduzione del flusso ematico in ambo le a. uterine (10bits)

**Successo Clinico:** risoluzione/marcato miglioramento dei sintomi senza terapia aggiuntiva

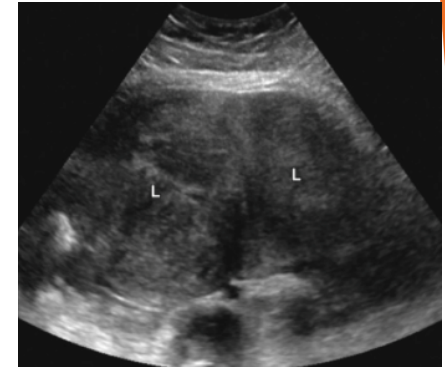




## Imaging Pretrattamento

MRI (con Gd ev) vs US (tp e tv)

?



(Livello 2 EBM)

Selezione Pz per UAE

N° e Sede (vs US tp)

Rapporto con parete (vs US tv)

Riproducibilità interosservatore



## Imaging Pretrattamento

MRI (con Gd ev) per UAE  
(3 piani T1-w & T2-w + Gd ev + MRA)

Dimensioni utero

Dimensioni fibromi

Sede fibromi

Numero fibromi

Peduncolo fibromi

Patologie concomitanti (per es: endometriosi)

Vascolarizzazione fibromi (Gd ev)

Mappa vascolare (3D MRA Gd ev)



## Indicazioni & Controindicazioni

### Indicazioni

#### *Livello EBM 1*

Dolore  
Cicli mestruali copiosi  
Dismenorrea  
Anemia  
Dispareunia

#### *Livello EBM 3*

Effetto massa su vescica o intestino

### Controindicazioni

#### *Absolute*

Stato di gravidanza  
Infezioni uterine  
Neoplasie maligne uterine/ovariche

#### *Relative*

Desiderio di gravidanza  
Fibromi sottosierosi peduncolati  
IUD

Controindicazioni generali per procedure endovasc

Dimensioni >8cm

## Preparazione della Paziente

Visita ginecologica

Colloquio con interventista

Emocromo & coagulazione (spesso Pz anemiche)

Funzione renale ( $\text{eGFR} > 60 \text{ ml/min/1.73m}^2$ )

Rimuovere IUD (infezioni)

## Materiali standard

Introduttore 5Fr  
Catetere 4-5Fr (Cobra, RUC etc.)  
Microcatetere  
Guida .035, .018 e .014  
Agente embolizzante (particelle 350-900 $\mu$  o  
spongo)  
Sistema di chiusura (opzionale)

## Medicazione della Paziente pre

Catetere di Foley

Accesso venoso periferico

Anestesia locale femorale

Profilassi antibiotica (1 gr Cefaz.): non raccomandata di routine

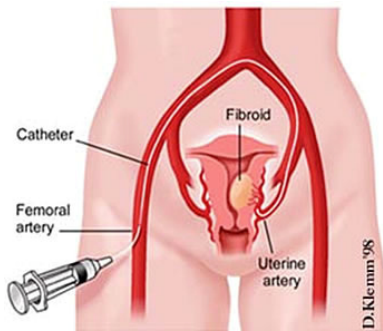
Profilassi nausea: metoclopramide etc.

Protocolli analgesici: sedazione cosciente (5mg midaz./100µg fentanyl), epidurale, anestesia generale



## Procedura

### Accesso femorale



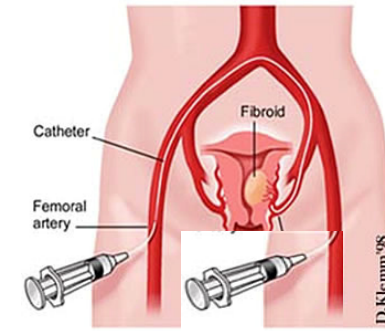
#### Mono

##### *Pro*

Puntura singola

##### *Cons*

> durata scopia  
Cateterismo ipogastrica omolat.



#### Bi

##### *Pro*

< durata scopia  
Cateterismo ipogastrica

##### *Cons*

Puntura doppia

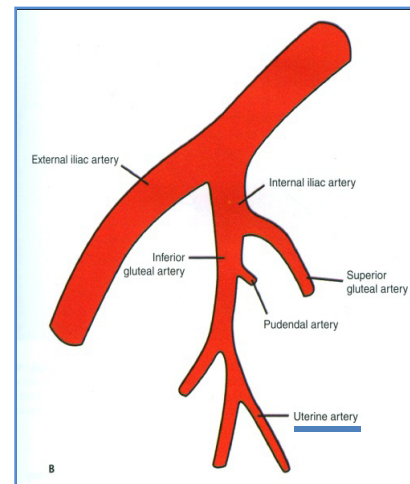
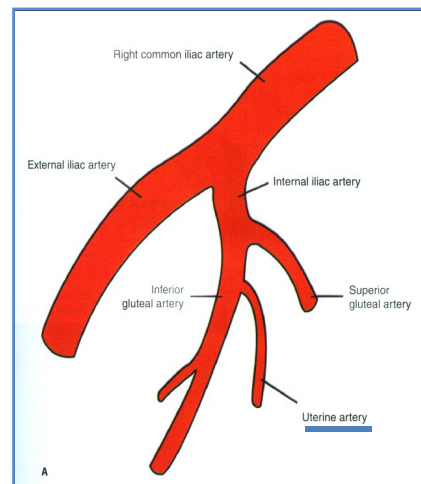
## Procedura

### Cateterismo a. uterina

1° o 2° ramo della divisione anteriore dell'a. ipogastrica

4 Fr – 5 Fr

5Fr + Microcat → < spasmi (Livello 5 EBM)





