

# **EXHIBIT 15**

Declaration of Rachel Clattenburg  
*Public Citizen v. FDA et al.*, 16-cv-781

**Harvard Medical School/Harvard School of Dental Medicine  
Format for the Curriculum Vitae**

**Date Prepared:** October 22, 2014

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**Place of Birth:** (b) (6)

**Education**

1980	B.S., Cum Laude	Biology	Dickinson College
1985	D.O., Honors	Osteopathic Medicine	Kirksville College of Osteopathic Medicine
July- November, 2010	Graduate, General Management Program; Alumnus, Harvard Business School	Business, General Management	Harvard Business School
2013	Honorary Doctorate of Arts		Harvard Medical School

**Postdoctoral Training**

7/1985- 6/1986	Internship	Rotating Medicine/Surgery	Flint Osteopathic Hospital (Currently Genesys Regional Medical Center)
7/1986- 6/1989	Resident	Internal Medicine	Cleveland Clinic Foundation
7/1989- 6/1990	Chief Resident	Internal Medicine	Cleveland Clinic Foundation
7/1991- 6/1992	Fellow	Vascular Medicine	Cleveland Clinic Foundation

**Faculty Academic Appointments**

7/1989 – 6/1990	Clinical Instructor	Medicine	Milton S. Hershey College of Medicine
7/1990- 6/1993	Assistant Professor	Medicine	Milton S. Hershey College of Medicine

## **Report of Clinical Activities and Innovations**

### **Current Licensure and Certification**

2013 Medical License, Commonwealth of Massachusetts

### **Practice Activities**

2004- Present Clinical Consultant in Vascular Medicine Massachusetts General Hospital, Boston, MA Full Time

## **Report of Education of Patients and Service to the Community**

### **Activities**

2003-2012 Vascular Disease Foundation and Peripheral Artery Disease Coalition—Board Member: Aid in development of patient materials for peripheral artery disease and other vascular disorders.

2011-Present Steering Committee, American Heart Association Heart Ball, Boston, Massachusetts

2013-Present Fibromuscular Dysplasia Society of America---Board Member

### **Recognition**

2007 Master, Society for Vascular Medicine Society for Vascular Medicine

2008 Honorary Doctorate of Science A.T. Still University

2010 Leader in Vascular Education Vascular Interventional Advance 2012

2012 Charles Tegtmeier, MD Award International Symposium on Endovascular Therapy

## **Report of Scholarship**

### **Publications**

#### **Peer reviewed publications in print or other media**

1. Abbate SL, **Jaff MR**, Fishleder AJ, Meeker DP. Lambda Light Chain Myeloma with Pleural Involvement. *Cleve Clin J Med* 1991; 58:235-239.
2. **Jaff MR**, Olin JW, Young JR. Failure of Acute-Phase Reactants to aid in the Diagnosis of Takayasu's Arteritis. *J. Vasc Med Biol.* 1993; 4:223-227.
3. **Jaff MR**, Medical Aspects of Pregnancy. *Cleve Clinic J Med* 1994; 61:263-271.
4. **Jaff MR**, Dorros G, Kumar K, Caballero G, Tector A. Percutaneous Endovascular Repair of an Ascending Aorta-to-Left Common Femoral Artery Graft With Aneurysmal Degeneration. *J Endovasc Surgery* 1995; 2:189-195.

137. Laird JR, Yeo KK, Rocha-Singh K, Das T, Joye J, Dippel E, Reddy B, Botti C, **Jaff MR**. Excimer laser with adjunctive balloon angioplasty and heparin coated self expanding stent grafts for the treatment of femoropopliteal artery in-stent restenosis: twelve month results from the SALVAGE trial. *Catheter Cardiovasc Intervent* 2012; 80:852-9.
138. Rocha-Singh KJ, **Jaff MR**, Joye J, Laird J, Ansel G, Schneider P. Major adverse limb events and wound healing following infrapopliteal artery stent implantation in patients with critical limb ischemia: The XCELL trial. *Catheter Cardiovasc Intervent* 2012.
139. Duval S, Massaro JM, **Jaff MR**, Boden WE, Alberts MJ, Califf RM, Eagle KA, D'Agostino RB, Pedley A, Fonarow GC, Murabito JM, Steg PG, Bhatt DL, Hirsch AT. An evidence-based score to detect prevalent peripheral artery disease (PAD). *Vascular Medicine* 2012;17:342-51.
140. White CJ, **Jaff MR**. Catch-22: Carotid stenting is safe and effective (Food and Drug Administration) but is it reasonable and necessary (Centers for Medicare and Medicaid Services)? *J Am Coll Cardiol Interv* 2012;5:694-6.
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142. Rogers JH, Goldstein I, Kandzari DE, Kohler TS, Stinis CT, Wagner PJ, Popma JJ, **Jaff MR**, Rocha-Singh KJ. Zotarolimus-eluting peripheral stents for the treatment of erectile dysfunction in subjects with suboptimal response to phosphodiesterase-5 inhibitors. *J Am Coll Cardiol* 2012;60:2618-27.
143. Touboul PJ, Hennerici MG, Meairs S, Adams H, Amarenco P, Bornstein N, Csiba L, Desvarieux M, Ebrahim S, Hernandez Hernandez R, **Jaff MR**, Kownator S, Naqvi T, Prati P, Rundek T, Schminke U, Tardif JC, Taylor A, Vicaut E, Woo KS. Mannheim Carotid Intima-Media Thickness and Plaque Consensus (2004-2006-2011). *Cerebrovasc Dis* 2012;34:290-6.
144. Weinberg I, Giri J, Calfon MA, Hawkins BM, Weinberg MD, Margey R, Hannon K, Schainfeld RM, **Jaff MR**. Anatomic correlates of supra-normal ankle brachial indices. *Catheter Cardiovasc Intervent* 2012 August 17.
145. (b) (4), **Jaff MR**, (b) (4) Accepted for publication.  
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146. Misra S, Lookstein R, Rundback J, Ahrar K, Conte M, Geraghty P, Hiatt W, Hirsch A, **Jaff MR**, Patel M, Rosenfield K, White C. Proceedings from the Society for Interventional Radiology Research Consensus Panel on Critical Limb Ischemia. *J Vasc Intervent Radiol* 2013;24:451-8.

