Pharmacist-initiated peripheral arterial disease screening program in a community pharmacy setting

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Abstract

Objectives: To evaluate the feasibility of implementing a pharmacist-initiated peripheral arterial disease (PAD) screening program in the community setting and to determine the ability of this screening to increase the number of patients identified with PAD.

Design: Prospective study.

Setting: Three locations of a large pharmacy grocery chain in the Cincinnati and Dayton, OH, area, from February 3, 2009, to May 31, 2009.

Patients: 39 patients 50 years or older with a diagnosis of hypertension, dyslipidemia, and/or diabetes.

Intervention: PAD screening, including an assessment of PAD symptoms and an ankle–brachial index (ABI) calculation using a handheld Doppler. Patients who screened positive were provided with appropriate counseling on possible treatments, medications, and lifestyle modifications and referred to their primary care physician for further evaluation.

Main outcome measures: Successful implementation of program, number of patients referred to their physician for follow-up, and number of patients with ABI scores indicating PAD.

Results: 17 of the 39 patients screened (44%) were referred to their physician for follow-up because they had ABI scores indicating PAD, symptoms indicating PAD, or noncompressible vessels. Using ABI scores, PAD was detected in nine patients (23.1%). Pharmacists implemented the program successfully.

Conclusion: This study successfully demonstrated the feasibility of implementing a pharmacist-initiated PAD screening program in the community setting. The implementation of this screening program included the acquisition of affordable equipment, training of pharmacists, and access to the appropriate patient population. This study also was effective in increasing the recognition of PAD in patients screened in the community setting.

Keywords: Pharmacy services, peripheral arterial disease, screening program, community pharmacy.

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Peripheral arterial disease (PAD), also known as peripheral vascular disease, affects approximately 8–12 million Americans 65 years or older.[1,2] It is accompanied by a high likelihood of symptomatic cardiovascular and cerebrovascular morbidity and is ultimately a risk factor for lower-extremity amputations. Risk factors for PAD are similar to those for coronary artery and cerebrovascular diseases: smoking, diabetes, age, hypertension, dyslipidemia, and history of stroke or myocardial infarction.

More than one-half of patients with PAD are asymptomatic, 33% experience atypical symptoms (such as nonspecific exercise intolerance and hip or other joint pain), and approximately 15% present with typical symptoms (such as intermittent claudication, which is defined as pain, cramping, or aching in the calves, thighs, or buttocks that is exacerbated with exercise and relieved by rest).[2] Because patients with PAD seldom present with typical symptoms, PAD is frequently underdiagnosed.[3–6] The PARTNERS (PAD Awareness, Risk and Treatment: New Resources for Survival) study found that if physicians relied on patients to report symptoms of intermittent claudication, only 10–15% of cases would be diagnosed.[7]

Growing recognition of the detrimental impact of PAD has spurred an interest in early detection. In 2008, the acting surgeon general issued a "call to action to prevent deep vein thrombosis and pulmonary embolism."[8] The plan emphasized an increased awareness among patients and health care providers about risk factors, triggering events, and symptoms of deep vein thrombosis, pulmonary embolisms, and other vascular diseases. It also called for the development of evidence-based practices for screening, preventing, diagnosing, and treating these conditions, especially among high-risk groups.[8] Because of the high estimated prevalence of PAD in patients with diabetes, a screening should be performed in patients older than 50 years who have diabetes and should be repeated every 5 years.[9]

Measurement of the ankle–brachial index (ABI) is an efficient, objective, and practical way to assess the presence and severity of PAD and therefore is ideally suited for inclusion in a screening program.[3] ABI is a quantitative measure of systolic-only blood pressure in the ankles and arms using a handheld Doppler device; the values obtained are used to calculate a ratio (i.e., ABI) (Table 1). ABI has a reported sensitivity of 95% and specificity of almost 100% for detecting PAD.[3] The test is valid in assessing prognosis in both symptomatic and asymptomatic patients. Its numerical value has a high correlation with mortality over 5 and 10 years; a lower ABI value is associated with a higher risk of cardiovascular and cerebrovascular morbidity.[3] An ABI greater than 1.3 could be associated with increased cardiovascular events.

Pharmacists are in a unique position to implement interventions aimed at increasing the detection of PAD. Research has shown that nurses in a community setting,[5] collaboration between physicians and nurses in a primary care setting,[4] and collaboration between physicians and pharmacists in a primary care setting[6] could effectively detect PAD in previously unscreened patients. However, no studies of pharmacists in the community setting screening for PAD without the aid of physician collaboration have appeared in the literature.

At a Glance

Synopsis: The feasibility of implementing a pharmacist-initiated peripheral arterial disease (PAD) screening program in the community setting was successfully demonstrated at three locations of a large pharmacy grocery chain in the Cincinnati and Dayton, OH, area. Of the 39 patients screened, 17 (44%) were referred to their physician for follow-up as result of ankle–brachial index (ABI) scores indicating PAD, symptoms indicating PAD, or noncompressible vessels. PAD was detected in nine patients (23.1%), according to ABI scores.

