A six-year study of diagnostic lower extremity imaging practice patterns and outcomes in the Veterans Affairs health care system

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BACKGROUND: The use of diagnostic imaging in the United States continues to increase, while investigations of the clinical implications following testing are lacking. The objectives of the present study are to describe the practice patterns and clinical outcomes that follow lower extremity diagnostic imaging. This is a retrospective cohort study with six years of data (1999 to 2004).

METHODS: The sources of data for the present study were Veterans Affairs Hospital administrative and clinical databases. The study population included 19,209 American veterans who had either contrast-enhanced magnetic resonance angiography (MRA) or digital subtraction angiography (DSA) for the assessment of peripheral artery occlusive disease. Descriptive statistics of the characteristics were provided, as well as adjusted ORs for having interventions or complications following an imaging procedure.

RESULTS: The number of patients initially imaged with a contrast-enhanced MRA increased from 1999 to 2004, while those imaged with DSA decreased. The overall imaging rate remained relatively constant. In the multivariate model adjusted for the risk of complications within 30 days of the initial imaging procedure, the risk of complications following DSA increased 2.29-fold (95% CI 1.60 to 3.30). More patients had an intervention following DSA (DSA 41% versus MRA 23%, $P < 0.0001$) but were also twice as likely to have an intervention with an amputation (adjusted OR 2.36, 95% CI 1.79 to 3.12).

CONCLUSIONS: The present study illustrates the need for prospective evaluation of diagnostic imaging to determine how best to employ screening strategies that will optimize diagnostic imaging and treatment in patients diagnosed with peripheral artery occlusive disease.

Key Words: Angiography; Diagnostic imaging; Magnetic resonance imaging; Peripheral artery occlusive disease; Peripheral vascular disease

While prescription drug expenditures receive great public attention, the escalation of diagnostic imaging costs represents an important contributor to increasing United States health care costs. In the United States, we spend approximately \$100 billion USD each year on diagnostic imaging (1). A vast number of drug efficacy clinical trials assess a variety of clinical outcomes, cost benefits and treatment effectiveness, but few studies investigate the outcomes, benefits and effectiveness of diagnostic imaging.

However, recent attention has been drawn to this segment of the health care sector, as illustrated by the testimony of Dr Mark Miller on behalf of the Medicare Payment Advisory Committee (2). In his testimony, he reported that diagnostic imaging grew more rapidly than any other type of physician service between 1999 and 2003. Advanced imaging services appear to be leading the growth, with magnetic resonance imaging (MRI; excluding MRI of the head) increasing 99%, nuclear medicine increasing 85% and computed tomography (CT; excluding CT of the head) increasing 82% between 1999 and 2003. Increases in imaging rates may be a reflection of the temporal and demographic trends in screening for prevalent conditions, such as peripheral artery disease.

Peripheral artery occlusive disease (PAOD), defined as non-coronary, nonintracranial occlusive arterial disease, is common

in the United States. Approximately 27 million individuals are believed to be afflicted with PAOD worldwide (3,4). Of the American population 40 years of age and older, 4.5% have peripheral arterial disease (5). The diagnosis of PAOD is associated with dire clinical consequences, such as amputation, as well as an increased risk for coronary artery disease and death (6). Conventional angiography remains the reference standard for evaluation of lower extremity arterial occlusive disease; however, magnetic resonance angiography (MRA) is a minimally invasive imaging procedure that provides a viable alternative option (7,8). Clinical studies assessing the value of both contrast-enhanced MRA (CE-MRA) and digital subtraction angiography (DSA) are limited in nature; they often consist of small clinical evaluations of the imaging precision of either testing strategy (7,8).