147. Vedantham S, Goldhaber SZ, Kahn SR, Julian J, Magnuson E, **Jaff MR**, Murphy TP, Cohen DJ, Comerota AJ, Gornik HL, Razavi MK, Lewis L, Kearon C. Rationale and design of the ATTRACT study: a multicenter randomized trial to evaluate pharmacomechanical catheter-directed thrombolysis for the prevention of post-thrombotic syndrome in patients with proximal deep vein thrombosis. *Am H Journal* 2013;165:523-530.
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149. Rooke TW, Hirsch AT, Misra S, Sidawy AN, Beckman JA, Findeiss L, Golzarian J, Gornik HL, Halperin JL, **Jaff MR**, Moneta GL, Olin JW, Stanley JC, White CJ, White JV, Zierler GE. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA Guidelines Recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2013;61(14):1555-70.
150. Maas MB, **Jaff MR**, Rordorf G. Risk Adjustment for Case Mix and the Effect of Surgeon on Morbidity. *JAMA Surg* 2013; Feb 20: 1-5.
151. Weinberg I, Kaufman J, **Jaff MR**. Inferior vena cava filters. *J Am Coll Cardiol Intervent* 2013;6:539-47.
152. Chi YW, Schul M, Gibson K, Rosenblatt M, Kabnick L, **Jaff MR**. Chronic venous disorder registry: a new perspective. *Phlebology* 2013.
153. Tierney ESS, Gal D, Gavreau K, Baker A, Trevey S, O'Neill S, **Jaff MR**, de Ferranti S, Fulton DR, Colan SD, Newburger JD. Vascular Health in Kawasaki Disease. *J Am Coll Cardiol* 2013;62:1114-21.
154. Dake MD, Ansel GM, **Jaff MR**, Ohki T, Saxon RR, Smouse HB, Snyder SA, O'Leary EE, Tepe G, Scheinert D, Zeller T. Sustained safety and effectiveness of paclitaxel-eluting stents for femoropopliteal lesions: two-year follow up from the Zilver PTX randomized and single-arm clinical studies. *J Am Coll Cardiol* 2013;61:2417-27.
155. Kim ES, Olin JW, Froehlich JB, Gu X, Bacharach JM, Gray BH, **Jaff MR**, Katzen BT, Kline-Rogers E, Mace PD, Matsumoto AH, McBane RD, White CJ, Gornik HL. Clinical manifestations of fibromuscular dysplasia vary by patient sex: a report of the United States Registry for FMD. *J Am Coll Cardiol* 2013; 62:2026-8.
156. Kabrhel C, **Jaff MR**, Channick R, Baker J, Rosenfield K. A multidisciplinary pulmonary embolism response team. *Chest* 2013;144:1738-9.
157. Romero JM, Pizzolata R, Atkinson W, Meader A, Lamuraglia G, **Jaff MR**, Buonanno F, Almandoz JD, Gonzalez G. Vasa vasorum enhancement on CT angiography correlates with symptomatic patients with 50-70% internal carotid artery stenosis. *Stroke* 2013;44:3344-9.

158. Keo HH, Duval S, Baumgartner I, Oldenburg NC, **Jaff MR**, Goldman J, Peacock JM, Tretinyak AS, Henry TD, Luepker RV, Hirsch AT. The Freedom from Ischemic Events—New Dimensions for Survival (FRIENDS) Registry: design of a prospective cohort study of patients with advanced peripheral artery disease. *BMC Cardiovascular Disorders* 2013;13:120-9.
159. Giri J, Yeh RW, Kennedy KF, Hawkins BM, Weinberg I, Weinberg MD, Parikh SA, Garasic J, **Jaff MR**, White CJ, Rosenfield K. Unprotected carotid artery stenting in modern practice. *Catheter Cardiovasc Interv*. 2014;83:595-602.
160. Del Conde I, Galin ID, Trost B, Jang J, Lookstein R, Woodward M, Gustavson S, Cambria RP, **Jaff MR**, Olin JW. Renal artery duplex ultrasound criteria for the detection of significant in-stent restenosis. *Catheter Cardiovasc Intervent* 2014;83:612-8.
161. Weinberg I, Keyes MJ, Giri J, Rogers KR, Olin JW, White CJ, **Jaff MR**. Blood pressure response to renal artery stenting in 901 patients from 5 prospective multicenter FDA-approved trials. *Catheter Cardiovasc Intervent* 2014;83:603-9.
162. Weinberg I, Gona P, O'Donnell CJ, **Jaff MR**, Murabito JM. The systolic blood pressure difference between arms: distribution, risk factor correlates, and prospective associations with cardiovascular disease in the Framingham Heart Study. *Am J Med* 2014;127:209-15.
163. Cooper CJ, Murphy TP, Cutlip DE, Jamerson K, Henrich W, Reid DM, Cohen DJ, Matsumoto AH, Steffes M, **Jaff MR**, Prince MR, Lewis EF, Tuttle KR, Shapiro JJ, Rundback JH, Massaro JM, D'Agostino RB, Dworkin LD. Stenting and medical therapy for atherosclerotic renal-artery stenosis. *N Engl J Med* 2014;370:13-22.
164. Weinberg I, Abtahian F, DeBiasi R, Cefalo P, MacKay C, Hawkins BM, **Jaff MR**. Effect of delayed inferior vena cava filter retrieval after early initiation of anticoagulation. *Am H Journal* 2014.113:389-94.
165. Provias T, Dudzinski D, **Jaff MR**, Rosenfield K, Channick R, Baker J, Weinberg I, Donaldson C, Narayan R, Rassi AN, Kabrhel C. The Massachusetts General Hospital Pulmonary Embolism Response Team (MGH PERT): Creation of a multidisciplinary program to improve care of patients with massive and submassive pulmonary embolism. *Hosp Prac* 2014;42:31-7.
166. Weinberg I, **Jaff MR**. Accelerated thrombolysis for pulmonary embolism: will clinical benefit be ULTIMATEly realized? *Circulation* 2014; 129:420-1.
167. Rocha Singh KJ, Zeller T, **Jaff MR**. Peripheral arterial calcification: prevalence, mechanism, detection and clinical implications. *Catheter Cardiovasc Intervent* 2014;Jan 8: epub ahead of print.