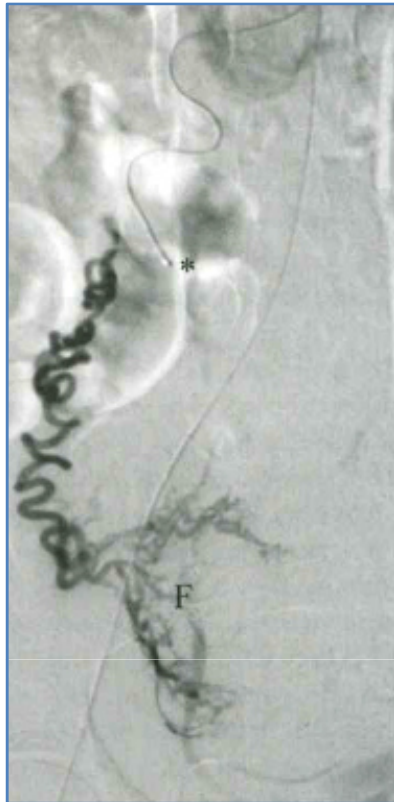
## Procedura

Spasmo a. uterina  
(donne giovani!)

1° causa insuccesso tecnico (embo flusso-guidata!)

Spasmolitici inefficaci

Indietreggiare + Wait & See  
(Livello 5 EBM)



## Procedura

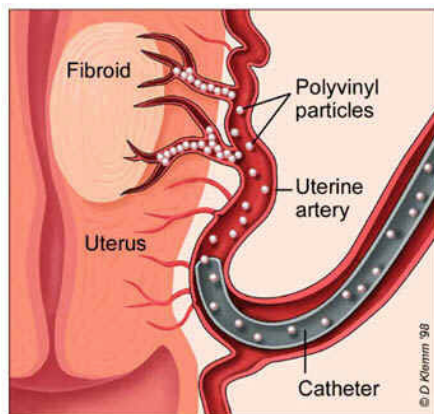
Embolizzazione: estremità del catetere

Back-flow & Collaterali

Evitare rami cervicali per necrosi vaginale

Se rifornimento da a. ovarica >> obbligatorio microcateterismo del fibroma





## Procedura

### Embolizzazione: agenti

Gelfoam, particelle PVA, microsfele PVA, trisacryl gelatina

Nessun evidenza di superiorità

Preferenza dell'operatore

Calibro particelle  $>350-500\mu$  per evitare danni alle ovaie

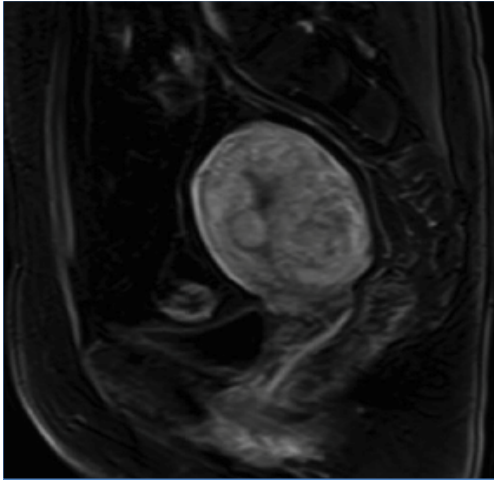


## **Medicazione della Paziente post**

Dolore né prima né durante ma dopo!  
Prime 24h post (picco a 7h)

Protocollo anestesiológico (pompa antalgica)

Antidolorifici orali al bisogno



## Follow-up

PES entro 7gg (non complicanza) >> FANS

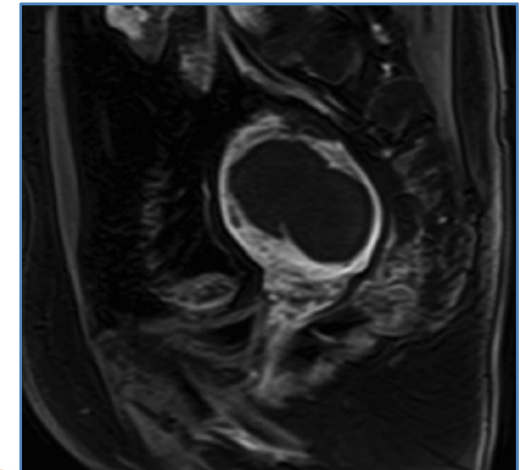
Complicanze entro 7gg (infezioni, necrosi vaginale etc.)

F-up telefonico a 7gg (consigliato)

I° mese: sintomi invariati

Recupero attività: 4-6 settimane

Effetto finale: 6° mese (f-up RM)



## Complicanze

### Maggiori

3 morti in letteratura post UAE

Espulsione transcervicale fibroma 5%

Infezioni 2.5%

TVP/Embolia polmonare <1%

### Minori

Febbre 4%

Insuccesso tecnico 4%

*PES* 3%

Amenorrea transitoria 4%

Amenorrea permanente <2%





## **STANDARDS OF PRACTICE**

# **Radiation Management for Interventions Using Fluoroscopic or Computed Tomographic Guidance during Pregnancy: A Joint Guideline of the Society of Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe with Endorsement by the Canadian Interventional Radiology Association**



## Take Home Points UAE vs Chirurgia (Livello 1 EBM)

Reale alternativa a chirurgia  
in Pz sintomatiche che vogliono preservare utero

QOL a 5aa =

Tasso complicanze =

20% isterectomia

< perdita ematica, ospedalizz, recupero, costi



CIRSE

Grazie

*francescogiurazza@hotmail.it*