There is limited information about the influence of either testing modality on subsequent surgical treatment interventions and the best diagnostic testing strategy. Because many individuals with PAOD are asymptomatic, routine clinical examination often cannot help determine the presence or severity of PAOD unless the disease is quite advanced (9,10). However, the United States Preventive Services Task Force guidelines recommend against routine screening of asymptomatic patients. PAOD screening was given a 'D' level recommendation, suggesting that

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it offers little or no benefit and poses potential harm (11). Yet, the concern over the fact that even asymptomatic PAOD increases mortality and the risk of subsequent cardiovascular disease (6,12,13) may lead some physicians to request noninvasive imaging instead of relying on physical examination findings suggestive of more advanced limb ischemia.

In the present study, we evaluated the patterns of diagnostic imaging of the lower extremities, the incidence of complications due to imaging and the frequency of lower extremity interventions following imaging. Because it focuses on 19,209 American veterans with PAOD over a six-year period, our study is, to our knowledge, the first study of sufficient scale that examines and describes the clinical outcomes that follow imaging in a large health care system.

METHODS

The present retrospective cohort study was approved by the Institutional Review Board of the Veterans Affairs Boston Healthcare System. It uses data from the Veterans Health Administration National Patient Care Database, which contains the patient treatment files, outpatient clinic files and Veterans Administration Beneficiary Identification Records Locator Subsystem. Patient treatment files represent patient hospitalizations and outpatient clinic files represent visits to the Veterans Administration Healthcare System. Mortality data was obtained from the Veterans Beneficiary Identification Records Locator Subsystem.

Using the national database, all users of the Veterans Health Affairs (VHA) system who underwent outpatient lower extremity imaging, either DSA or CE-MRA, were identified (*International Statistical Classification of Diseases and Related Health Problems, Ninth Revision, Clinical Modification* (14) [ICD-9-CM] codes 88.48, 00.23, Current Procedural Terminology [CPT] (15) codes 75716, 75630, 73725). The first imaging procedure was defined as the primary imaging procedure used for the diagnosis or assessment of PAOD (ICD-9-CM code 443.9). Information was collected about demographics (age, sex, race, and VHA clinic site), clinical risk factors, complications occurring within 30 days of imaging, lower extremity interventions within one year of the first imaging procedure and death following imaging.

The final sample included 19,209 of 20,343 individuals (94.4%) who underwent diagnostic lower extremity imaging procedures (CE-MRA or DSA) between October 1, 1998 (start of the fiscal year of 1999) and September 30, 2004 (end of the fiscal year of 2004). All subjects in the cohort used the VHA between the years 1999 and 2004. In total, 1134 subjects were excluded from the original data set because they did not have a follow-up one year after the primary lower extremity imaging procedure.

To describe the patterns of lower extremity imaging procedures for the diagnosis of PAOD, the cohort was categorized into two groups – CE-MRA or DSA – based on the primary imaging procedure.

Outcomes of interest

In the present study, the primary outcomes of interest were lower extremity revascularizations or surgical interventions, complications within 30 days and death within one year of the imaging procedure.

Interventions included percutaneous transluminal angioplasty (PTA; ICD-9-CM code 39.50; CPT codes 75962,

75964), stenting (ICD-9-CM code 39.90; CPT code 75960), bypass surgery (ICD-9-CM codes 39.25, 39.29; CPT codes 35582, 35583, 35585, 35587) and amputations (ICD-9-CM codes 84.1, 84.12, 84.17, 84.10, 84.11, 84.15, 84.14).

Allergies due to radiological dye (ICD-9-CM code V15.08), hematomas (ICD-9-CM code 996.62), and vascular (ICD-9-CM code 997.2) and renal complications (ICD-9-CM codes 584, 580-583) were documented as complications.

Clinical risk factors

With regard to practice pattern differences, baseline characteristics such as age, race and sex were assessed, along with information on the following disease covariates: diabetes mellitus (ICD-9-CM codes 250-250.9), hypertension (ICD-9-CM codes 401, 401.01, 401.1, 401.9), cardiovascular disease (ICD-9-CM codes 00.66, 36, 410-414), baseline peripheral vascular disease (PVD) (ICD-9-CM code 443.9), chronic renal disease (ICD-9-CM code 585), atherosclerosis of extremities with intermittent claudication (ICD-9-CM code 440.21) and baseline revascularization or surgical interventions for PVD (PTA, stent, bypass or amputation, ICD-9-CM codes specified earlier). In addition, a Charlson Comorbidity Index was derived.

