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PERIPHERAL VASCULAR DISEASE

Original Studies

Temporal Trends in Peripheral Arterial Interventions: Observations From the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2 PVI)

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Objectives: The aim is to examine trends in procedural indication, arterial beds treated, and device usage in peripheral arterial interventions (PVIs). Background: There is little data on indication, vascular beds treated and devices utilized for peripheral arterial interventions. Methods: We used data from 43 hospitals participating in the BMC2 VIC registry. PVIs were separated by year and divided by arterial segment. Lower extremity PVIs were subclassified as having been performed for claudication or critical limb ischemia (CLI). Yearly device usage was also included. A repeated measure ANOVA was used to determine trends. Results: 44,650 PVIs were performed from 2006 to 2013. Renal interventions decreased from 18% of interventions in 2006 to 5.6% in 2013 ($P < 0.001$) and femoral-popliteal increased from 54.9% in 2006 to 64.5% in 2013 ($P < 0.001$). No significant trend was seen for aorta-iliac or below-the-knee interventions. 58.6% of PVIs were performed for claudication in 2006 and this decreased to 44.6% in 2013 ($P = 0.025$). Indications for CLI were 24.1% in 2006 and 47.5% in 2013 ($P < 0.001$). There were significant increases in the use of balloon angioplasty ($P = 0.029$) and cutting/scoring balloons ($P < 0.001$) while cryoballoon usage decreased ($P < 0.001$). No significant changes were found with stenting, atherectomy, and laser. Conclusions: There is a significant increase in patients presenting with CLI. Renal artery intervention rates are decreasing while femoral-popliteal interventions are

Additional Supporting Information may be found in the online version of this article.

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increasing. Additionally, balloon angioplasty and cutting/scoring balloon usage is increasing.

Key words: peripheral arterial disease; peripheral vascular interventions; temporal trends; claudication; critical limb ischemia; device usage

INTRODUCTION

Peripheral arterial disease (PAD) affects approximately 8.5 million Americans >/= 40 years of age. PAD is associated with significant morbidity and mortality, potential limb loss, and a negative impact on quality of life. The manifestations of PAD are broad and range from asymptomatic to intermittent claudication to critical limb ischemia (CLI) with tissue loss [1]. In recent years, multi-society efforts have resulted in guidelines for PAD management [2]. Endovascular peripheral vascular interventions (PVI) continue to increase and often offer advantages over surgical intervention [3]. PVIs have become an important part of practice of interventional cardiologists, interventional radiologists, and an increasingly utilized approach for vascular surgeons. Additionally, the PVI device market continues to grow. However, there are little contemporary data on the treatment patterns in PVI. It is in this setting that we sought to examine trends in current PVI practice including indication, vascular beds treated, and devices utilized.

METHODS

Study Population

The study population consisted of consecutive PVIs (renal, aorto-iliac, femoral-popliteal, and below-the-knee) from 1/2006 to 12/2013 in the Blue Cross Blue Shield of Michigan Cardiovascular Consortium PVI (BMC2 PVI) Registry.

BMC2 PVI Registry

The details of the BMC2 PVI Registry have been described previously [4]. Briefly, BMC2 PVI is a prospective, multicenter, observational quality improvement registry funded by Blue Cross Blue Shield of Michigan. The registry is a regional collaborative effort aimed to improve the quality of care and patient outcomes and overcome barriers of traditional market and academic competition. The registry collects, audits, and organizes data and reports procedural variables and outcomes to individual operators and institutions. A data form is compiled for each patient, including demographic information, past medical history, laboratories pre- and post-PVI, patient history, presenting symptoms, procedural indications, medication details, PVI types, details of procedure, and associated complications if present. Data quality are ensured by ad hoc queries, random chart reviews, and a series of diagnostic routines included in the database. Peri-procedural and in-hospital data are collected from each individual. The registry has been approved or the need for approval waived by the institutional review board of each participating hospital.