Analysis: *The current work showed that community pharmacists can successfully implement programs that improve disease detection for patients at risk for PAD. By increasing early detection, pharmacists can encourage early treatment of PAD. One barrier to PAD screening was lack of space for massage tables, which were needed for proper service provision, at many of the potential community pharmacy screening locations. As the profession of pharmacy continues to expand clinical services, adequate facility design for additional private space should be considered.*

Objectives

The purpose of this study was to develop, implement, and evaluate a PAD screening program in a community pharmacy. We sought to (1) implement a pharmacist-initiated PAD screening program in the community setting and (2) determine the ability of this screening to increase the number of physician referrals for patients who are at risk for PAD.

Methods

The Cincinnati–Dayton Kroger Marketing Area consists of 103 pharmacies, 28 of which have established private or semiprivate patient care centers. Many services and programs are offered by clinical pharmacists at the patient care centers.[10] The diabetes and heart healthy coaching programs offer education, training, and disease management tools to patients with diabetes, hypertension, and/or hypercholesterolemia through collaborative agreements with private insur-

Table 1. Interpretation of ankle–brachial index[3]

Ankle–brachial index	Description
>1.30	Noncompressible
0.90–1.30	Normal
0.70–0.89	Mild PAD
0.40–0.69	Moderate PAD
<0.40	Severe PAD

Abbreviation used: PAD, peripheral arterial disease.

ance companies. Kroger currently has contracts with several self-insured employer groups that provide reimbursement for these pharmacist services. Patients insured by these employer groups can enroll in the coaching programs provided at the pharmacy at no cost to the patient.

Patients enrolled in the diabetes or heart healthy coaching programs who were 50 years or older were eligible for the PAD screening. Inclusion criteria included patients with at least one PAD risk factor, including hypertension, hypercholesterolemia, or diabetes, which was a prerequisite for either of the coaching programs, and age 50 years or older. Patients aged less than 50 years were excluded. Participants were recruited through direct discussions during coaching appointments.

Program development

Three of the 28 patient care centers, which are staffed by clinical pharmacists, were selected because they had adequate space to perform the screenings (i.e., private and ample room for patients to lie down on tables). The screenings required patients to lie down; therefore, massage tables were purchased. The start-up costs for each location was estimated at $950 (Table 2). The cost of equipment and supplies was covered by a grant from the APhA Foundation ($1,000) and support from Kroger. Six clinical pharmacists were trained to use a handheld Doppler using the manufacturer's training CD, and the pharmacists were educated on PAD using an education packet created by the community pharmacy resident. PAD education included signs and symptoms, lifestyle modifications for symptom improvement, and current guidelines for treatment (www.padcoalition.org).

A PAD screening protocol was developed to ensure standardization across the three sites. Two forms were created, including a risk assessment worksheet to measure risk factors and a questionnaire to assess possible intermittent claudication. The questionnaire was used to measure whether the patient had typical symptoms associated with PAD. Questions from two validated intermittent claudication questionnaires (ICQs) were combined to create a more comprehensive questionnaire (Appendix 1 in electronic version of this article, available online at www.japha.org).[11,12] The ICQ had five questions, with a total of 13 points possible; a score of 4 or more indicated possible signs and symptoms of typical PAD. The program began February 3, 2009, and ended May 31, 2009. The University of Cincinnati Institutional Review Board exempted this study protocol from review because of the low risk to participants.

Program overview

The PAD screening was incorporated into an upcoming heart healthy or diabetes coaching appointment and performed by clinical pharmacists. Patients were asked in advance to wear appropriate clothing (i.e., short sleeve shirts and short socks) in order to use the Doppler on the arm and ankle arteries. At the beginning of the screening appointment, patients signed Kroger-designed consent, release, and waiver liability forms, allowing the trained pharmacists to perform the ABI and screening. Clinical pharmacists then administered screening forms inquiring about personal and family history, including PAD, and administered ICQs. Patients were asked to lay supine for 5 minutes before the ABI was measured to ensure an accurate blood pressure reading. After ABI was calculated, pharmacists educated patients on interpretation of ABI values and their PAD risk factors. Pharmacists provided appropriate counseling on possible treatments, medications, and lifestyle modifications. Patients were referred to their primary care physician if ABI values were less than 0.9, greater than 0.9 with symptoms reported on ICQ, or greater than 1.30 or if blood pressure was unable to be detected. Physician referral was accomplished by instructing patients to follow-up with their primary care physician within 6 months and by faxing a physician communication forms with patient results to physicians' offices. The screening and counseling took approximately 15 minutes to complete (including consent, questionnaire, and 5-minute resting period).