Statistical analyses

For the Veterans Affairs New England Healthcare System, systematic chart reviews of 200 subjects were conducted to determine how often a chart was interpreted as adequate, and how often it was determined to be of limited interpretability, therefore requiring additional diagnostic imaging. A panel of physicians (a radiologist and two internists) reviewed all radiographic reports and clinical history, and recorded information on indications for imaging, comorbid conditions and outcomes.

After refining the administrative listing of practice patterns, the next phase of the present study was conducted. In this phase, any variations in the way CE-MRA guided clinical decision-making were acknowledged, based on the presence of several patient factors, such as age, race, sex and the presence of comorbid conditions. To achieve this research objective, descriptive statistics of the patient characteristics undergoing each imaging modality (CE-MRA versus DSA) were obtained. Those patients having an intervention were compared with those who did not have an intervention.

The distribution of interventions following imaging for both groups was assessed. The occurrence of clinically meaningful complications (complications within 30 days of imaging) in the two groups was also assessed. After adjusting for age, clinical risk factors (renal disease, hypertension, PVD, coronary artery disease, previous lower extremity surgical procedures) and Charlson Comorbidity Index score, any variations in treatment patterns were acknowledged, as well as the occurrence of clinically meaningful complications within 30 days of the first imaging procedure. Using logistic regression models (logistic procedure using SAS 9.1, SAS Institute Inc, USA), adjusted ORs were generated for having an intervention or complication within 30 days following an imaging procedure.

RESULTS

Between the years 1999 and 2004, 19,209 patients underwent an initial diagnostic imaging procedure at a VHA facility. Of these patients, 3183 (16.6%) underwent CE-MRA as the first

TABLE 1
Baseline characteristics of patients in the Veterans Health Affairs system, by imaging modality, between 1999 and 2004

Characteristic, n=19,209	CE-MRA, n=3183	DSA, n=16,026	P
Age, years	64.13±12.34	65.14±9.90	<0.0001
Men	3079 (96.7)	15,825 (98.7)	<0.0001
Diabetes mellitus	1246 (39.1)	6290 (39.2)	0.9132
Cardiovascular disease	1835 (57.7)	10,809 (67.4)	<0.0001
Documented history of peripheral vascular disease (peripheral vascular disease or claudication)	2282 (71.7)	14,377 (89.7)	<0.0001
History of PTA, stent, bypass or amputation	289 (9.1)	3013 (18.8)	<0.0001
Chronic renal disease	409 (12.8)	895 (5.6)	<0.0001
Hypertension	2436 (76.5)	12,852 (80.2)	<0.0001
Race			
Caucasian	1905 (59.8)	11,377 (71.0)	<0.0001
African-American	405 (12.7)	1894 (11.8)	
Other	170 (5.3)	619 (3.9)	
Unknown	703 (22.1)	2136 (13.3)	
Died within one year of imaging procedure	213 (6.7)	1172 (7.3)	0.2158
Charlson Comorbidity Index	2.5±1.9	2.6±1.5	0.0006

Results presented as n (%); age and Charlson Comorbidity Index presented as mean ± SD. CE-MRA Contrast-enhanced magnetic resonance angiography; DSA Digital subtraction angiography; PTA Percutaneous transluminal angioplasty

Figure 1) Lower extremity outpatient imaging procedures performed in the Veterans Health Affairs system from 1999 to 2004. CE-MRA Contrast-enhanced magnetic resonance angiography; DSA Digital subtraction angiography

imaging procedure and 16,026 (83.4%) underwent DSA as the first imaging procedure. Table 1 lists the differences between baseline characteristics in the CE-MRA and DSA groups. Patients who had DSA were older than patients undergoing CE-MRA ($P<0.0001$). There was a greater prevalence of documented history of PVD or claudication in the DSA group than in the CE-MRA group (89.7% versus 71.7%, $P<0.0001$). Chronic renal failure was more prevalent in the CE-MRA group than the DSA group (12.8 versus 5.6%, $P<0.0001$).