Statistical Analysis

Location and indication. Consecutive PVIs from 1/2006 to 12/2013 were separated by year and were divided by arterial segment (renal, aorto-iliac, femoral-popliteal or below-the-knee) The lower extremity PVIs were subclassified as having been performed secondary to either claudication or CLI defined as rest pain or ulcer. To determine changes in temporal trends, the *P*-value was calculated using a repeated measure ANOVA.

Device usage. PVI devices included balloon, stent, atherectomy, cryoballoon, cutting balloon, and laser. A repeated measure ANOVA was used to determine temporal trends in device usage.

Sensitivity analysis. The analysis was repeated utilizing only the original 6 hospitals in the registry from 2006 to 2013 to ensure that the changes observed were not secondary to a difference in treatment culture within the new centers.

RESULTS

A total of 44,650 consecutive patients undergoing PVI were prospectively enrolled from 43 hospitals in

TABLE I. Hospital Count and Case Number

	2006	2007	2008	2009	2010	2011	2012	2013	Total
Discharges	1677	2074	3965	5395	6240	7614	8500	9185	44650
Original 6 Hospitals[a]	1677	1848	1793	1636	1830	1524	1323	1752	13383
Hospital Count	6	7	16	16	18	37	41	43	

[a]Six hospitals that were included since 2006.

TABLE II. Baseline Demographic and Clinical Characteristics

	2006	2007	2008	2009	2010	2011	2012	2013
N =	1677	2074	3965	5395	6240	7614	8500	9185
Gender (F)	726 (43.4%)	905 (43.6%)	1760 (44.4%)	2403 (44.5%)	2736 (43.9%)	3319 (43.6%)	3622 (42.6%)	3786 (41.2%)
Current Smoker	455 (27.1%)	626 (30.2%)	1166 (29.4%)	1736 (32.2%)	2096 (33.6%)	2499 (32.8%)	2846 (33.5%)	3223 (35.1%)
Former Smoker	981 (58.5%)	1128 (54.4%)	1961 (49.5%)	2347 (43.5%)	2782 (44.6%)	3563 (46.8)	4167 (49%)	4596 (50%)
Age (mean)	69.2	68.1	68.8	68.5	68.3	68.6	68.4	68.4
BMI (mean)	30.4	31.5	30.1	28.5	28.3	28.2	28.4	28.9
Family Hx of CAD	500 (29.8%)	620 (29.9%)	1043 (26.3%)	1439 (26.7%)	1610 (25.8%)	1955 (25.7%)	1617 (19%)	1841 (20%)
Hyperlipidemia	1372 (81.8%)	1753 (84.5%)	3394 (85.6%)	4494 (83.3%)	5442 (87.2%)	6598 (86.7%)	7391 (87%)	8075 (87.9%)
Hypertension	1525 (90.9%)	1920 (92.6%)	3626 (91.5%)	4944 (91.6%)	5738 (92%)	6968 (91.5%)	7776 (91.5%)	8419 (91.7%)
Diabetes	720 (42.9%)	953 (46%)	1851 (46.7%)	2552 (47.3%)	2914 (46.7%)	3525 (46.3%)	4119 (48.5%)	4517 (49.2%)
History of CHF	352 (21%)	473 (22.8%)	787 (19.9%)	1080 (20%)	1238 (19.8%)	1521 (20%)	1793 (21.1%)	2099 (22.9%)
Significant valve disease	76 (4.5%)	171 (8.2%)	238 (6%)	347 (6.4%)	447 (7.2%)	323 (4.2%)	680 (8%)	729 (7.9%)
COPD	446 (26.6%)	553 (26.7%)	1130 (28.5%)	1519 (28.2%)	1764 (28.3%)	1912 (25.1%)	2423 (28.5%)	2742 (29.9%)
CVD or TIA	484 (28.9%)	670 (32.3%)	1208 (30.5%)	1583 (29.3%)	1864 (29.9%)	2150 (28.2%)	2434 (28.6%)	2696 (29.4%)
Hx of CAD	1131 (67.4%)	1394 (67.2%)	2491 (62.8%)	3399 (63%)	3921 (62.8%)	4554 (59.8%)	5094 (59.9%)	5473 (59.6%)
Previous PCI	587 (35%)	763 (36.8%)	1279 (32.3%)	1671 (31%)	2076 (33.3%)	2323 (30.5%)	2743 (32.3%)	2956 (32.2%)
Previous MI	585 (34.9%)	793 (38.2%)	1377 (34.7%)	1527 (28.3%)	1770 (28.4%)	2123 (27.9%)	2412 (28.4%)	2673 (29.1%)
Previous CABG	474 (28.3%)	638 (30.8%)	1180 (29.8%)	1421 (26.3%)	1575 (25.2%)	1859 (24.4%)	2067 (24.3%)	2176 (23.7%)
GI Bleed	24 (1.43%)	40 (1.93%)	61 (1.54%)	80 (1.48%)	97 (1.6%)	70 (0.9%)	154 (1.8%)	189 (2.1%)
Atrial Fibrillation	234 (14%)	293 (14.1%)	530 (13.4%)	716 (13.3%)	804 (12.9%)	994 (13.1%)	1200 (14.1%)	1384 (15.1%)
Other AVD	1 (0.1%)	1046 (50.4%)	1395 (35.2%)	1309 (24.3%)	931 (14.9%)	1398 (18.4%)	1950 (22.9%)	2493 (27.1%)
Renal Failure CRD	78 (4.7%)	102 (4.9%)	187 (4.7%)	253 (4.7%)	363 (5.8%)	398 (5.2%)	491 (5.8%)	533 (5.8%)
Renal Transplant	0 (0%)	9 (0.4%)	27 (0.7%)	53 (1%)	59 (1%)	80 (1.1%)	76 (0.9%)	96 (1.1%)

