

Morbidity, Vascular Events, and Interventional Therapy for Fibromuscular Dysplasia: A Report of the United States Registry for Fibromuscular Dysplasia

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Abstract

Background: The natural history of fibromuscular dysplasia (FMD) has not been clearly described. **Methods:** Vascular events, revascularization procedures, and outcomes are reported for the first 339 patients enrolled in the United States FMD Registry from 7 clinical centers. **Results:** 91.1% of patient were female (mean age at diagnosis 51.9 ± 13.6 years). Hypertension occurred in 73.2% (mean age of onset 43.4 ± 14.8 years). Headaches were common (62.6%) and daily in 15.1%. The prevalence of vascular events is shown in the tables, including cerebrovascular events, arterial dissection, and aneurysm. No deaths were reported during median follow-up from date of diagnosis of 21.1 months. Half of the patients (171/339) underwent at least one therapeutic vascular procedure. An endovascular approach occurred in the majority of procedures [balloon angioplasty alone (54.3%) or with stenting (21.3%), arterial bypass surgery (8.8%), other (7.9%)]. The most common target arteries were renal artery (73.2%), extracranial carotid (12.8%), celiac/mesenteric (5.2%), and intracranial cerebral (2.1%). The most frequent procedural indications were hypertension, dissection, and aneurysm. Procedural success was reported in 82% of procedures with symptomatic improvement in 48.5% and complication(s) in 9.8% of procedures. **Conclusions:** FMD is a morbid condition but mortality was low in the early period of follow up. Dissection, TIA, or stroke occur frequently and dissections and aneurysms may involve multiple vascular beds. Half of the patients in the registry required invasive therapeutic procedures with a high technical success rate.

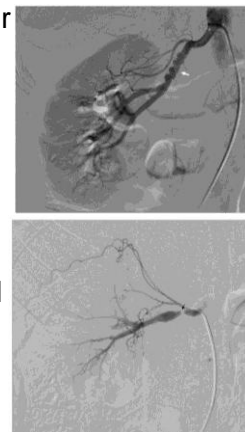
Conflict of Interest Disclosure

Sponsor: Fibromuscular Dysplasia Study of America, a non-profit organization.

Disclosure: Drs. Gornik and Olin are volunteer medical advisory board members to the FMDSA. Ms. Pamela Mace is a paid employee of FMDSA.

Fibromuscular Dysplasia (FMD)

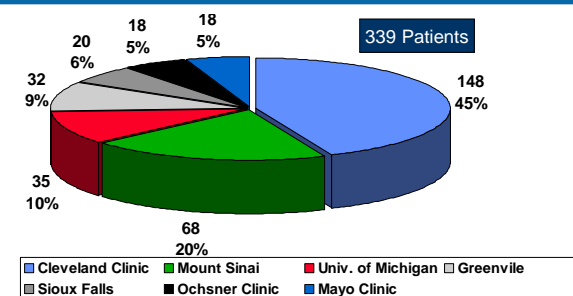
- Non-inflammatory artery disorder first described in 1938.
- Uncommon condition, but true prevalence unknown with minimal prospective research over past 50 years.
- Reported throughout the circulation with renal and carotid arteries as most common sites.
- May lead to arterial narrowing, dissection, or aneurysm



Methods

- Multi-center registry of FMD patients formed 2008.
- 7 U.S. clinical centers.
- Michigan Cardiovascular Outcomes Research and Reporting Program (M-CORRP) coordinating center.
- Standardized data collection form completed for each FMD patient enrolled.
- Standardized follow-up data form for each subsequent patient contact.
- On-line data entry environment (Drupal) into MySQL database maintained by M-CORRP.

Patient Enrollment by Center



Results

Table 1: Patient Demographics and Comorbidities

Age at diagnosis (mean ± SD)	55.7 ± 13.2 years
Female (%)	91.1%
White	95.7%
Hypertension	73.2%
Age at onset	43.4 ± 14.8 years range 4-79 yrs
Median # anti-HTNsives	2 [IQR 1-3 medications]
Significant headache	62.6%
Occurs weekly	13.6%
Occurs daily	15.1%
Migraine type	33.5%
Requires suppressive rx	13.9%

Table 2: Prevalence of Major Vascular Events at Time of Enrollment

Cerebrovascular	Any coronary artery disease
TIA or stroke	20.7%
Hemispheric TIA	14.5%
Stroke	10.3%
Amaurosis fugax	5.6%
Subarachnoid hemorrhage	1.5%
Myocardial infarction	3.5%
Coronary revascularization	1.8%

Renal	
Renal failure	1.2%
Renal infarction	1.2%
Venous thrombosis	3.8%

Death 0*
*Zero deaths in registry cohort at median 21.1 months follow-up from initial enrollment for 108 patients with follow-up data available

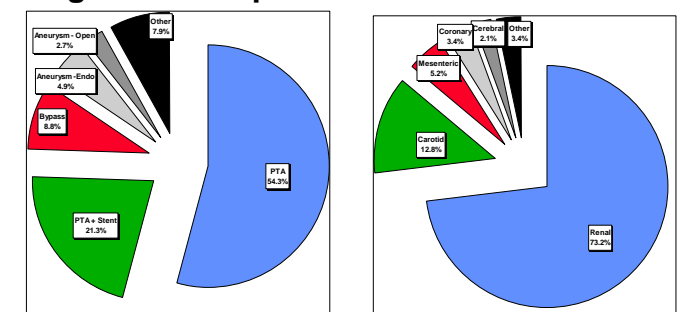
Results

Table 3: Prevalence and Distribution of Arterial Dissection and Aneurysm

Any arterial dissection	19.2%
<u>Frequent locations</u>	
Carotid artery	14.2%
Renal artery	3.5%
Vertebral artery	3.0%
Mesenteric artery	1.2%
Coronary artery	0.9%
Other	1.2%
Any aneurysm	17.1%
<u>Frequent locations</u>	
Renal artery	5.3%
Carotid artery	3.8%
Aorta	3.5%
Celiac artery	2.7%
Cerebral arteries	2.4%
Mesenteric	1.2%

Other aneurysm sites (<1%): basilar, vertebral, subclavian, popliteal arteries

Figure: Therapeutic Vascular Procedures



- 328 procedures reported in 171/339 (50.4%) of patients
- Mean 1.9 ± 1.6 procedures per patient (range 1-12) among those who underwent at least 1 procedure
- Procedural outcomes:
 - Technical success 82.0%
 - Symptomatic improvement 48.5%
 - Procedural complication 9.8%

Conclusions

- FMD associated with high prevalence of hypertension, significant headaches, major cerebrovascular events, and arterial dissection