Uterine Fibroid Embolization Complications in the Scientific Literature and the FDA's MAUDE Database

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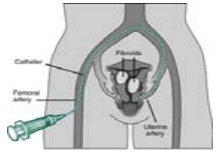

Abstract

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 747 individual complications following UFE were identified from review of the literature and 216 complications were identified in the MAUDE database. 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, non-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.

Background

- Originally described as a primary treatment for uterine fibroids in 1995, uterine fibroid embolization (UFE) is an increasingly popular, minimally invasive therapy for uterine fibroids, with over 50,000 patients treated.
- Compared to hysterectomy and myomectomy, UFE has been reported to have an overall lower rate of complications.
- The US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database serves as a publicly accessible collection of voluntarily reported adverse events related to medical devices and procedures (www.fda.gov/cdr/maude.html).
- To date, there has been no comparison between the complications cited in the medical literature and those reported in the MAUDE database following UFE.

Materials & Methods

- Medline was searched from 1995 to 2004 using the keyword "uterine artery embolization" and "uterine fibroid fibroid embolization". All complications identified were included in our study.
- Using the same keywords, we searched the US Food and Drug Administration (FDA) MAUDE database from 1995 to 2004.
- We grouped complications into 9 categories. These results were further divided into major and minor complications (Table 1).
- Complications reported in the literature and MAUDE database were compared using Chi-square and Fisher's exact test.

Table 1.

	MAUDE			Literature			
Complications	**Total %**	**Major**	**Minor**	**Total %**	**Major**	**Minor**	**P value**
General	36.6	1	78	50.5	4	373	0.0004
Failure / Need for Surgery	15.3	0	33	23.4	105	70	0.014
Non-Target Embolization	5.1	11	0	7.0	52	0	0.411
Bleeding / Vascular	18.5	2	38	6.7	11	39	<0.0001
Fibroid Expulsion	2.8	0	6	5.8	9	34	0.114
Infection	5.6	9	3	3.1	23	0	0.132
Miscellaneous	1.9	1	3	1.7	8	5	0.5
GU / GI	5.1	1	10	1.1	3	5	0.0005
Neuro / Psych	9.3	3	16	0.8	4	2	<0.0001
Total		29	187		219	528	<0.0001

Results

- We identified 747 complications following UFE in the scientific literature and 216 in the MAUDE database.
- Complications following UFE were identified in 94 / 253 studies found in the literature, with many reporting > 1 complication.
- In the literature, 29.3% of complications following UFE were major and 70.7% were minor.
- In the MAUDE database, 13.4% of complications were major and 86.6% were minor.
- Major complications were significantly more frequent in the literature compared to the MAUDE database ($p < 0.0001$).
- The largest category of complications reported in both the literature and the MAUDE database was the General category (post-embolization syndrome, fatigue, cramping, vaginal discharge, rash). The majority of General complications were minor.
- Complications listed in the MAUDE database, but not the literature, included alopecia, acne flare, myocardial infarction, pseudoaneurysm, depression, pityriasis rosea, and bone pain.
- Overall distribution of all complications was significantly different between the literature and the MAUDE database ($p < 0.0001$).

Conclusions

- **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 those in the MAUDE database.**

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