The number of patients initially imaged with CE-MRA increased from 1999 to 2005, while those imaged with DSA decreased (Figure 1). Therefore, the overall number of patients imaged remained relatively constant. In the multivariate

TABLE 2
Complications within 30 days following an outpatient lower extremity imaging procedure in the Veterans Health Affairs system (1999 to 2004)

Type of complication	Complications after an imaging procedure			
	CE-MRA n=3183	DSA n=16,026	DSA versus CE-MRA OR (95% CI)*	P
Renal	20 (0.63)	94 (0.58)	1.18 (0.71–1.95)	0.53
Vascular	1 (0.03)	8 (0.05)	Not estimable	
Allergies	1 (0.03)	3 (0.02)	Not estimable	
Hematomas	13 (0.4)	281 (1.8)	4.02 (2.29–7.07)	<0.0001
Any complication	34 (1.1)	378 (2.4)	2.29 (1.60–3.30)	<0.0001

Results presented as n (%) unless otherwise stated. *OR and 95% CI after adjustment for age, renal disease, hypertension, peripheral vascular disease, coronary artery disease and previous lower extremity surgical procedures. CE-MRA Contrast-enhanced magnetic resonance angiography; DSA Digital subtraction angiography

TABLE 3
Interventions in the year following outpatient lower extremity imaging procedures in the Veterans Health Affairs system (1999 to 2004)

Type of intervention	Interventions after an imaging procedure			
	MRA n=3183	DSA n=16,026	DSA versus MRA adjusted OR* (95% CI)	P
PTA, stent, bypass or amputation	745 (23)	6544 (41)	2.14 (1.95–2.35)	<0.0001
PTA, stent or bypass	612 (19)	5235 (33)	1.86 (1.69–2.06)	<0.0001
PTA or stent only	259 (8.1)	1181 (7.4)	0.85 (0.73–0.98)	0.02
Revascularization only	353 (11)	4054 (25)	2.49 (2.20–2.80)	<0.0001
Amputation with any intervention	61 (1.9)	686 (4.3)	2.36 (1.79–3.12)	<0.0001
Amputation only	72 (2.3)	623 (3.9)	1.99 (1.54–2.59)	<0.0001

*OR and 95% CI after adjustment for age, renal disease, hypertension, peripheral vascular disease, coronary artery disease and previous lower extremity surgical procedures. CE-MRA Contrast-enhanced magnetic resonance angiography; DSA Digital subtraction angiography; PTA Percutaneous transluminal angioplasty

model (Table 2), the risk of complications following DSA increased more than twofold (OR 2.29; 95% CI 1.60 to 3.30, $P<0.0001$). This difference is largely explained by the greater frequency of hematomas following DSA compared with CE-MRA (1.8% for DSA; 0.4% for CE-MRA, $P<0.0001$). Of note, the proportion of subjects having renal complications following either procedure was similar; however, after adjusting for comorbid conditions (chronic renal disease was three times more prevalent among the CE-MRA group), the odds of a renal complication following DSA were not significant.

Approximately one-third of the patients had a revascularization procedure or amputation within the year following their initial imaging procedure (Table 3). More patients had an intervention following DSA (DSA 41% versus CE-MRA 23%, $P<0.0001$). Patients who underwent DSA as the first imaging procedure were twice as likely to have an intervention with an amputation (adjusted OR 2.36; 95% CI 1.79 to 3.12, $P<0.0001$) or an amputation only (adjusted OR 1.99; 95% CI 1.54 to 2.59, $P<0.0001$). Among 16,026 patients who underwent DSA, 1679 (10.48%) had PTA or stenting performed on the same day, compared with 15 of the 3183 patients (0.47%)

who underwent CE-MRA. Bypass surgery was performed on the same day as DSA in 28 of 16,026 patients (0.17%). Amputations were performed on 63 patients on the same day as the imaging procedure, of which 61 (0.38%) were performed following DSA.