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Accepted for publication. (b) (4)
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Accepted for publication. (b) (4)
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171. Klein AJ, Pinto DS, Gray BH, **Jaff MR,** White CJ, Drachman DE. SCAI Expert consensus statement for femoropopliteal arterial intervention appropriate use. *Catheter Cardiovasc Intervent* 2014 Apr 17.
172. Laird JR, Jain A, Zeller T, Feldman R, Scheinert D, Popma JJ, Armstrong EJ, **Jaff MR.** Nitinol stent implantation in the superficial femoral and proximal popliteal artery: 12-month results from the COMPLETE SE multicenter trial. *J Endovasc Ther* 2014 Apr 21.
173. Pietzsch JB, Geisler BP, Garner AM, Zeller T, **Jaff MR.** Economic analysis of endovascular interventions for femoropopliteal arterial disease: a systematic review and budget impact model for the United States and Germany. *Catheter Cardiovasc Intervent* 2014 Apr 30.
174. Chrysant GS, Bates MC, Sullivan TM, Bachinsky WB, Popma JJ, Peng L, Omran H, **Jaff MR.** Proper patient selection yields significant and sustained reduction in systolic blood pressure following renal artery stenting in patients with uncontrolled hypertension: long-term results from the HERCULES trial. *J Clin Hypertens* 2014; June 7: epub ahead of print.
175. Chatterjee S, Chakraborty A, Weinberg I, Kadakia M, Wilensky RL, Sardar P, Kumbhani DJ, Mukherjee D, **Jaff MR,** Giri J. Thrombolysis for pulmonary embolism and risk of all-cause mortality, major bleeding, and intracranial hemorrhage. A meta-analysis. *JAMA* 2014;311:2414-21.
176. Gray BH, **Jaff MR,** White CJ. Introduction to appropriate use for peripheral intervention articles: expert consensus documents from the Society for Cardiovascular Angiography and Interventions. *Catheter Cardiovasc Intervent* 2014; April 30: epub ahead of print.
177. (b) (4) **Jaff MR,** (b) (4)  
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179. (b) (4) Jaff MR,  
(b) (4). Accepted for publication. (b) (4).
180. Gulur P, Williams L, Chaudhary S, Koury K, **Jaff MR**. Opioid tolerance: a predictor of length of stay and higher readmission rates. *Pain Physician* 2014;17:e503-7.
181. Zimmet SE, Min RJ, Comerota AJ, Meissner MH, Carman TL, Rathbun SW, **Jaff MR**, Wakefield TW, Feied CF. Core content for training in venous and lymphatic medicine. *Phlebology* 2014; July 24. Epub ahead of print.
182. Gray BH, Diaz-Sandoval L, Dieter RS, **Jaff MR**, White CJ. SCAI expert consensus statement for infrapopliteal arterial intervention appropriate use. *Catheter Cardiovasc Intervent* 2014;July 18.
183. Hara T, Truelove J, Tawakol A, Wojtkiewicz GR, Hucker WJ, MacNabb MH, Brownell AL, Jokivarsi K, Kessinger CW, **Jaff MR**, Henke PK, Weissleder R, Jaffar FA. FDG-PET/CT enables the detection of recurrent same-site deep vein thrombosis by illuminating recently formed, neutrophil-rich thrombus. *Circulation* 2014; Jul 28. Epub ahead of print.
184. McKinsey JF, Zeller T, Rocha-Singh K, **Jaff MR**, Garcia LA. Lower extremity revascularization using directional atherectomy. *JACC Cardiovasc Intervent* 2014;7:923-33.
185. Parikh SA, Shishebor MH, Gray BH, White CJ, **Jaff MR**. SCAI expert consensus statement for renal artery stenting appropriate use. *Catheter Cardiovasc Intervent* 2014.
186. Rundek T, Brown SC, Wang K, Dong C, Farrell MG, Heller GV, Gornik HL, Hutchisson M, Needleman L, Benenati JF, **Jaff MR**, Meier GH, Perese S, Bendick P, Hamburg NM, Lohr JM, LaPerna L, Leers SA, Lilly MP, Tegeler C, Alexandrov AV, Katanick SL. Accreditation status and geographic location of outpatient vascular testing facilities among Medicare beneficiaries: the VALUE (Vascular Accreditation, Location and Utilization Evaluation) study. *Vasc Med* 2014;Sep 1.
187. (b) (4) **Jaff MR**, (b) (4). Accepted for publication. (b) (4).
188. (b) (4), **Jaff MR**, (b) (4). Accepted for publication. (b) (4).



189. Ohki T, Yokoi H, Kichikawa K, Kimura T, Snyder SA, Ragheb AO, O'Leary E, **Jaff MR**, Ansel GM, Dake MD. Two-year analysis of the Japanese cohort from the Zilver PTX randomized controlled trial supports the validity of multinational clinical trials. *J Endovasc Ther* 2014;21:644-53.
190. Duval S, Keo HH, Oldenburg NC, Baumgartner I, **Jaff MR**, Peacock JM, Tretinyak AS, Henry TD, Luepker RV, Hirsch AT. The impact of prolonged lower limb ischemia on amputation, mortality, and functional status: the FRIENDS registry. *Am Heart J* 2014;168:577-87.
191. Granada JF, Stenoien M, Buszman PP, Tellez A, Langanke D, Kaluza GL, Leon MB, Gray W, **Jaff MR**, Schwartz RS. Mechanisms of tissue uptake and retention of paclitaxel-coated balloons: impact on neointimal proliferation and healing. *Open Heart* 2014;1:e000117.