Abbreviations: F = female; BMI = body mass index; Hx = history; CAD = coronary artery disease; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; CVD = cerebrovascular disease; TIA = transient ischemic attack; PCI = percutaneous coronary intervention; MI = myocardial infarction; CABG = coronary artery bypass grafting; GI = gastrointestinal; AVD = Arterial Vascular Disease; CRD = chronic renal disease.

Michigan state from January 2006 through December 2013 (Table I). Baseline demographic and clinical characteristics are detailed in Table II. Across any given year, approximately 41–45% of the patients were female and the cohort had an average age of 68-year old with a BMI ranging from 28 to 32 kg/m^2. Nearly one-third of patients were current smokers and 43.5%–58.5% had a history of smoking. Nearly one-half of patients had a history of diabetes and approximately two-thirds had concomitant coronary artery disease. Additionally, over 80% of patients had a history of hyperlipidemia while over 90% had a history of hypertension.

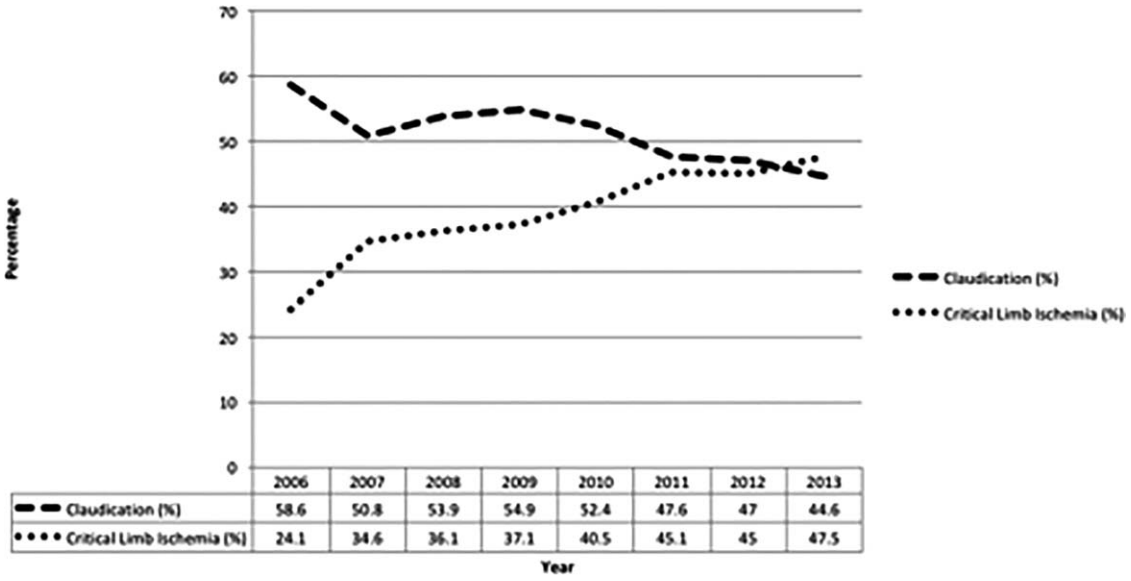
A significant temporal trend was observed for procedural indication from 2006 to 2013. In 2006, 58.6% of the 1677 PVIs were performed for claudication while 44.6% of the 9185 PVIs were performed for claudication in 2013 ($P = 0.025$). CLI comprised 24.1% of the interventions in 2006 and increased to 47.5% of the PVIs in 2013 ($P < 0.001$). (Fig. 1)

There were also significant changes in the location of the vascular beds that were treated over the study period. Renal interventions accounted for 18% of the overall PVIs in 2006 and decreased to 5.6% of the interventions in 2013 ($P < 0.001$). Femoral-popliteal interventions accounted for 54.9% of PVIs in 2006 and increased to comprise 64.5% of the interventions in 2013 ($P < 0.001$). No significant trend was seen in the percent of overall cases comprised of aorta-iliac or below-the-knee interventions from 2006 to 2013 (Table III)

