

Uterine Artery Embolization using Biodegradable Echogenic Microspheres – A Prospective Study

Richard J Owen MD, Bilal Ahmed MD, Vimal Patel MD, Christopher I Fung MD, Joanne Mcgoey RN - Department of Radiology and Diagnostic Imaging, University of Alberta Hospital, Canada.

Purpose

- To assess safety and effectiveness of uterine artery embolization using biodegradable, echogenic, embolic microspheres in uterine artery embolization.

Materials and Methods

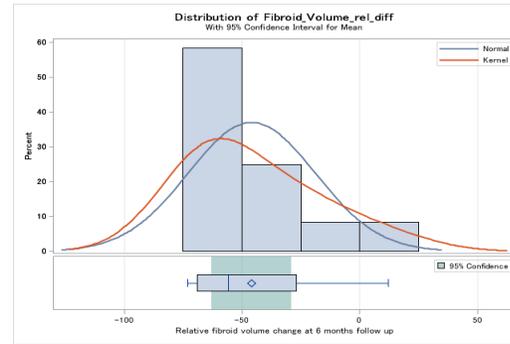
- Twelve women with symptomatic uterine fibroids were treated using biodegradable, echogenic microspheres comprising polylactide-co-glycolide (PLGA) coated with collagen. (Ekobi[®] microspheres, IM biotechnologies, Suite 216 9650 20 Av NW, Edmonton)
- Microspheres were suspended to iso-buoyancy in Omnipaque 240 and delivered to the uterine vasculature to a near stasis endpoint.
- Subjects assessed pre procedure, at 1-week, 1-month, and 6-months post-embolization with quality of life scores, MRI, adverse events and serology

Results

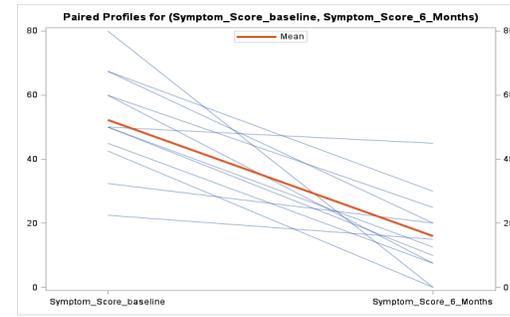
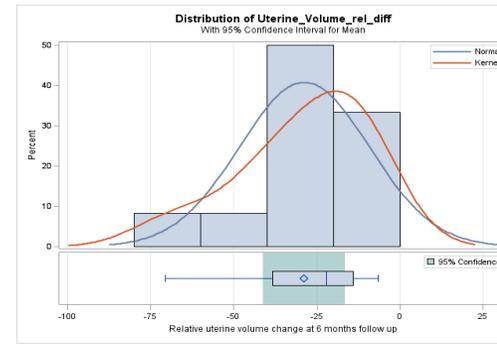
- Mean decrease in fibroid volume on MRI relative to baseline was $45.9 \pm 26.9\%$ ($p=0.0015$) at 6-month follow up (primary endpoint).
- Mean decrease in uterine volume on MRI relative to baseline was $28.8\% \pm 19.6\%$ ($p = 0.0005$) at 6-month follow up.
- Mean symptom scores as determined by UFS-QoL improved at 6-months post-embolization relative to baseline by $36.3 \pm 20.7\%$ ($p = 0.0005$).
- Quality of life scores as determined by UFS-QoL improved at 6 months post-embolization relative to baseline by $43.7 \pm 26.4\%$ ($p = 0.0001$).
- No adverse events were attributed to the administration of the study device. All subjects reported low to moderate pain scores 1-week post-embolization (range on a 10-point scale = 0.5 to 4.5; median = 2.0).
- There were no clinically significant findings in vital signs, physical examination, or clinical laboratory assessments in any of the patients. One subject showed an increase in FSH and LH hormone levels 1-month post-embolization with return of her menstrual cycle at 5 weeks post-treatment followed by menopause.
- The microspheres were detectable using B-mode ultrasound and confirmed localization of the microspheres in the target tissue, with no indication of the product traveling to non-target locations.

Conclusions

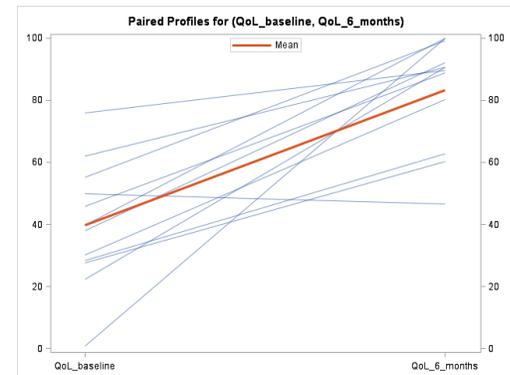
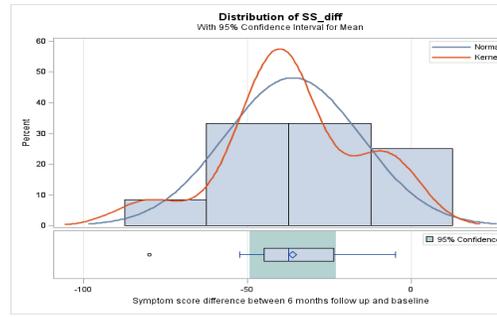
- Treatment of symptomatic uterine fibroid patients with biodegradable, echogenic microspheres resulted in a statistically significant decrease in fibroid volume, uterine volume, symptom scores, and quality of life scores at 6-months post-embolization.



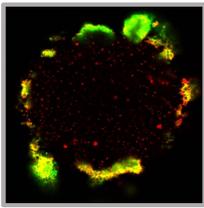
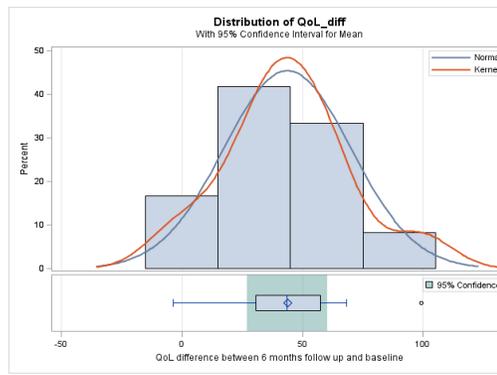
Fibroid and Uterine volumes at 6 months c/w baseline



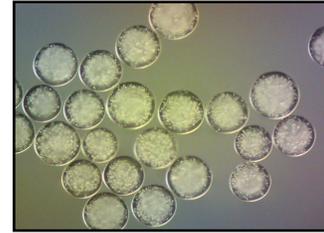
Symptom score c/w baseline, paired profiles and boxplot



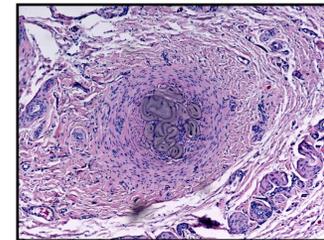
QoL score at 6 months c/w baseline, paired profiles and boxplot



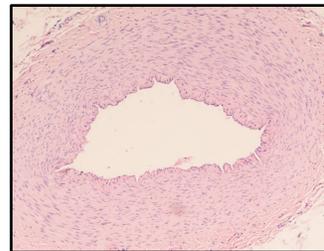
Particle with adherent platelets



Appearance of particles at microscopy



3 Months post embolization In vivo study*



12 Months post embolization In vivo study*