#### [Non-peer reviewed scientific or medical publications/materials in print or other media](#)

##### **Reviews, Chapters, Monographs and Editorials**

1. **Jaff MR**, Paganini EP. Meeting the Challenge of Geriatric UTIs. *Geriatrics* 1989; 44(Dec):60-69.
2. **Jaff MR**. Recognition and treatment of cocaine abuse. *Cleve Clinic J Med* 1990; 57(7):595-6.
3. **Jaff MR**. Medical aspects of pregnancy. *Cleve Clin J Med* 1992.
4. **Jaff MR**, Olin JW. Diseases of the Aorta. *Current Opinions in Cardiology* 1992; 7:820-826.
5. **Jaff MR**, Graor RA. Meta-Analysis. Focus on peripheral vascular disease. 1992;May:3.
6. **Jaff MR**, Solomon GD. Headaches associated with medical diseases. In *Headache: diagnosis and interdisciplinary treatment*. Ed. by Tollison D, Kunkel RS, Williams and Wilkins, 1993.
7. **Jaff MR**, Olin JW. Venous Stasis Ulcers. In *Conn's Current Therapy* 1993. Ed. by Rakel R. 805-807.
8. **Jaff MR**. Low Molecular Weight Heparin as a Method of Prophylaxis Against Venous Thromboembolic Disease in Total Joint Replacement Patients. *Orthopod* 1995; 32:41-42.
9. **Jaff MR**, Dorros G. Percutaneous interventions of the below knee arteries. In: *Handbook of cardiovascular interventions*. Churchill Livingstone, Medical Division, Longman, UK, Ltd., London, England, 1996.
10. Iyer SS, **Jaff MR**, Roubin GS, Dorros G. Peripheral Vascular Disease. In *Women's Medicine*. Ed. by Blackwell RE. Blackwell Scientific, 1996.

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**Office Address:** Massachusetts General Hospital  
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**Work Email:** [mjaff@partners.org](mailto:mjaff@partners.org)  
**Work FAX:** 617-724-0371  
**Place of Birth:** Hempstead, New York United States of America

**Education**

1980	B.S., Cum Laude	Biology	Dickinson College
1985	D.O., Honors	Osteopathic Medicine	Kirksville College of Osteopathic Medicine
July- November, 2010	Graduate, General Management Program; Alumnus, Harvard Business School	Business, General Management	Harvard Business School
2013	Honorary Doctorate of Arts		Harvard Medical School

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7/1985- 6/1986	Internship	Rotating Medicine/Surgery	Flint Osteopathic Hospital (Currently Genesys Regional Medical Center)
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**Faculty Academic Appointments**

7/1989 – 6/1990	Clinical Instructor	Medicine	Milton S. Hershey College of Medicine
7/1990- 6/1993	Assistant Professor	Medicine	Milton S. Hershey College of Medicine

Recognition

2007	Master, Society for Vascular Medicine	Society for Vascular Medicine
2008	Honorary Doctorate of Science	A.T. Still University
2010	Leader in Vascular Education	Vascular Interventional Advance 2012
2012	Charles Tegtmeier, MD Award	International Symposium on Endovascular Therapy

**Report of Scholarship**PublicationsPeer reviewed publications in print or other media

1. Abbate SL, **Jaff MR**, Fishleder AJ, Meeker DP. Lambda Light Chain Myeloma with Pleural Involvement. Cleve Clin J Med 1991; 58:235-239.
2. **Jaff MR**, Olin JW, Young JR. Failure of Acute-Phase Reactants to aid in the Diagnosis of Takayasu's Arteritis. J. Vasc Med Biol. 1993; 4:223-227.
3. **Jaff MR**, Medical Aspects of Pregnancy. Cleve Clinic J Med 1994; 61:263-271.
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5. Dorros G, **Jaff MR**, Jain A, Dufek C, Mathiak L. Followup of Primary Palmaz-Schatz Stent Placement for Atherosclerotic Renal Artery Stenosis. Am J Cardiol 1995; 74:1051-1055.
6. Wann S, **Jaff MR**, Dorros G, Sampson C. Intramural Hematoma of the Aorta Caused by a Penetrating Atheromatous Ulcer. Clin Cardiol. 1996;19:438-9.
7. **Jaff MR**, Olin JW, Piedmonte M, Pirzada C, Young JR. Heparin Administration Via Nomogram Versus a Standard Approach in Venous and Arterial Thromboembolic Disease. Vascular Medicine 1996; 1:97-101.
8. Dorros G, Parodi J, Schonholz C, **Jaff MR**, Diethrich EB, White G, Miahle C, Marin ML, Stelter WJ, White R, Coppi G, Bergeron P. Evaluation of Endovascular Abdominal Aortic Aneurysm Repair; Anatomical Classification, Procedural Success, Clinical Assessment, and Data Collection. J Endovasc Surg 1997;4:203-225.
9. Dorros G, Cohn JM, **Jaff MR**. Percutaneous endovascular stent-graft repair of iliac artery aneurysms. J Endovasc Surg 1997;4:370-5.
10. **Jaff MR**. Carotid Endarterectomy: what is not always revealed about carotid artery surgery. J Intervent Cardiol 1997;10:465-7.