In 2006, 67.6% of PVIs utilized balloon angioplasty and this increased to 85.4% in 2013 ($P = 0.029$). Cryoballoon usage decreased from 5% in 2006 to 0.6% in 2013 ($P < 0.001$) while cutting/scoring balloon use increased from 1.8% in 2006 to 15.1% in 2013 ($P < 0.001$). There was no significant temporal trend found in the use of stenting, atherectomy, and laser from 2006 to 2013. (Table IV)

Sensitivity Analysis

A total of 13,383 consecutive PVIs were performed at the original six hospitals in the registry from 2006 through 2013 (Table I). A significant temporal trend was observed for procedural indication as claudication decreased ($P = 0.046$) and CLI increased ($P < 0.001$). (Supporting Information Figure 1) In regards to vascular beds treated, there was a significant decrease in renal artery interventions and increase in femoral-popliteal and below-the-knee interventions while there was no significant trend observed in aorto-iliac



	2006	2007	2008	2009	2010	2011	2012	2013
Claudication (%)	58.6	50.8	53.9	54.9	52.4	47.6	47	44.6
Critical Limb Ischemia (%)	24.1	34.6	36.1	37.1	40.5	45.1	45	47.5

Fig. 1. Procedural indication. Shown are the temporal changes in the proportion of patients undergoing peripheral vascular intervention for claudication and critical limb ischemia.

interventions. (Supporting Information Table I) There were significant increases observed in the use of balloon and cutting/scoring balloons while there were significant decreases seen in stenting, cryoballoon, and laser therapy. There was no significant trend observed with the use of atherectomy. (Supporting Information Table II)

DISCUSSION

In this large cohort of PVI patients from 2006 to 2013, we observed several changes in indication for the procedure, vascular bed treated and device utilization over the study period. In more recent years, there have been a greater proportion of patients being treated for CLI. The rates of renal artery interventions decreased over time, while the rates of femoral-popliteal artery interventions increased. Additionally, balloon angioplasty and cutting balloon usage increased, while cryoballoon therapy declined. Atherosclerotic risk factors were widely prevalent in this cohort and there were no major changes in the patient baseline characteristics.

