

Endovascular Versus Open Revascularization for Peripheral Arterial Disease

A review of 12-year data revealing changes in amputation and limb salvage rates associated with a shift in revascularization modalities.

BY NILESH N. BALAR, MD; RANJITH DODLA, MD; PARIND OZA, MD;

PARTH N. PATEL; AND MAYANK PATEL, MD

Peripheral arterial disease (PAD) affects approximately 12% to 14% of the general population, which steadily increases with age and affects up to 20% of patients who are older than 75 years.¹

The prevalence of PAD markedly increases in patients with diabetes, hypertension, hyperlipidemia, and a history of smoking.² The most sensitive tool to detect PAD is the ankle-brachial index.² Various treatment options include lifestyle modifications, endovascular revascularization, and open revascularization. In the past, most of these patients with significant limb ischemia have been treated with surgical revascularization. However, with rapid advances in catheter-based technology, there has been a significant shift toward endovascular interventions.^{3,4}

There are very few data regarding limb salvage rates and lower extremity amputation rates after infrainguinal endovascular procedures.⁵ To examine the impact of endovascular interventions on the amputation and limb salvage rates and determine its relationship to open revascularization, we set forth to retrospectively examine a 12-year period of data from this patient population at our center.

METHODS

We performed a retrospective review of patients who underwent peripheral lower extremity vascular procedures from 1999 to 2010. The peripheral lower extremity vascular procedures that were included in our study were endovascular and surgical revascularization and major

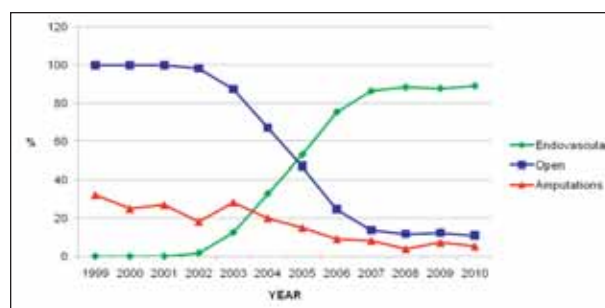


Figure 1. Trends in endovascular revascularization, surgical revascularization, and amputation over 12 years.

lower extremity amputations. All amputations were performed by vascular surgeons only. Surgical revascularization procedures were femoropopliteal artery bypass, femorofemoral crossover bypass, femorotibial vessel bypass, and other distal vessel bypasses. Both native and prosthetic conduits were included in the study. Because few axillary femoral and aortobifemoral bypass procedures were performed in any given year, these procedures were not included.

The endovascular revascularization procedures included atherectomy and balloon angioplasty with or without stent placement. Both surgical and endovascular revascularization procedures were performed by vascular surgeons. The various kinds of atherectomy devices used included the SilverHawk plaque excision system (Covidien, Mansfield, MA), orbital atherectomy, and laser atherectomy.

TABLE 1. COMPARISON OF THE ODDS OF UNDERGOING LOWER LIMB PROCEDURES BETWEEN TWO GROUPS OF PATIENTS

	1999–2004 Group	Odds	2005–2010 Group	Odds	OR	P Value
Endovascular revascularization rate	7.8% ± 13.2%	0.06	79.9% ± 14.2%	4.6	0.01	< .01
Open revascularization rate	92.2% ± 13.2%	14.7	20.1% ± 14.2%	0.2	67.86	< .01
Limb salvage rate	74.9% ± 5.3%	3.1	91.9% ± 3.9%	12.08	0.26	< .01
Major amputation rate	25.1% ± 5.3%	0.32	8.1% ± 3.9%	0.08	3.89	< .01

Abbreviation: OR, odds ratio.

TABLE 2. PERCENTAGE OF VASCULAR PROCEDURES AND THE CORRESPONDING YEAR

	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Endovascular revascularization (%)	0	0	0	1.6	12.5	32.9	52.9	75.3	86.3	88.3	87.7	89
Open revascularization (%)	100	100	100	98.4	87.5	67.1	47.1	24.7	13.7	11.7	12.3	10.9
Amputation (%)	32.3	25	27	18.2	28.4	20	15	9.1	8.2	3.8	7.2	5.2

All endovascular revascularization procedures were performed under local anesthesia with moderate conscious sedation. It is generally accepted that approximately 10% of patients will undergo repeat endovascular revascularization.⁶ Because the unit of analysis in our study was mainly the procedures, we only included one endovascular revascularization procedure per patient. Above- and below-the-knee amputations were also studied.

