CLINICAL STUDY

Comparison of Polyvinyl Alcohol Microspheres and Tris-Acryl Gelatin Microspheres for Uterine Fibroid Embolization: Results of a Single-Center Randomized Study

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ABSTRACT

Purpose: To assess the efficacy of two embolic agents in the treatment of symptomatic uterine leiomyomas.

Materials and Methods: A randomized, prospective, single-center study enrolled 60 women with symptomatic uterine leiomyomas. Uterine artery embolization (UAE) with spherical polyvinyl alcohol (SPVA) microspheres (n = 30; 700–900 μm and 900–1,200 μm; near-stasis or stasis endpoint) and tris-acryl gelatin (TAG) microspheres (n = 30; 500–700 μm; "pruned-tree" endpoint) was performed. Infarction rates were calculated for the dominant tumor and for small (< 2 cm) and large (> 2 cm) nondominant tumors. The primary endpoint was tumor infarction at 24 hours measured by contrast-enhanced magnetic resonance imaging assessed by a blinded reviewer.

Results: Baseline characteristics were similar between groups. The primary endpoint was similar in both treatments (≥ 91% dominant tumor infarction; SPVA. 86.2%; TAG, 93.3%, $P = .35$). Complete infarction (100%) was also similar between arms at 24 hours and 3 months. Symptom severity was reduced and quality of life improved equally at 3 and 12 months in each treatment group. Complications were minor in both groups.

Conclusions: Uterine leiomyoma infarction at 24 hours and 3 months after treatment with SPVA or TAG microspheres was comparable when using near-stasis as a procedural endpoint with SPVA microspheres. Symptom relief was maintained for as long as 12 months for both embolic agents.

ABBREVIATIONS

FDA = Food and Drug Administration, SPVA = spherical polyvinyl alcohol, TAG = tris-acryl gelatin, UAE = uterine artery embolization, UFS-QoL = Uterine Fibroid–Specific Quality of Life

Uterine artery embolization (UAE), also known as uterine fibroid embolization, significantly improves the symptoms associated with uterine fibroid disease (1–3). Overall, the procedure has a very high success rate in treating the symptoms from uterine leiomyomas, with a significant improvement in quality-of-life outcomes in addition to a low complication rate (1–3). Although UAE is effective, patients undergoing UAE do have a higher need for additional procedures (1,4). The need for additional procedures ranges between 5% to 17%

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of patients but depends on the length of time after embolization (1). The durability of the procedure is presumably dependent on the degree of tumor infarction after embolization (5). Initially, irregularly shaped polyvinyl alcohol (PVA) particles were used, but other embolic agents have been developed with a spherical shape to make administration easier. PVA, as opposed to spherical embolic particles, may clump and clog microcatheters (6). The first microspheres, made of tris-acryl gelatin (TAG), were approved for UAE by the United States Food and Drug Administration (FDA) after comparison versus hysterectomy in the treatment of fibroid disease (7). Spherical PVA (SPVA) microspheres were initially investigated in a porcine model (8). After a clinical trial in UAE that used 500–700-μm particles, SPVA was also approved by the FDA based on outcomes compared with those of myomectomy (9).

After FDA approval, some studies suggested that the 500–700-μm SPVA microspheres did not devascularize the leiomyomas as well as TAG microspheres (10,11). Animal research suggested that a larger size of SPVA microspheres was needed to obtain the same level of occlusion achieved with the use of TAG microspheres, possibly because of greater deformation secondary to differences in compressibility (12,13). Further clinical investigation suggested that a larger size of SPVA microspheres, 700–900 μm, was needed to obtain the same degree of infarction as seen with the use of TAG microspheres (14). In addition, although clinical outcome may represent an adequate choice of endpoint after tumor embolization, the degree of infarction by contrast-enhanced magnetic resonance (MR) imaging may be better to gauge the success of an embolic agent in its ability to produce a more durable clinical outcome (5,15). The purpose of the present study was to perform a randomized trial of patients with symptomatic fibroid disease to compare the degree of tumor infarction between SPVA and TAG microspheres.

MATERIALS AND METHODS

This was a prospective, randomized, single-center, single-blind, parallel-group, noninferiority study registered on the National Institutes of Health Web site (www.clinicaltrials.gov) under identifier NCT00628901. The study was funded by Boston Scientific (Natick, Massachusetts). Institutional review board approval was obtained, and the protocol and consent forms were consistent with US FDA Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance, the Declaration of Helsinki, the International Conference on Harmonisation, and all local regulations as appropriate. Follow-up office visits and contrast-enhanced MR imaging evaluation occurred at 24 hours and 3 months after the procedure. A further follow-up office visit was conducted at 1 year after treatment.

Patients were enrolled at a single center from February 2006 to December 2009. Long-term follow-up of patients was completed in November 2010. A series of consecutive patients undergoing UAE for symptomatic leiomyomas that met the study criteria were approached for consent. All investigators were interventional radiologists. Included in the study were adult women (ie, age $>$ 18 y) with symptoms warranting invasive treatment who were willing to complete the follow-up requirements and sign an informed consent form. Symptoms attributed to leiomyomas included abnormal menstrual bleeding, infertility, pelvic pain, and pressure-related symptoms. Exclusion criteria were active pelvic inflammatory disease or infection, malignancy of the pelvic region, endometrial neoplasia or hyperplasia, presence of one or more submucosal fibroid tumors with more than 50% growth into the uterine cavity, presence of a pedunculated serosal leiomyoma as the dominant tumor, leiomyomas with significant collateral feeding by vessels other than the uterine arteries, presence of arteries supplying the tumor that were not large enough to accept 700–900-μm or 900–1200-μm microspheres (ie, smaller than a microcatheter), coagulopathy, atypical anatomy that would not allow for bilateral UAE, known severe contrast agent allergy, and known moderate to severe renal disease (creatinine level $>$ 2 mg/dL). On the day of the procedure, subjects were randomly assigned by computer program (at a 1:1 ratio) to receive SPVA (Contour SE microspheres; Boston Scientific; 700–900 μm and/or 900–1,200 μm) or TAG microspheres (Embosphere microspheres; BioSphere, Rockland, Massachusetts; 500–700 μm). To determine treatment allocation of each subject, the investigator opened a sealed envelope containing the type of embolic particle to be used. An equal number of envelopes were available, and future allocations were concealed from the investigators. The subject remained blinded to treatment throughout the study. Thirty patients were randomized to each group.

The stasis endpoint for SPVA microsphere UAE was complete or near-stasis of the main uterine artery. To confirm that complete or near-stasis was achieved, the uterine artery was visualized under fluoroscopy for five cardiac beats after contrast medium injection, indicating minimal antegrade flow. The embolization endpoint was again confirmed after 5 minutes with an injection of contrast medium. Additional SPVA microspheres were administered if flow restoration resulting from redistribution was identified with this contrast medium injection.

The stasis endpoint for TAG group was a "pruned-tree" appearance of the uterine artery. Specifically, embolization was stopped when the vasculature surrounding the leiomyoma could no longer be visualized but before complete stasis in the uterine artery. Additional embolization to the extent of stasis was performed if there was any uncertainty of adequacy of the embolization of the uterine vessels. After five bottles of the 500–700-μm particles, if the endpoint had not been

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