Procedural Indication

The key finding of our study is that there has been a significant shift in the type of procedures that are being performed. Over the study period, there was an increase in the PVI procedural indication of CLI and decrease in claudication from 2006 through 2013. In 2006, approximately one in four cases (24.1%) were completed for CLI while this increased to nearly one-half in 2013 (47.5%).

It is likely that the increased prevalence of CLI as an indication in our study is a reflection of the increasing recognition of the safety and efficacy of percutaneous versus surgical revascularization in patients with significant co-morbidities. Nasr et al. reviewed single center institutional revascularization rates for CLI from 1994 to 1999. They found that PTA rates increased from 44% in 1994–1995 to 69% in 1998–1999 while surgical rates declined. There was no statistically significant difference between the groups in regards to patient survival, limb salvage rates, and mean hospital stay [5]. Plaisance et al. examined the safety of PVI in the elderly in a statewide registry consisting of 7,769 patients. The authors found that the elderly patients presented with more severe PAD including rest pain or goal of limb salvage, however, after adjustment for baseline covariates, advanced age was not associated with increased rates of MACE, transfusion, contrast induced nephropathy, or amputation [6]. Furthermore, surgical revascularization for CLI has been found to be associated with a higher 30-day and 1-year mortality in octogenarians when compared to younger patients [7]. Also, Faglia et al. found that percutaneous revascularization was feasible in 84% of diabetic patients presenting with CLI as a first choice revascularization procedure and had an associated low complication rate (3.4%) [8]. Therefore, it is not surprising that there is increased utilization of PVI for CLI patients.

Arterial Bed Treated

Renal artery interventions decreased from 2006 to 2013 while rates of femoral-popliteal increased. There

TABLE III. Arterial Bed Treated

	2006	2007	2008	2009	2010	2011	2012	2013	*P*-value for trend
Renal	301 (18%)	260 (12.5%)	416 (10.5%)	439 (8.1%)	360 (5.8%)	460 (6%)	482 (5.7%)	514 (5.6%)	<.001
Aorto-Iliac	482 (28.7%)	597 (28.8%)	1165 (29.4%)	1485 (27.5%)	1737 (27.8%)	2124 (27.9%)	2340 (27.5%)	2555 (27.8%)	0.295
Femoral-Popliteal	921 (54.9%)	1238 (59.7%)	2380 (60%)	3324 (61.6%)	3910 (62.7%)	4732 (62.2%)	5593 (65.8%)	5926 (64.5%)	<.001
Below Knee	261 (15.6%)	429 (20.7%)	968 (24.4%)	1466 (27.2%)	1652 (26.5%)	2061 (27.1%)	2181 (25.7%)	2396 (26.1%)	0.092

TABLE IV. Device Usage

	2006	2007	2008	2009	2010	2011	2012	2013	*P*-value for trend
Balloon	1134 (67.6%)	1537 (74.1%)	3263 (82.3%)	4670 (86.6%)	5529 (88.6%)	6745 (88.6%)	7434 (87.5%)	7845 (85.4%)	0.029
Stent	932 (55.6%)	1106 (53.3%)	2059 (51.9%)	2477 (45.9%)	2752 (44.1%)	3530 (46.4%)	3969 (46.7%)	4146 (45.1%)	0.131
Atherectomy	401 (23.9%)	559 (27%)	1218 (30.7%)	1743 (32.3%)	1961 (31.4%)	2113 (27.8%)	2114 (24.9%)	2127 (23.2%)	0.558
Cryoballoon	83 (5%)	74 (3.6%)	122 (3.1%)	215 (4%)	213 (3.4%)	155 (2%)	136 (1.6%)	59 (0.6%)	<.001
Cutting Balloon	30 (1.8%)	43 (2.1%)	146 (3.7%)	174 (3.2%)	302 (4.8%)	550 (7.2%)	1068 (12.6%)	1388 (15.1%)	<.001
Laser	87 (5.2%)	189 (9.1%)	436 (11%)	631 (11.7%)	584 (9.4%)	555 (7.3%)	484 (5.7%)	676 (7.4%)	0.298