We divided our data into two groups: patients who were treated from 1999 to 2004 and those who were treated from 2005 to 2010 (Table 1). Data were analyzed in terms of percentages of procedures per year. The rates of limb salvage, revascularization, and amputation were calculated (Table 2). All analyses were performed using Microsoft Excel and GraphPad software. A *t*-test was used to calculate the statistical significance between the two groups. We also calculated the odds ratio to assess the probability of having revascularization and/or amputation between the two groups.

RESULTS

A total of 1,615 lower extremity peripheral vascular procedures from 1999 to 2010 were included in our study. A total of 1,377 (85.3%) patients underwent some form of lower extremity revascularization (Table 3): 738 (53.6%) patients had endovascular procedures, and 639 (46.4%) had open revascularizations. Two hundred thirty-eight patients had major amputations, accounting for an overall rate of 14.7%. We also calculated the percentage of procedures per year (Table 2).

The rates of endovascular revascularization significantly increased from 7.8% before 2005 to 79.9% after 2005 (Figure 1). The rates of surgical revascularization significantly declined from 92.2% to 20.1% before and after 2005, respectively. It was interesting to note that major amputation rates also showed statistically significant decline between the two groups ($P < .01$).

As seen in Table 1, the odds of having endovascular revascularization after 2005 is 4.6 as compared to 0.06

TABLE 3. DISTRIBUTION OF TOTAL PERIPHERAL VASCULAR PROCEDURES AND THE CORRESPONDING YEAR

	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Endovascular revascularization	0	0	0	2	6	25	45	113	145	136	136	130
Open revascularization	44	87	138	124	42	51	40	37	23	18	19	16
Amputation	21	29	51	28	19	19	15	15	15	6	12	8

before 2004. This demonstrates a significant increase in endovascular revascularization versus open revascularization in patients with CLI ($P < .01$). Furthermore, the odds of undergoing open revascularization before 2005 were higher than after 2005. This represents a significant shift toward endovascular revascularization as the preferred mode of revascularization in the last 5 to 6 years at our center. It is also interesting to note that this shift has resulted in an increase in limb salvage rates from 74.9% to 91.9% ($P < .01$). Both types of amputation (above- and below-the-knee) also decreased after 2005, achieving statistical significance.

DISCUSSION

Endovascular intervention for the treatment of limb ischemia has become the first line of therapy in many centers.⁷⁻⁹ Vascular surgeons and cardiologists perform endovascular interventions in most centers;¹⁰ however, in our study, only vascular surgeons were involved in all of the procedures. Undoubtedly, in our analysis, we have seen a rapid growth of endovascular revascularization during the last 5 years, which has lead to a significant decline in surgical revascularization.

There are several reasons for the rapid growth of endovascular revascularization. First, endovascular interventions fall under the broad category of minimally invasive surgery, making it more attractive to patients. In the past, patients with critical limb ischemia would have undergone surgical revascularization provided their general condition allowed it; if not, they would either receive no treatment or perhaps undergo an amputation. However, studies have shown that even in octogenarians, endovascular interventions are associated with improved outcomes.¹¹ Similarly, patients with claudication who would have avoided surgery in the past now elect to have endovascular revascularization because of the minimally invasive nature of these procedures.³

Second, to sustain long-term patency, we might need to perform repeat endovascular interventions. This translates to the fact that patients may undergo multiple endovascular revascularizations as opposed to a single

surgical bypass. Furthermore, patients with failed bypass grafts who have undergone endovascular revascularization have shown significant improvement in terms of limb salvage rates.¹² It is not uncommon to see this as a reasonable choice in those with poor target vessels, conduits, or factors for excess surgical risk.¹²

Any discussion on endovascular revascularization raises the question, how has endovascular intervention affected the treatment of PAD? The answers will be difficult to determine because the outcome of any intervention will vary according to the type and degree of intervention. Clinical success in terms of graft patency and amputation-free survival does not necessarily translate into favorable outcomes from the patient's perspective.

The conclusion from our study that endovascular intervention has significantly increased our center's limb salvage rates cannot be directly established but, at the same time, cannot be ignored as well. Most of these patients will have multiple medical comorbidities including diabetes, coronary artery disease, and hypertension. Adequate management of these associated conditions, in addition to vascular revascularization, has significantly improved patient outcomes.^{13,14} We must remember that outcomes are determined by the patient's intrinsic factors and not solely by the method of revascularization.¹⁵

We should note that there are several limitations to our study. The exact details of the indications for the interventions, locations and type of lesions and stenoses, primary patency, assisted primary patency, and secondary patency rates were not included in this study. Also, there was no long-term follow-up of these patients. Patients who underwent previous surgical revascularization might have had endovascular interventions to sustain graft patency, increasing the number of endovascular interventions in these patients. We also did not take into account the multiple medical comorbidities of these patients and how well these issues were managed. Therefore, our future work aims to look into these intrinsic patient factors to gain valuable insight into the impact of endovascular revascularization on the management of patients with PAD.