134. Weinberg I, **Jaff MR**. Non-atherosclerotic arterial disorders of the lower extremities. *Circulation* 2012;126:213-22.
135. **Jaff MR**, Bates M, Sullivan T, Popma JJ, Gao X, Zaugg M, Verta P. Significant reduction in systolic blood pressure following renal artery stenting in patients with uncontrolled hypertension: results from the HERCULES trial. *Catheter Cardiovasc Intervent* 2012;80:343-50.
136. Olin JW, Froehlich J, Gu X, Bacharach JM, Eagle K, Gray BH, **Jaff MR**, Kim ESH, Mace P, Matsumoto AH, McBane RD, Kline-Rogers E, White CJ, Gornik HL. The United States Registry for Fibromuscular Dysplasia: Results from the first 447 patients. *Circulation* 2012; 125:3182-90.
137. Laird JR, Yeo KK, Rocha-Singh K, Das T, Joye J, Dippel E, Reddy B, Botti C, **Jaff MR**. Excimer laser with adjunctive balloon angioplasty and heparin coated self expanding stent grafts for the treatment of femoropopliteal artery in-stent restenosis: twelve month results from the SALVAGE trial. *Catheter Cardiovasc Intervent* 2012; 80:852-9.
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## Research & Publications



### Research Summary

Dr. Jaff is the founder and Medical Director of the Vascular Ultrasound Core Laboratory, the largest of its kind in the World. The Vascular Ultrasound Core Laboratory has participated in trial design and independent analysis of vascular laboratory images for more than 180 prospective multicenter trials dedicated to the field of vascular medicine and intervention.

### Publications

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[SCAI/SVM expert consensus statement on Carotid Stenting: Training and credentialing for Carotid Stenting.](#)

Aronow HD, Collins TJ, Gray WA, Jaff MR, Kluck BW, Patel RA, Rosenfield KA, Safian RD, Sobieszcyk PS, Wayangankar SA, White CJ.

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J Am Coll Cardiol. 2015 Dec 1;66(21):2329-38.

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*Ann Vasc Surg.* 2014 Nov;28(8):1816-22. doi: 10.1016/j.avsg.2014.06.065. Epub 2014 Jul 7.

## Popliteal venous aneurysms: characteristics, management strategies, and clinical outcomes--a modern single-center series.

Donaldson CW<sup>1</sup>, Oklu R<sup>2</sup>, Watkins MT<sup>1</sup>, Donaldson MC<sup>3</sup>, Abtahian F<sup>1</sup>, Schainfeld RM<sup>1</sup>, Jaff MR<sup>1</sup>, Weinberg I<sup>4</sup>.

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#### Abstract

**BACKGROUND:** Popliteal vein aneurysm (PVA) may be an incidental finding on imaging, but often presents in the context of acute venous thromboembolism (VTE). The role of anticoagulation with or without surgical excision versus expectant management is ill defined.

**METHODS:** In this single-center, retrospective, cohort study, patient records from January 2002 to December 2013 were queried for terminology consistent with PVA. Demographic data and clinical outcomes were extracted via chart review.

**RESULTS:** A total of 21 patients with PVA were identified (57% male). Mean follow-up was  $38 \pm 31$  months. Mean PVA diameter was  $2.5 \pm 1.1$  cm; 67% were saccular (with the remainder being fusiform), 19% contained thrombus, 67% were left sided, and bilateral PVA was present in 24% of cases. At the time of PVA diagnosis, 14% had pulmonary embolism. Treatment consisted of observation only (62%), anticoagulation (19%), surgery (5%), or both anticoagulation and surgery (14%). There were no recurrences of VTE once treated, although there was 1 acute deep venous thrombosis in a patient who was managed conservatively. Two patients had recurrent PVA after surgery, and there were 2 surgical complications (transient foot drop and hematoma).

**CONCLUSIONS:** PVA is associated with VTE. Based on our series, it is unclear if incidentally discovered PVA (without VTE) warrants treatment with anticoagulation and/or surgical repair. Further multicenter studies are needed to establish the indications for safety and durability of surgery.

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*Am J Med.* 2014 Nov;127(11):1111-7. doi: 10.1016/j.amjmed.2014.06.025. Epub 2014 Jul 2.

**Inferior vena cava filter usage, complications, and retrieval rate in cancer patients.**

Abtahian F<sup>1</sup>, Hawkins BM<sup>2</sup>, Ryan DP<sup>3</sup>, Cefalo P<sup>4</sup>, Nasser NJ<sup>5</sup>, MacKay C<sup>6</sup>, Jaff MR<sup>6</sup>, Weinberg I<sup>7</sup>.

**Author information****Abstract**

**BACKGROUND:** Venous thromboembolism contributes significantly to morbidity and mortality in cancer patients. Because cancer patients frequently have contraindications to anticoagulation, inferior vena cava filters are commonly placed. The use, safety, and retrieval of retrievable inferior vena cava filters in cancer patients have not been well studied.

**METHODS:** A retrospective review of retrievable inferior vena cava filter use at a tertiary referral hospital was conducted between January 1, 2009 and December 31, 2011. Indications for inferior vena cava filter placement, anticoagulation practices, complications, filter retrieval, and patient outcomes were analyzed for patients with and without active cancer and for cancer subtypes, including localized and metastatic cases.

**RESULTS:** Of 666 patients receiving retrievable inferior vena cava filters during this time period, 247 (37.1%) had active cancer. Of these, 151 (22.7%) had carcinoma, 92 (13.8%) had sarcoma, and 115 (17.3%) had metastatic disease. Overall, follow-up was available for a median of 401.0 (interquartile range: 107.5-786.5) days. Indwelling filter-related complications occurred in 19.8% of patients without cancer and 17.7% with an active cancer ( $P = .50$ ). Patients with cancer were less likely to have the filter retrieved (28.0% vs 42.0%,  $P < .001$ ). In multivariable analysis, cancer was not associated with filter-related complications but was associated with a lower rate of filter retrieval.

