Safety and Efficacy of HydroPearl Microspheres in Uterine Artery Embolization for the Treatment of Symptomatic Uterine Fibroids

Matthew A. Patetta, Ari J. Isaacson, Jessica K. Stewart

Division of Vascular and Interventional Radiology, Department of Radiology, University of North Carolina

Purpose

- The purpose of this retrospective study is to investigate the safety and efficacy of using HydroPearl Microspheres for UAE for the treatment of symptomatic uterine fibroids.

Background

- UAE is a minimally invasive procedure that can treat symptomatic uterine leiomyomata, also known as uterine fibroids (1).
- This procedure involves the administration of embolic agents (such as gelfoam, non-spherical polyvinyl alcohol, or spherical embolization particles) into the bilateral uterine arteries to deprive the uterine fibroids of their blood supply, resulting in necrosis and shrinkage of the uterine fibroids (1, 2).
- The HydroPearl Microsphere (Terumo Medical, Inc) is a tightly calibrated spherical embolic agent composed of polyethylene glycol that is FDA approved for UAE and other embolization procedures.

Methods

Subjects:

- This retrospective chart review investigated 21 patients who underwent a UAE procedure and had documented follow-up at University of North Carolina Medical Center from May 1, 2018 through December 31, 2019.

Follow-up:

- Of the 21 patients, 18 had a documented 3-month or later post-procedure follow-up note recorded in the electronic medical record. Patients without at least 3-month follow-up were excluded.
- Average time between the UAE procedure and the latest clinical note available was 145 days (4.8 months).
- The provider documented the discussion in the electronic medical record, including whether they had experienced any complications and whether their bulk and/or menorrhagia symptoms improved.
- Bulk symptoms were defined as the patient reporting abdominal pain, pelvic fullness, constipation and/or urinary symptoms.

Patient Demographics

Table 1: Characteristics and clinical outcomes of patients who underwent UAE for the treatment of symptomatic uterine fibroids with HydroPearl Microspheres.

Patient Number	Age	Race	Parity	BMI	Number of Fibroids	Max size of dominant fibroid (cm)	Improvement in Menorrhagia	Improvement in Bulk Symptoms	Complications
1	54	NH-W	3	26.6	1	8.4	Yes	Yes	Amenorrhea
2	54	NH-B	0	27.5	>6	8.4	Yes	-	
3	49	NH-W	unknown	24.2	2	9	Yes	Yes	Amenorrhea
4	31	NH-B	1	42.0	4	5.5	Yes	Yes	
5	47	NH-B	2	30.7	1	3.6	No	-	
6	44	NH-B	3	43.4	4	3.1	No	No	
7	38	NH-W	0	31.7	1	8.8	Yes	Yes	
8	39	NH-B	4	28.3	>6	3	Yes	-	
9	43	NH-B	1	22.4	>6	10.1	Yes	Yes	
10	47	NH-W	3	35.0	1	4	Yes	-	Amenorrhea
11	53	NH-B	1	28.3	>6	6.3	Yes	-	Amenorrhea
12	54	NH-B	0	40.2	>6	9.8	-	Yes	
13	47	NH-B	0	24.3	>6	6.6	Yes	Yes	
14	41	NH-B	0	55.3	1	8.5	No	Yes	
15	42	NH-B	1	43.3	1	10.9	-	Yes	
16	43	NH-B	2	65.5	1	8.3	Yes	Yes	
17	42	NH-B	0	45.3	>6	9.6	Yes	Yes	
18	47	American Indian	2	22.0	>6	11.8	Yes	Yes	

Max size of dominant fibroid was the maximum dimension in centimeters reported for the largest fibroid on the pre-procedural MRI report. Bulk symptoms include pelvic fullness, pelvic heaviness, pelvic pain, constipation, dyspareunia, and urinary symptoms.

