Uterine fibroid embolization complications in the scientific literature and the FDA's MAUDE database

J Seibel-Seamon, A Ness, J Goldberg (Jefferson Medical College
Department of Obstetrics and Gynecology, Philadelphia, PA)

Objective: The objective of this study was to compare reported complications or adverse events following uterine fibroid embolization (UFE) in the scientific literature and in the US Food and Drug Administration (FDA) and User Facility Device Experience (MAUDE) database.

Methods: MEDLINE and the FDA's MAUDE database were searched for complications following UFE between 1995 and 2004. Types of complications from these two resources were categorized into nine categories. For comparison between types of complications reported in MEDLINE and the MAUDE database, Chi square and Fisher's exact test were used.

Results: A total of 216 individual complications following UFE were identified in the MAUDE database and 747 from review of the literature. The distribution of the individual complications over all categories was significantly different between the two groups ($p < .0001$). In the MAUDE database only 13.4% of reported complications were considered major, rather than minor, compared with 29.3% in the literature ($p < .0001$). The categories containing the most major complications were need for surgery, nonu-target embolization, infection, and vascular injury/bleeding.

Conclusion: The types of complications following UFE reported in the FDA's MAUDE database do not correlate with those reported in the scientific literature. A larger percentage of complications reported in the literature were considered major, rather than minor, compared to the MAUDE database.