**CONCLUSIONS:** In a modern cohort of patients undergoing retrievable inferior vena cava filter placement, active diagnosis of cancer is not associated with a significant increase in filter-related complications, but is associated with a reduced rate of filter retrieval.

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**KEYWORDS:** Cancer; Deep venous thrombosis; Inferior vena cava; Malignancy; Pulmonary embolism

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## Abstract

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*Catheter Cardiovasc Interv.* 2015 Aug;86(2):E81-7. doi: 10.1002/ccd.25583. Epub 2015 May 13.

## Thrombectomy using suction filtration and veno-venous bypass: single center experience with a novel device.

Donaldson CW<sup>1</sup>, Baker JN<sup>2</sup>, Narayan RL<sup>1</sup>, Provias TS<sup>1</sup>, Rassi AN<sup>1</sup>, Giri JS<sup>3</sup>, Sakhuja R<sup>4</sup>, Weinberg J<sup>1</sup>, Jaff MR<sup>1</sup>, Rosenfield K<sup>1</sup>.

### Author information

### Abstract

**OBJECTIVES:** To describe the first single center experience with a novel aspiration thrombectomy device.

**BACKGROUND:** The appearance of inferior vena cava or right-sided intracardiac thrombus may prompt consideration of percutaneous thrombectomy as a method to prevent new or worsening pulmonary embolism (PE). The AngioVac is a novel thrombectomy device composed of a cannula and extracorporeal circuit with filter for pump-assisted removal of intravascular debris which is coupled with a reinfusion catheter for return of blood to the patient. The device has been approved by the United States Food and Drug Administration since 2009. This report represents the first significant case series describing its use, feasibility and outcomes in evacuating large caval thrombi or intracardiac masses in PE.

**METHODS:** This is a retrospective analysis of patient and case characteristics and in-hospital clinical outcomes of AngioVac thrombectomy in 14 consecutive patients treated between April 2010 and July 2013 at our institution.

**RESULTS:** Fourteen consecutive patients (mean age 50, 64% female) underwent 15 AngioVac procedures over 40 months. Indications included intracardiac mass (73%), acute PE (33%), and caval thrombus (73%). Four patients (27%) were in shock at the start of the procedure. Peri-procedure mortality was 0% and in-hospital mortality was 13% at a mean follow-up of 23 days. There were no pulmonary hemorrhages, strokes or myocardial infarctions. Though 73% had a post procedural drop in hematocrit, only two bleeding events were related to access site and required a transfusion.

**CONCLUSIONS:** AngioVac thrombectomy is feasible in critically ill patients with acute DVT or PE and large caval thrombi or intracardiac masses.

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**KEYWORDS:** deep venous thrombosis; peripheral venous catheterization; pulmonary embolism; thrombectomy

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*J Vasc Surg.* 2014 Aug;60(2):454-461.e1. doi: 10.1016/j.jvs.2014.02.037. Epub 2014 Mar 27.

## Human type I pancreatic elastase treatment of arteriovenous fistulas in patients with chronic kidney disease.

Hye RJ<sup>1</sup>, Peden EK<sup>2</sup>, O'Connor TP<sup>3</sup>, Browne BJ<sup>4</sup>, Dixon BS<sup>5</sup>, Schanzer AS<sup>6</sup>, Jensik SC<sup>7</sup>, Dember LM<sup>8</sup>, Jaff MR<sup>9</sup>, Burke SK<sup>10</sup>.

### Author information

### Abstract

**OBJECTIVE:** This study explored the safety and efficacy of recombinant type I pancreatic elastase (PRT-201) topically applied once to the external surface of an arteriovenous fistula.

**METHODS:** This was a randomized, double-blind, placebo-controlled trial. Adults with kidney disease undergoing creation of a radiocephalic fistula (RCF) or brachiocephalic fistula were randomized to treatment with placebo (n = 51), PRT-201 at 10 µg (n = 51), or PRT-201 at 30 µg (n = 49). The primary efficacy measure was unassisted primary patency (PP) over 1 year. Secondary efficacy measures were secondary patency (SP), unassisted maturation by ultrasound interrogation, use for hemodialysis, and hemodynamically significant lumen stenosis.

**RESULTS:** Median PP was 224 days for placebo and >365 days for the PRT-201 groups. At 1 year, 45%, 54%, and 53% of placebo, 10-µg, and 30-µg patients retained PP. The risk of PP loss was nonsignificantly reduced for 10 µg (hazard ratio [HR], 0.69; P = .19) and 30 µg (HR, 0.67; P = .17) vs placebo. In the subset (44% of patients) with a RCF, the median PP was 125 days for placebo and >365 days for the PRT-201 groups. At 1 year, 31%, 50%, and 63% of placebo, 10-µg, and 30-µg RCFs retained PP. The risk of RCF PP loss was nonsignificantly reduced by 10 µg (HR, 0.59; P = .18) and significantly reduced by 30 µg (HR, 0.37; P = .02) vs placebo. At 1 year, 77%, 81%, and 83% of placebo, 10-µg, and 30-µg patients retained SP. The risk of SP loss was nonsignificantly reduced for 10 µg (HR, 0.79; P = .61) and 30 µg (HR, 0.76; P = .55) vs placebo. In the subset with RCFs, 65%, 82%, and 90% of placebo, 10-µg, and 30-µg patients retained SP at 1 year. The risk of RCF SP loss was nonsignificantly reduced for 10 µg (HR, 0.45; P = .19) and 30 µg (HR, 0.27; P = .08) vs placebo. At month 3, 67%, 87% (P = .03), and 92% (P < .01) of the placebo, 10-µg, and 30-µg group fistulas had unassisted maturation by ultrasound interrogation. At month 3 in the subset with an RCF, 47%, 74% (P = .17), and 93% (P < .01) of placebo, 10-µg, and 30-µg group fistulas had unassisted maturation by ultrasound interrogation. Adverse event reports were not meaningfully different between groups.