A comparison of the characteristics of patients who underwent an intervention with those of patients who did not are shown in Table 4. Patients undergoing interventions were more likely to have diabetes, cardiovascular disease and pre-existing PVD. Similar percentages of subjects died within the year following either imaging modality regardless of whether they had an intervention. Caucasians were more likely to have an intervention; however, the greater percentage of unknown race or ethnicity in the nonintervention group limits the interpretation because the other race categories were similar in both groups.

DISCUSSION

In the present retrospective study of 19,209 patients undergoing diagnostic imaging of the lower extremities, the number of new patients imaged remained relatively constant over the follow-up period. The overall rates of diagnostic imaging remained approximately the same. The proportion of new imaging procedures shifted over time in favour of CE-MRA over DSA, particularly for patients with diagnoses of chronic renal disease. This may reflect the belief that CE-MRA is safer than DSA in patients with underlying renal disease. Owing to the observation period of the present study (1999 to 2004) and the recent concern over the risk for gadolinium-associated nephrogenic systemic fibrosis (NSF), these trends may not persist. Complications following diagnostic imaging, although rare, were twice as likely to occur following DSA. The majority of these complications were vascular (ie, hematomas).

Despite the seemingly high burden of illness and prevalent disease, on average, only 38% of new patients imaged with either modality underwent lower extremity interventions within one year of imaging. The majority of these procedures were revascularizations; however, 20% of all patients who underwent interventions received amputations. Amputation is not the preferred outcome because the goal is early diagnosis and limb preservation. This presents what some may consider a paradox. Few people go on to have surgery following diagnostic imaging, and of those that do have surgery, a fair number have amputations. One could make the argument that DSA was being used more appropriately because a greater percentage of those who were imaged had a subsequent surgical intervention. However, subjects following a DSA were also more likely to have had an amputation, suggesting that perhaps they were indeed 'sicker', but it also suggests the pathway to receiving a meaningful intervention occurred late in the disease process.

In addition to describing the surgical procedures following diagnostic imaging, we also described the complications likely attributable to the imaging modalities. In the literature, the most frequent complications reported with DSA were vascular, which occurred in up to 7.3% of cases, with a rate of 1.3% for systemic complications (16). Our complication rates are similar; hematomas account for the majority of the complications. Hematomas remained a significant and important type of complication following DSA after adjustment for potential confounders. Although residual confounding may explain group differences, our findings are consistent with the understanding that vascular complications are more commonly associated with

TABLE 4
Comparison of characteristics between patients receiving and not receiving interventions following lower extremity imaging procedures in the Veterans Health Affairs system (1999 to 2004)

Characteristic, n=19,209	No interventions (n=11,920)	Interventions (n=7289)	P
Mean age, years	65.4±10.7	64.3±9.8	<0.0001
Men	11,693 (98)	7211 (99)	<0.0001
Diabetes mellitus	4534 (38)	3002 (41)	<0.0001
Cardiovascular disease	7792 (65)	4852 (67)	0.03
Peripheral vascular disease	9859 (83)	6800 (93)	<0.0001
History of previous PTA, stent, bypass, amputation or diagnosis of claudication	2101 (18)	1201 (16.5)	0.04
Chronic renal disease	801 (6.7)	503 (6.9)	0.63
Hypertension	9528 (80)	5760 (79)	0.13
Race			
Caucasian	8051 (68)	5231 (72)	<0.0001
African-American	1398 (12)	901 (12)	
Other	495 (4.2)	294 (4.0)	
Unknown	1976 (17)	863 (12)	
Died within one year of imaging procedure	834 (7.0)	551 (7.6)	0.14

Results presented as n (%); mean age presented as mean ± SD. PTA Percutaneous transluminal angioplasty

