

Initial U.S. Experience with Embosphere® Microspheres for Embolization of Uterine Leiomyomata

Category: UAE Outcomes

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Purpose: To determine the effectiveness and safety of Embosphere® Microspheres for embolization of uterine leiomyomata.

Methods: As part of an FDA-Approved phase 1 trial, 28 patients underwent uterine artery embolization with Embosphere® Microspheres (BioSphere Medical, Rockland, MA), which are microspheres of a trisacryl polymer matrix embedded with gelatin. To assess outcome and symptom status, a variety of measures were used, including a validated menorrhagia questionnaire, a pictorial blood loss assessment chart, and the SF-12 (a 12-question validated questionnaire based on the SF-36). The same measures were used at baseline and three months post-procedure. Imaging was obtained at baseline and three months post-procedure with either ultrasound or magnetic resonance. Procedure-related data was recorded prospectively, including all complications.

Results: The average age of the patients was 43.3 (range 34-50). Twenty-four of 28 patients presented with heavy menstrual bleeding, 20 had pelvic pain or pressure and 1 presented with only urinary symptoms. Mean uterine volume prior to treatment was 645 cc and mean dominant fibroid volume was 307 cc. All procedures were technically successful, with a mean procedure time of 87.4 minutes. There were 8 minor complications, with drug reaction the most common (n=5). There was one hematoma that required three weeks to resolve. There were no cases of uterine injury or infection. Three-month follow-up was available on 10 patients, with menstrual bleeding improved in 8 of 9. Pelvic pain and pressure was improved or resolved in 8 of 9. Imaging follow-up was available in 9 patients with a mean decrease of dominant fibroid volume of 31%.

Conclusions: The initial experience with Embosphere® Microspheres suggests that they are effective in treating leiomyomata, controlling symptoms and reducing fibroid volume. Additional patient data is needed to establish their effectiveness and safety and to determine the durability of symptom control.