

September 26, 2011

Alexander Corvello, MD
President
Sociedade Brasileira de Radiologia Intervencionista e
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RE: Uterine Artery Embolization

Dear Dr. Corvello:

On behalf of the Society of Interventional Radiology (SIR), I am writing to express our support for your efforts to ensure that patients in Brazil have access to uterine artery embolization (UAE) as a quality treatment choice. We were surprised to hear that a procedure that is an accepted standard of care by interventional radiologists and gynecologists in the United States and other countries has been designated as experimental in Brazil.

SIR is a professional association that represents more than 4,700 physicians and allied health professionals committed to improving the health of the public through pioneering advances in image-guided therapy. Our members are at the forefront of new and minimally invasive therapies to treat an array of diseases and conditions without surgery. Interventional radiology treatments have become first-line care for a wide variety of conditions and patients, including peripheral arterial disease, deep vein thrombosis, osteoporosis patients with spinal fractures, stroke patients, and uterine fibroids. In fact, Interventional Radiologists perform the majority of uterine artery embolization procedures in the United States.

As stated in the *SIR Quality Improvement Guidelines for Uterine Artery Embolization for Symptomatic Leiomyomas*, “Transcatheter embolization of the uterine arteries for treatment of uterine leiomyomas was first reported by Ravina et al in 1995 (1). The procedure was based on established techniques for treating pelvic bleeding related to trauma or obstetrical emergencies, such as postpartum hemorrhage. Goodwin et al (2) reported the first experience in the United States of treating leiomyomas with UAE in 1997. Since those initial reports, UAE has become a widely accepted alternative to hysterectomy and myomectomy, with approximately 25,000 UAE procedures performed annually worldwide (3).”

1. Ravina JH, Herbreteau D, Ciraru-Vigneron N, et al. Arterial embolisation to treat uterine myomata. *Lancet* 1995; 346: 671-672.
2. Goodwin SC, Vedantham S, McLucas B, Forno AE, Perella R. Preliminary experience with uterine artery embolization for uterine fibroids. *J Vasc Interv Radiol* 1997; 8:617 – 526.

3. Goodwin SC, Spies JB, Worthington-Kirsch R, et al. Uterine artery embolization for treatment of leiomyomata: long-term outcomes from the FIBROID registry. *Obstet Gynecol* 2008; 111:22-23.

In August 2008, the American College of Obstetricians and Gynecologists (ACOG) published the *ACOG Practice Bulletin: Alternatives to Hysterectomy in the Management of Leiomyomas*, which states: “Based on long- and short-term outcomes, uterine artery embolization is a safe and effective option for appropriately selected women who wish to retain their uteri.” The Bulletin summarizes level 1 evidence as a basis for this recommendation.

In 2009, *The New England Journal of Medicine* published *Uterine Fibroid Embolization* by Scott Goodwin, MD and James Spies, MD, MPH. This article also summarizes level 1 evidence and states: “The Society of Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe state that uterine artery embolization is indicated for the presence of uterine leiomyomata that are causing significant lifestyle-altering symptoms, specifically mass effect on the bladder or intestines, and/or dysfunctional uterine bleeding that is prolonged, associated with severe dysmenorrhea, or is causing severe anemia.”

Additionally, there is a large volume of peer-reviewed literature illustrating the effectiveness of UAE. The following reference list includes randomized control trials (RCTs) either comparing UAE to surgery or looking at specific aspects of UAE. Please see especially the papers that are highlighted in bold.

1: Goodwin SC, Spies JB. Uterine Fibroid Embolization. N Engl J Med 2009 August 13. 361:7:690-697.

2: Alternatives to Hysterectomy in the Management of Leiomyomas. ACOG Practice Bulletin: Clinical Management Guidelines for Obstetrician-Gynecologists. The American College of Obstetricians and Gynecologists. Number 96, August 2008.

3: Yu SC, Lok I, Ho SS, Tong MM, Hui JW. Comparison of Clinical Outcomes of Tris-acryl Microspheres Versus Polyvinyl Alcohol Microspheres for Uterine Artery Embolization for Leiomyomas: Results of a Randomized Trial. *J Vasc Interv Radiol*. 2011 Sep;22(9):1229-35. Epub 2011 Jul 28. PubMed PMID: 21802314.

4: Worthington-Kirsch RL, Siskin GP, Hegener P, Chesnick R. Comparison of the efficacy of the embolic agents acrylamido polyvinyl alcohol microspheres and tris-acryl gelatin microspheres for uterine artery embolization for leiomyomas: a prospective randomized controlled trial. *Cardiovasc Intervent Radiol*. 2011 Jun;34(3):493-501. Epub 2010 Dec 3. PubMed PMID: 21127866.