DSA – a more invasive procedure compared with CE-MRA. All other complications, including renal, were infrequent. However, the United States Food and Drug Administration recently raised concerns about the occurrence of NSF and nephrogenic fibrosing dermopathy among patients with moderate to end stage renal disease who underwent MRI (17). Our study demonstrates a preferential likelihood of subjects with underlying renal disease for undergoing PAOD diagnostic testing with CE-MRA rather than DSA. The period of the present study (1999 to 2004) did not expose any occurrence of NSF or nephrogenic fibrosing dermopathy among patients with moderate to end stage renal disease who underwent CE-MRA. This preference highlights the need to evaluate any untoward outcomes for the potential of confounding. Our study did not find a greater risk for renal failure after CE-MRA imaging than after DSA imaging, after adjusting for baseline risk factors. However, our complication rates in general may be underestimated because we relied on clinical events that generate ICD-9-CM codes.

Given the recommendations against screening asymptomatic PAOD, it was our assumption that routine use of diagnostic imaging was being used to inform surgical decision-making and to guide interventions. Whether the surgery rate was lower than expected is subject to debate, but the question does perhaps drive some of the concerns over whether diagnostic imaging drives up the costs of hospital care (18). One explanation for this low proportion of limb-preserving interventions may be that patients presented too late for meaningful interventions. Amputation-free survival is greatly reduced among patients with renal impairment and underlying coronary artery disease (19). Morbidity was indeed high in our study population, as evidenced by prevalent coronary artery disease, diabetes and renal disease, and may explain why a small percentage of those imaged received limb-preserving surgical interventions. Perhaps subjects had additional comorbid conditions that reduced their chances of surviving a surgical procedure.

One potential explanation as to why only one-third of the subjects undergoing diagnostic imaging received limb-preserving surgery was due to mortality. The fact that 7% of the study cohort died in the year following their imaging is a testament to the heightened disease burden of the population undergoing imaging. However, the proportion dying after imaging was the same regardless of whether an intervention was performed.

Another possibility is that patients were found not to have PAOD or disease severe enough to necessitate a revascularization procedure. The latter is more likely, given that the majority of the study population had a pre-existing diagnosis or was diagnosed following the imaging test. If a surgical intervention was not indicated, they may have opted for medical management. Recent studies suggest that antiplatelet therapies, statins, angiotensin receptor inhibitors and exercise improve survival rates (20). However, we were not able to establish whether these therapies were newly initiated or were intensified following imaging.

Study limitations and strengths

Unfortunately, we were unable to provide definitive insight as to why some patients received limb-preserving surgery while the majority did not. Answering this question is complex because it involves assessing physician and patient decision-making data, which are not readily attainable, particularly for a study of this size. However, the present study is one of the first studies of sufficient scale in a large health care system to evaluate the patterns of diagnostic imaging of lower extremities and describe the clinical outcomes that follow diagnostic imaging. We believe our study illustrates the need for the prospective evaluation of diagnostic screening to determine how to optimize treatments and therefore improve outcomes of patients diagnosed with PAOD. For instance, during the present

study window, CT angiography was not readily available in the VHA system. As this diagnostic imaging modality becomes more pervasive in the VHA system, it will be important to assess its use with regard to outcomes.

CONCLUSIONS

The overall rates of diagnostic imaging remained approximately the same between 1999 and 2004, while the proportion of new imaging procedures shifted over time in favour of CE-MRA over DSA, particularly for patients with a diagnosis of chronic renal disease. Despite the seemingly high burden of illness and prevalent disease, on average, only 38% of the new patients imaged with either modality underwent lower extremity interventions within one year of imaging. Hematomas remained a significant and important type of complication following DSA, after adjustment of potential confounders. We believe our study illustrates the need for the prospective evaluation of diagnostic screening to determine how best to deploy screening strategies that will optimize diagnostic imaging and treatments in patients diagnosed with PAOD. By continuing to study trends in vascular imaging relative to outcomes, the information gained should eventually lead to an efficient diagnostic and treatment algorithm. This is paramount because we continue to grapple with how to best apportion our health care spending.

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