BMI: body mass index. NH-W: Non-Hispanic White. NH-B: Non-Hispanic Black

Procedure

Uterine Artery Embolization Procedure:

- Access was first gained from the left radial artery for the UAE procedure. A 5 French vertebral catheter was then advanced over a wire to just above the aortic bifurcation.
- For pain control, a superior hypogastric nerve block containing of 20mL of 0.5% bupivacaine, 40mg triamcinolone, and approximately 7mL of contrast was then administered under fluoroscopic guidance.
- Uterine artery embolization was performed by advancing the 5 French vertebral catheter and a 2.8 French microcatheter into the uterine artery to the distal horizontal segment,
- Embolization was completed to achieve an endpoint of 3-5 beat stasis utilizing 600, 800, and/or 1100um HydroPearl particles.
- After successful embolization of this artery, this process was repeated on the contralateral uterine artery.

Results

Improvement in Menorrhagia:

- 16 patients initially presented with symptoms of menorrhagia.
- Following the UAE, 13 patients (81.3%) reported improvement with their bleeding symptoms, at an average of 4.8 months after the procedure.

Improvement in Bulk:

- 13 patients initially presented with bulk symptoms.
- Following the procedure, 12 patients (92.3%) reported improvement with these symptoms (average of 4.8 months post-procedure).

Comparison to Other Embolic Agents:

- Clinical improvement of symptoms using Hydropearl particles is similar to that reported in the literature
- Per the literature, improvement in menorrhagia and bulk symptoms at 6-months post-UAE using other embolic agents:
  - 85.7% and 75.6% for polyvinyl alcohol with or without Gelfoam (3)
  - 84.0% and 96.4% for polyphosphazene- coated hydrogel microspheres (Embozene, Varian Medical, Palo Alto, CA) (4)
  - 89.6% and 86.4% for tris-acryl gelatin spheres (Embospheres and Embogold, Merit Medical, South Jordan, UT) (5,6)

Complications:

- The only noted complication related to the procedure is that the embolization may have caused amenorrhea in 4/18 patients (22.2%).
  - Average age of these 4 patients was 51 years old
  - Amenorrhea is a known complication of UAE, particularly for older patients, and is likely non-specific to the use of the HydroPearl Microsphere.

Conclusions

- HydroPearl Microsphere particles appear to be a safe embolic agent for UAE for the treatment of symptomatic uterine fibroids.
- Treatment response for menorrhagia and bulk symptoms are largely similar to success rates reported in the literature for other embolic agents.

References

1. Spencer EB, Stratil P, Mizones H. Clinical and periprocedural pain management for uterine artery embolization. Semin Intervent Radiol. 2013 Dec;30(4):354-63. PubMed PMID: 24436562. Pubmed Central PMCID: PMC3835579.
2. Kohi MP, Spies JB. Updates on Uterine Artery Embolization. Semin Intervent Radiol. 2018 Mar;35(1):48-55. PubMed PMID: 29628616. Pubmed Central PMCID: PMC5886769.
3. Salehi M, Jalilian N, Salehi A, Ayazi M. Clinical Efficacy and Complications of Uterine Artery Embolization in Symptomatic Uterine Fibroids. Glob J Health Sci. 2015 Dec 18;8(7):245-50. PubMed PMID: 26925914. Pubmed Central PMCID: PMC4965640. Epub 2015/01/01.
4. Stampfl U, Radeleff B, Sommer C, Stampfl S, Dahlke A, Bellemann N, et al. Midterm results of uterine artery embolization using narrow-size calibrated embozene microspheres. Cardiovasc Intervent Radiol. 2011;34(2):295-305.
5. Joffre F, Tubiana JM, Pelage JP, Groupe F. FEMIC (Fibromes Embolises aux MICrospheres calibrees): uterine fibroid embolization using tris-acryl microspheres. A French multicenter study. Cardiovasc Intervent Radiol. 2004;27(6):600-6.
6. Lohle PN, Boekkooi FP, Smeets AJ, Pieters JJ, Vervest HA, Lampmann LE, et al. Limited uterine artery embolization for leiomyomas with tris-acryl gelatin microspheres: 1-year follow-up. J Vasc Interv Radiol. 2006;17(2 Pt 1):283-7.