5: Bilhim T, Pisco JM, Duarte M, Oliveira AG. Polyvinyl alcohol particle size for uterine artery embolization: a prospective randomized study of initial use of 350-500 µm particles versus initial use of 500-700 µm particles. *J Vasc Interv Radiol*. 2011 Jan;22(1):21-7. Epub 2010 Nov 24. PubMed PMID: 21106390.

6: Miller DL. Re: bilateral versus unilateral femoral access for uterine artery embolization—results of a randomized comparative trial. *J Vasc Interv Radiol*. 2010 Nov;21(11):1773; author reply 1773-4. PubMed PMID: 21029952.

7: van der Kooij SM, Hehenkamp WJ, Volkers NA, Birnie E, Ankum WM, Reekers JA. Uterine artery embolization vs hysterectomy in the treatment of symptomatic uterine

fibroids: 5-year outcome from the randomized EMMY trial. Am J Obstet Gynecol. 2010 Aug;203(2):105.e1-13. Epub 2010 Jul 1. PubMed PMID: 20579960.

8: Ruuskanen A, Hippeläinen M, Sipola P, Manninen H. Uterine artery embolisation versus hysterectomy for leiomyomas: primary and 2-year follow-up results of a randomised prospective clinical trial. Eur Radiol. 2010 Oct;20(10):2524-32. Epub 2010 Jun 6. PubMed PMID: 20526776.

9: Rashid S, Khaund A, Murray LS, Moss JG, Cooper K, Lyons D, Murray GD, Lumsden MA. The effects of uterine artery embolisation and surgical treatment on ovarian function in women with uterine fibroids. BJOG. 2010 Jul;117(8):985-9. Epub 2010 May 11. PubMed PMID: 20465558.

10: Costantino M, Lee J, McCullough M, Nsouli-Maktabi H, Spies JB. Bilateral versus unilateral femoral access for uterine artery embolization: results of a randomized comparative trial. J Vasc Interv Radiol. 2010 Jun;21(6):829-35; quiz 835. Epub 2010 Apr 15. Erratum in: J Vasc Interv Radiol. 2010 Nov;21(11):1786. Nsouli-Maktabi, Hala [corrected to Nsouli-Maktabi, Hala]. PubMed PMID: 20399113.

11: Chrisman HB, Dhand S, Rajeswaran S, Nikolaidis P, Vogelzang RL, Corpuz B, Gilbertson P, Omary RA. Prospective evaluation of the embolic agent bead block in the treatment of uterine leiomyomas with uterine artery embolization: a phase II study. J Vasc Interv Radiol. 2010 Apr;21(4):484-9. Epub 2010 Feb 9. PubMed PMID: 20149690.

12: Hald K, Noreng HJ, Istre O, Kløw NE. Uterine artery embolization versus laparoscopic occlusion of uterine arteries for leiomyomas: long-term results of a randomized comparative trial. J Vasc Interv Radiol. 2009 Oct;20(10):1303-10; quiz 1311. Epub 2009 Aug 26. PubMed PMID: 19713130.

13: Pisco JM, Bilhim T, Duarte M, Ferreira A, Santos D, Pires FM, Oliveira AG. Pelvic pain after uterine artery embolization: a prospective randomized study of polyvinyl alcohol particles mixed with ketoprofen versus bland polyvinyl alcohol particles. J Vasc Interv Radiol. 2008 Nov;19(11):1537-42. Epub 2008 Sep 25. PubMed PMID: 18818095.

14: Volkens NA, Hehenkamp WJ, Smit P, Ankum WM, Reekers JA, Birnie E. Economic evaluation of uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids: results from the randomized EMMY trial. J Vasc Interv Radiol. 2008 Jul;19(7):1007-16; quiz 1017. PubMed PMID: 18589314.

15: Cunningham E, Barreda L, Ngo M, Terasaki K, Munro MG. Uterine artery embolization versus occlusion for uterine leiomyomas: a pilot randomized clinical trial. J Minim Invasive Gynecol. 2008 May-Jun;15(3):301-7. Epub 2008 Mar 20. PubMed PMID: 18439501.

16: Hehenkamp WJ, Volkens NA, Birnie E, Reekers JA, Ankum WM. [Uterine artery embolisation in the treatment of uterine fibroids: outcomes of randomized trials]. Ned Tijdschr Geneesk. 2008 Mar 22;152(12):663-5. Dutch. PubMed PMID: 18438059.

17: Siskin GP, Beck A, Schuster M, Mandato K, Englander M, Herr A. Leiomyoma infarction after uterine artery embolization: a prospective randomized study comparing tris-acryl gelatin

microspheres versus polyvinyl alcohol microspheres. *J Vasc Interv Radiol*. 2008 Jan;19(1):58-65. PubMed PMID: 18192468.

18: Hehenkamp WJ, Volkers NA, Birnie E, Reekers JA, Ankum WM. Symptomatic uterine fibroids: treatment with uterine artery embolization or hysterectomy—results from the randomized clinical Embolisation versus Hysterectomy (EMMY) Trial. *Radiology*. 2008 Mar;246(3):823-32. Epub 2008 Jan 9. PubMed PMID: 18187401.