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was no significant trend observed in rates of aorto-iliac or below-the-knee interventions during this time period. As shown in Table III, rates of aorto-iliac are relatively stable while the proportion of below-the-knee interventions does increase over time, but is not statistically significant. This may be secondary to the smaller number of hospitals in the Registry in the earlier time points as one would expect an increase in the below-the-knee interventions with an increased proportion of procedures performed for CLI.

In our study, the rate of renal artery intervention dropped from 18% in 2006 to approximately 6% in 2010. This percentage remained relatively stable through 2013. Notably, this decrease in the rate of renal artery intervention was prior to the publication of the CORAL study in 2014, which confirmed that effective medical therapy should be the first line of treatment in patients with presumed renovascular hypertension [9]. It is likely that the widespread uncertainty and the clinical equipoise about the efficacy of renal stenting resulted in a decline of this procedure even prior to the publication of the CORAL trial.

Goodney et al. examined trends in lower extremity revascularization practices in Medicare beneficiaries from 1996 to 2006 and found that endovascular treatment increased three-fold during this time period while lower-extremity bypass decreased by 42% [10]. This change in practice may have been partially driven by patient preference for less invasive procedures that paralleled advances in catheter-based technologies. This practice pattern is consistent with our observation of an increase in the rate in femoral-popliteal interventions from 2006 to 2013.

Device Utilization

Data from our large registry would suggest that plain balloon angioplasty and cutting/scoring balloon angioplasty has increased while cryoballoon therapy is decreased. In fact, the cryoballoon was withdrawn from the U.S. market for a period of time and recently reintroduced. Therefore, these rates may begin to increase again. Additionally, there was no significant trend identified in the use of stents, atherectomy devices, or laser from 2006 to 2013. The ACC/AHA guidelines for the management of patients with PAD provide a basic framework for utilization of these devices [11]. Stenting for iliac artery stenosis is a Class I LOE B recommendation while stenting and other adjunct therapies can be useful for salvage therapy from balloon dilatation of femoral, popliteal, or tibial vessels (Class IIb LOE C recommendation).

Along with these basic guidelines, the device market for treatment of PAD continues to expand rapidly and adjunct therapies are more readily available including drug eluting balloons and atherectomy devices. Given the number and variability in treatment modalities, as well as practitioner-preference and the lack of significant clinical trial data, the interventionalist or surgeon has a wide array of devices to choose from in treating in a specific lesion.

To our knowledge, this is the largest study to examine changes in device usage in treatment of PAD.

Limitations

The results in this study are based on observational data that are not adjudicated by a central facility. The use of a large registry with clinical heterogeneity and reporting variability leads to the possibility for confounding variables and treatment bias. Additionally, all patients in our study underwent PVI at hospitals participating in a quality improvement initiative and therefore, these findings may not apply to other institutions or patients from other areas. However, the data are based on a large registry and reflects continuous data on unselected patients undergoing PVI procedures performed by multiple specialists from different backgrounds (interventional cardiology, interventional radiology, vascular surgery) and offers a contemporary insight into treatment in this population.

CONCLUSIONS

In this study, there was a significant increase in the proportion of patients that presented for lower extremity PVI with CLI, while fewer presented with claudication. From 2006 to 2013, the rates of renal artery interventions decreased while femoral-popliteal interventions increased. Additionally, the use of balloon angioplasty and cutting/scoring balloon increased from 2006 to 2013. These findings shed light on contemporary practice patterns related to the percutaneous management of PAD and suggest the need for additional studies to define optimal treatment strategies.

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