CONCLUSION

In this day and age of increased technological advancement, even though a direct cause-and-effect link cannot be established between endovascular revascularization and limb salvage, it cannot be ignored that endovascular intervention has significantly affected the decline in amputation rates, allowing our patients to live independent and dutiful lives. ■

Nilesh N. Balar, MD, is with Westchester Square Medical Center in Bronx, New York. He has disclosed that he is a paid consultant to Cardiovascular Systems Inc. and Covidien. Dr. Balar may be reached at (201) 206-9937; nilbalar@aol.com.

Ranjith Dodla, MD, is a surgical resident with East Tremont Vascular in Bronx, New York. He has disclosed that he has no financial interests related to this article.

Parind Oza, MD, is with Westchester Square Medical Center in Bronx, New York. He has disclosed that he has no financial interests related to this article.

Parth N. Patel is a student with Westchester Square Medical Center in Bronx, New York. He has disclosed that he has no financial interests related to this article.

Mayank Patel, MD, is with Westchester Square Medical Center in Bronx, New York. He has disclosed that he is a paid consultant to Spectranetics and Covidien.

1. Shammass NW. Epidemiology, classification, and modifiable risk factors of peripheral arterial disease. *Vasc Health Risk Manag.* 2007;3:229-234.
2. McDermott MM. The magnitude of the problem of peripheral arterial disease: epidemiology and clinical significance. *Cleve Clin J Med.* 2006;73(suppl 4):S2-7.
3. Keeling WB, Stone PA, Armstrong PA, et al. Increasing endovascular intervention for claudication: impact on vascular surgery resident training. *J Endovasc Ther.* 2006;13:507-513.
4. Nowygrod R, Egorova N, Greco G, et al. Trends, complications, and mortality in peripheral vascular surgery. *J Vasc Surg.* 2006;43:205-216.
5. Kudo T, Chandra FA, Kwun WH, et al. Changing pattern of surgical revascularization for critical limb ischemia over 12 years: endovascular vs open bypass surgery. *J Vasc Surg.* 2006;44:304-313.
6. Cronenwett JL, Likosky DS, Russell MT, et al. A regional registry for quality assurance and improvement: the Vascular Study Group of Northern New England (VSGNNE). *J Vasc Surg.* 2007;46:1093-1101; discussion 1101-1102.
7. DeRubertis BG, Faries PL, McKinsey JF, et al. Shifting paradigms in the treatment of lower extremity vascular disease: a report of 1,000 percutaneous interventions. *Ann Surg.* 2007;246:415-424.
8. Sadek M, Ellozy SH, Turnbull IC, et al. Improved outcomes are associated with multilevel endovascular interventions involving the tibial vessels compared with isolated tibial intervention. *J Vasc Surg.* 2009;49:638-643; discussion 643-644.
9. Black JH 3rd, LaMuraglia GM, Kwolek CJ, et al. Contemporary results of angioplasty-based infrainguinal percutaneous interventions. *J Vasc Surg.* 2005;42:932-939.
10. Weaver FA, Hood DB, Shah H, et al. Current guidelines produce competent endovascular surgeons. *J Vasc Surg.* 2006;43:992-998; discussion 998.
11. Brosi P, Dick F, Do DD, et al. Revascularization for chronic critical lower limb ischemia in octogenarians is worthwhile. *J Vasc Surg.* 2007;46:1198-1207.
12. Simosa HF, Malek JY, Schermerhorn ML, et al. Endoluminal intervention for limb salvage after failed lower extremity bypass graft. *J Vasc Surg.* 2009;49:1426-1430.
13. Schanzer A, Hevelone N, Owens CD, et al. Statins are independently associated with reduced mortality in patients undergoing infrainguinal bypass graft surgery for critical limb ischemia. *J Vasc Surg.* 2008;47:774-781.
14. Conte MS, Bandyk DF, Clowes AW, et al. Risk factors, medical therapies and perioperative events in limb salvage surgery: observations from the PREVENT III multicenter trial. *J Vasc Surg.* 2005;42:456-464; discussion 464-465.
15. Taylor SM, Kalbaugh CA, Blackhurst DW, et al. Determinants of functional outcome after revascularization for critical limb ischemia: an analysis of 1,000 consecutive vascular interventions. *J Vasc Surg.* 2006;44:747-755; discussion 755-756.