19: Mara M, Maskova J, Fucikova Z, Kuzel D, Belsan T, Sosna O. Midterm clinical and first reproductive results of a randomized controlled trial comparing uterine fibroid embolization and myomectomy. *Cardiovasc Intervent Radiol*. 2008 Jan-Feb;31(1):73-85. Epub 2007 Oct 18. PubMed PMID: 17943348; PubMed Central PMCID: PMC2700241.

20: Hehenkamp WJ, Volkers NA, Bartholomeus W, de Blok S, Birnie E, Reekers JA, Ankum WM. Sexuality and body image after uterine artery embolization and hysterectomy in the treatment of uterine fibroids: a randomized comparison. *Cardiovasc Intervent Radiol*. 2007 Sep-Oct;30(5):866-75. PubMed PMID: 17671809; PubMed Central PMCID: PMC2039794.

21: Hehenkamp WJ, Volkers NA, Broekmans FJ, de Jong FH, Themmen AP, Birnie E, Reekers JA, Ankum WM. Loss of ovarian reserve after uterine artery embolization: a randomized comparison with hysterectomy. *Hum Reprod*. 2007 Jul;22(7):1996-2005. PubMed PMID: 17582145.

22: Volkers NA, Hehenkamp WJ, Birnie E, Ankum WM, Reekers JA. Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids: 2 years' outcome from the randomized EMMY trial. *Am J Obstet Gynecol*. 2007 Jun;196(6):519.e1-11. PubMed PMID: 17547877.

23: Edwards RD, Moss JG, Lumsden MA, Wu O, Murray LS, Twaddle S, Murray GD; Committee of the Randomized Trial of Embolization versus Surgical Treatment for Fibroids. Uterine-artery embolization versus surgery for symptomatic uterine fibroids. *N Engl J Med*. 2007 Jan 25;356(4):360-70. PubMed PMID: 17251532.

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26: Spies JB. The EMMY trial of uterine artery embolization for the treatment of symptomatic uterine fibroid tumors: randomized, yes, but a flawed trial nonetheless. *J Vasc Interv Radiol*. 2006 Mar;17(3):413-5. PubMed PMID: 16567666.

27: Hehenkamp WJ, Volkers NA, Birnie E, Reekers JA, Ankum WM. Pain and return to daily activities after uterine artery embolization and hysterectomy in the treatment of symptomatic uterine fibroids: results from the randomized EMMY trial. *Cardiovasc Intervent Radiol*. 2006 Mar-Apr;29(2):179-87. PubMed PMID: 16447002.

28: Spies JB, Allison S, Flick P, Cramp M, Bruno J, Jha RC, Ascher SA. Spherical polyvinyl alcohol versus tris-acryl gelatin microspheres for uterine artery embolization for leiomyomas: results of a limited randomized comparative study. J Vasc Interv Radiol. 2005 Nov;16(11):1431-7. PubMed PMID: 16319148.

29: Mara M, Fucikova Z, Maskova J, Kuzel D, Haakova L. Uterine fibroid embolization versus myomectomy in women wishing to preserve fertility: preliminary results of a randomized controlled trial. Eur J Obstet Gynecol Reprod Biol. 2006 Jun 1;126(2):226-33. Epub 2005 Nov 15. PubMed PMID: 16293363.

30: Hehenkamp WJ, Volkers NA, Donderwinkel PF, de Blok S, Birnie E, Ankum WM, Reekers JA. Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids (EMMY trial): peri- and postprocedural results from a randomized controlled trial. Am J Obstet Gynecol. 2005 Nov;193(5):1618-29. PubMed PMID: 16260201.

31: Spies JB, Allison S, Flick P, McCullough M, Sterbis K, Cramp M, Bruno J, Jha R. Polyvinyl alcohol particles and tris-acryl gelatin microspheres for uterine artery embolization for leiomyomas: results of a randomized comparative study. J Vasc Interv Radiol. 2004 Aug;15(8):793-800. PubMed PMID: 15297582.

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34. Stokes LE, Wallace MJ, Godwin RB, Kundu S, Cardella JF. Quality Improvement Guidelines for Uterine Artery Embolization for Symptomatic Leiomyomas. J Vasc Interv Radiol 2010; 21:1153-1163.

In summary, it is SIR's position that UAE is an accepted standard of care and an effective alternative to hysterectomy and myomectomy. If we can provide any additional information or if you would like to discuss our comments in more detail, please do not hesitate to contact me at tmurphy@lifespan.org or Tricia McClenny at tricia@sirweb.org.

Sincerely,



Timothy Murphy, MD, FSIR
President

cc: Marshal Hicks, MD
Scott Goodwin, MD
James Spies, MD, MPH
Sue Holzer

Attachments