**CONCLUSIONS:** PRT-201 appeared safe. The primary efficacy end point was not met. However, both PRT-201 doses were associated with improved unassisted maturation. The 30-µg dose was associated with increased PP in the subset with RCF.

**TRIAL REGISTRATION:** ClinicalTrials.gov [NCT01305824](https://clinicaltrials.gov/ct2/show/study/NCT01305824).

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[J Vasc Access](#). 2014 Sep-Oct;15(5):376-84. doi: 10.5301/jva.5000235. Epub 2014 May 3.

## Application of human type I pancreatic elastase (PRT-201) to the venous anastomosis of arteriovenous grafts in patients with chronic kidney disease.

[Dwivedi AJ<sup>1</sup>](#), [Roy-Chaudhury P](#), [Peden EK](#), [Browne BJ](#), [Ladenheim ED](#), [Scavo VA](#), [Gustafson PN](#), [Wong MD](#), [Magill M](#), [Lindow E](#), [Blair AT](#), [Jaff MR](#), [Franano FN](#), [Burke SK](#).

### Author information

### Abstract

**PURPOSE:** To explore the safety and efficacy of PRT-201 applied to the outflow vein of a newly created arteriovenous graft (AVG).

**METHODS:** Randomized, double-blind, placebo-controlled, single-dose escalation study of PRT-201 (0.01 to 9 mg) applied to the graft-vein anastomosis and adjacent outflow vein immediately after AVG placement. The primary outcome measure was safety. The efficacy measures were intraoperative increases in outflow vein diameter and blood flow rate, primary unassisted patency, and secondary patency by dose groups (placebo, low, medium, high and All PRT-201).

**RESULTS:** A total of 89 patients were treated (28 placebo and 61 PRT-201). There were no significant differences in the proportion of placebo and PRT-201 patients reporting adverse events. Intraoperative outflow vein diameter increased 5% ( $p=0.14$ ) in the placebo group compared with 13% ( $p=0.01$ ), 15% ( $p=0.07$ ) and 12% ( $p<0.001$ ), in the low, medium and high groups, respectively. The comparison between the high and placebo groups was marginally statistically significant ( $p=0.06$ ). The intraoperative blood flow did not change in the placebo group, and increased in the low, medium and high groups by 19% ( $p=0.34$ ), 36% ( $p=0.09$ ) and 46% ( $p=0.02$ ), respectively. The low group had the longest primary unassisted and secondary patency and the fewest procedures to restore or maintain patency; however, the differences between groups were not statistically significant.

**CONCLUSIONS:** PRT-201 was well tolerated and increased AVG intraoperative outflow vein diameter and blood flow. Low dose tended to increase secondary patency and decrease the rate of procedures to restore or maintain patency. Larger studies with these doses will be necessary to confirm these results.

**TRIAL REGISTRATION:** [ClinicalTrials.gov](http://ClinicalTrials.gov) [NCT01001351](https://doi.org/10.1186/17454219/1351).

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## Clinical risk predictors for cerebral hyperperfusion syndrome after carotid endarterectomy.

Maas MB<sup>1</sup>, Kwolek CJ, Hirsch JA, Jaff MR, Rordorf GA.

### Author information

### Abstract

**BACKGROUND:** Cerebral hyperperfusion syndrome (CHS) is an important complication of carotid endarterectomy (CEA), yet prior research has been limited to small cohorts and retrospective analyses, or studies using radiographic rather than clinical definitions.

**METHODS:** A prospective monitoring system was implemented to monitor CEA outcomes at a major academic medical centre. Independent, trained monitors from the neurology department examined all patients undergoing CEA preoperatively and postoperatively at 24 h and 30 days. Clinical variables were analysed to identify risk factors for CHS, which was defined as cases with postoperative development of a severe headache, new neurological deficits without infarction, seizure or intracerebral haemorrhage.

**RESULTS:** Between 2008 and 2010, 841 CEAs were monitored and CHS occurred in 14 (1.7%) subjects, including seizures in 5 (0.6%) and intracerebral haemorrhage in 4 (0.5%). Univariate analysis identified a history of dyslipidaemia, coronary artery disease, diastolic blood pressure, intraoperative shunt use and non-elective CEA (performed during hospitalisation for a symptomatic ipsilateral stroke, transient ischaemic attack or amaurosis fugax) as potential risks for CHS (all  $p \leq 0.15$ ); other variables-including the degree of ipsilateral and contralateral stenosis, operative time, intraoperative EEG slowing, history of prior CEA or carotid stent and time from prior carotid interventions- were not significant. Logistic regression confirmed the risk association between non-elective CEA and CHS ( $p=0.046$ ).

**CONCLUSIONS:** Independent, prospective monitoring of a large cohort of CEA cases identified a brief time interval between ischaemic symptoms and endarterectomy as the clearest risk factor for CHS.

PMID: 23243262 [PubMed - indexed for MEDLINE]

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# **EXHIBIT 16**

Declaration of Rachel Clattenburg  
*Public Citizen v. FDA et al.*, 16-cv-781

OCTOBER 2012

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**Career Interruptions**

(b) (6)

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- 1990, 91 University of Toronto Open Fellowship
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### PUBLICATIONS

#### Articles in Refereed Journals:

(\* (b) (6)

75. (b)(4) not published

(in press).

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**FELLOWSHIPS**

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## PUBLICATIONS

1. Schuchter LM, Hendricks CB, Holland KH, Shelton BK, Hutchins GM, Baughman KL, Ettinger DS: Eosinophilic myocarditis associated with high-dose interleukin-2 therapy. *Am J Med*, 88 (4):439-440, 1990.
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7. Patrick DL, Ferketich SL, Frame PS, Harris JJ, Hendricks CB, Levin B, Link MP, Lustig C, McLaughlin J, Reid LD, Turrisi AT 3<sup>rd</sup>, Unutzer J, Vernon SW: National Institutes of Health State-of-the-Science Conference Statement: Symptom management in cancer pain, depression and fatigue, July 15-17, 2002. *JNCI Mongr* 32:9-16, 2004.
8. Hendricks CB: Re-engineering a small oncology practice for quality using the ASCO Quality Oncology Practice Initiative. *JOP*, 9:169-170.
9. (b) (4) Hendricks CB, (b) (4)  
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# **EXHIBIT 15**

Declaration of Rachel Clattenburg  
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**Education**

1996 - 2000 PhD, Biostatistics, Emory University  
1994 - 1996 MS, Mathematics, University of Florida. Graduated Honors  
1990 - 1994 BS, Mathematics, University of Florida. Graduated Honors

**Professional Experience**

2011-Present Associate Professor, Department of Biostatistics, UNC  
2010-Present Director, Biostatistics Core, Center for AIDS Research, UNC  
2006-2011 Research Associate Professor, Department of Biostatistics, UNC  
2004-2006 Research Assistant Professor, Department of Biostatistics, UNC  
2000-2004 Staff Scientist, Program in Biostatistics, Fred Hutchinson Cancer Research Center  
2000-2004 Visiting Scholar, Department of Biostatistics, University of Washington

**Honors**

2011 Charles C. Shepard Science Award, Centers for Disease Prevention and Control  
2006 Developmental Award, UNC Center for AIDS Research  
2004 Young Investigator Award, Section on Statistics in Epidemiology, American Statistical Association  
2000 ENAR Distinguished Student Paper Award  
1997-2000 NIAID AIDS Training Grant Fellowship, Emory University  
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M.S., Statistics, Carnegie Mellon University, May 2000  
B.S., Biomedical Engineering, Texas A&M University, May 1997

**WORK EXPERIENCE:**

Berry Consultants, Statistical Scientist, 2006-present  
Director & Senior Statistical Scientist, 2013-present  
Statistical Scientist, 2006-2013  
University of Central Florida College of Medicine,  
Assistant Professor of Medical Education, 2008 - present  
Johns Hopkins University, Visiting Assistant Professor, Summers 2010-2013  
Carnegie Mellon University, Adjunct Faculty,  
Master of Information Science Management Program, 2004  
Cleveland Clinic Foundation, 2000-2003  
Senior Biostatistician, Associate Team Leader, 2002-2003  
Biostatistician, 2000-2002  
National Institute of Standards and Technology, Intern, Summers 1996 & 1997  
Mineral County News-Tribune, Reporter, 1992-1997

**EDITORSHIPS:**

*Comparative Effectiveness Research*, Editorial Board, 2011-present  
*American Journal of Gastroenterology*, Associate Editor, 2004-2009

**TEACHING:**

University of Central Florida College of Medicine

- Focused Individualized Research Experience (Medical course)

Johns Hopkins University

- Bayesian Adaptive Trials (Graduate course)

Carnegie Mellon University

- Statistics for IT Managers (Graduate course)
- Statistical Reasoning
- Statistical Reasoning & Practice
- Statistics for IT Managers (Graduate course, teaching assistant)
- Quantitative Methods of Public Policy Analysis (Graduate course, teaching assistant)
- Statistical Computing (Graduate course, teaching assistant)

**PROFESSIONAL SERVICE / ELECTED POSITIONS** FDA Neurology Devices Advisory Panel of the Medical Devices Advisory Committee, 2013-present  
 Appointed Member, American College of Gastroenterology FDA Committee, 2008-11  
 FDA Gastroenterology and Urology Devices Advisory Panel of the Medical Devices Advisory Committee, 2007-2011  
 Appointed Member, American College of Gastroenterology Research Committee, 2006-2010  
 Appointed Member, ENAR Regional Advisory Board, 2005-2007  
 Vice President, Cleveland Chapter, American Statistical Association, 2003  
 Councilman, Parks and Recreation Commissioner, Town of Barton, MD, 1995-1996

**OTHER CONSULTING:** Brigham & Women’s Hospital, 2006  
 SAS Institute, 2006  
 Cleveland Clinic Foundation, 2003-2006  
 Leadership Choice Group, Inc., 2001-2002  
 Golf.com, 1999-2000  
 Carnegie Mellon University, 1999

**MEMBERSHIPS:** Society for Clinical Trials, 2011-present  
 American College of Gastroenterology, 2004-present  
 Biometrics Society, ENAR 2003-present  
 American Statistical Association, 1998-present

**HONORS, AWARDS, AND FELLOWSHIPS:** Runner-up, Best Contributed Paper Award, American Statistical Association Biopharmaceutical Section: A Case Study of a Bayesian Adaptive Cardiology Device Trial Leading to Approval. Montreal QC, August 2013.

Fellow, American College of Gastroenterology, 2004.

Auxiliary Award, Best Scientific Paper: Fecal Lactoferrin as an Aid in Diagnosis of Symptomatic Patients with Ileal Pouch Anal Anastomosis. Parsi MA, Shen B, Achkar J-P, Remzi F, Goldblum, JR, Lin D, Connor JT, Boone J, Fazio VW, Lashner BA. American College of Gastroenterology Meeting, Baltimore MD, October 2003.

Finalist Best Poster Award: Validation of Equations Used to Predict Warfarin Dosing Decisions. Shermock KM, Connor JT, Thomas N, Fink J, Bragg L. Encore poster at the International Society for Pharmacoeconomics and Outcomes Research Annual Meeting, May 2003.

National Institutes of Health Trainee Fellowship, August 1997-August 1998.  
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Connor JT, Luce BR, Ishak KJ, Mullins CD, Broglio KB, Vanness DJ, Fleurence R, Saunders E, and Davis BR. Do Bayesian Adaptive Trials Offer Advantages for CER? Protocol for the RE-ADAPT Study. *Clinical Trials*. October 2013, p807-827, Vol. 10, No. 5.

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