Table 2. Costs for PAD screening per location

Expense	Cost ($)
Nicolet Elite 200 ultrasound Doppler; includes training CD and booklet	750
Massage table	150
Ultrasound gels and T-Spray cleaning solutions	25
Patient information guides, brochures, printing supplies	25
Total	950

Abbreviation used: PAD, peripheral arterial disease.

Results

Of the 121 patients enrolled in the heart healthy or diabetes coaching programs at the three patient care centers, 39 completed the screening program (Figure 1). The baseline characteristics of the 39 patients screened for PAD are shown in Table 3. No patients reported active nicotine use. One documented case of PAD was noted at baseline and was therefore excluded from the study.

PAD was detected in 9 of the 39 patients screened (23.1%). Of those, seven patients had an ABI score indicating mild PAD, one patient had an ABI indicating moderate PAD, and one patient had an ABI indicating severe PAD. In addition, two patients had an ABI greater than 1.3, indicating noncompressible blood vessels. Six patients indicated symptoms for PAD as shown by their ICQ scores, but they had normal ABI scores. Therefore, 17 of 39 patients (44%) were referred to their physician for follow-up. Patients with ABI scores indicating PAD had a greater rate of diabetes (77.78% vs. 35.72%, $P = 0.03$) than patients with normal ABI scores (Table 4).

The cost to provide this service was estimated because cost data were not collected. As previously stated, start-up costs were estimated at $950 for each location. Using an estimate of $65.05 per hour as the mean hourly wage of a community pharmacist in 2009,[13] the labor cost for a pharmacist to provide the 15-minute assessment was $16.26. Therefore,

Table 3. Baseline characteristics of screened patients

Characteristic	No. (%)
n	39
Mean age (years)	65.0
Age (years)	
50–69	26 (66.7)
≥70	13 (33.3)
Men	14 (35.9)
PAD risk factors	
Diabetes	17 (43.6)
Hypertension	37 (94.8)
Dyslipidemia	34 (87.2)
Nicotine use	0

Table 4. Patient characteristics by ABI score

	PAD (ABI <0.90) No. (%)	Normal (ABI 0.90–1.30) No. (%)	P[a]
n	9	28	
Age (years), mean ± SD	67.67 ± 8.80	65.82 ± 10.82	0.65
Diabetes	7 (77.78)	10 (35.71)	0.03
Hypertension	9 (100.00)	26 (92.86)	0.57
Dyslipidemia	9 (100.00)	24 (85.71)	0.31
Nicotine use	0	0	0
ABI (mean ± SD)	0.73 ± 0.18	1.06 ± 0.10	<0.01
ICQ score (mean ± SD)	5.22 ± 5.14	2.11(4.04)	0.068

Abbreviation used: ABI, ankle–brachial index; ICQ, intermittent claudication questionnaire; PAD, peripheral arterial disease.
Patients with an ABI >1.3 are excluded from this table.
[a]For continuous variables, t test was used to compare means. For categorical variables, Fisher's chi-square test was used.

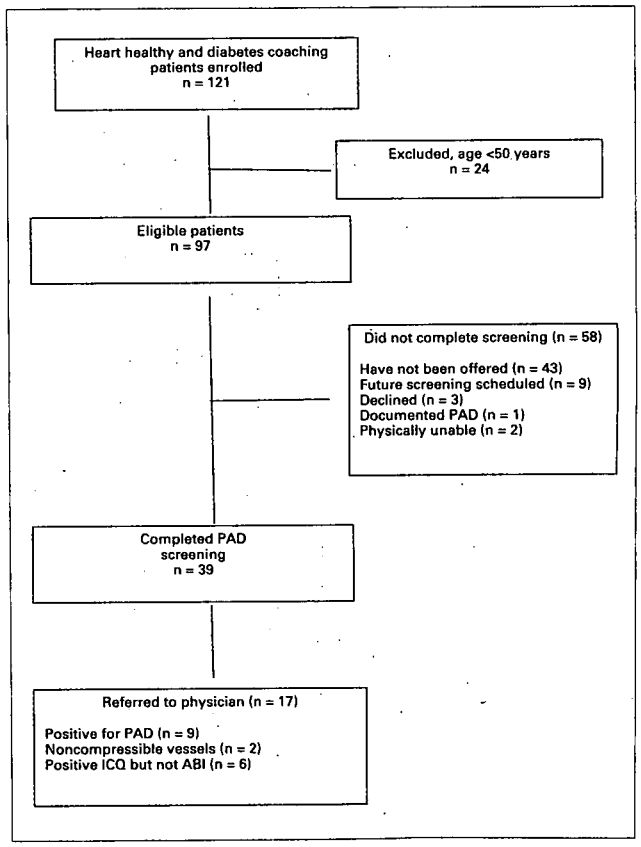

Figure 1. Participant enrollment in the heart healthy or diabetes coaching programs
Abbreviations used: ICQ, intermittent claudication questionnaire; PAD, peripheral arterial disease.

it was estimated that if patients paid a small fee of $25–30 for the screening, 32–38 patients would need to be screened to compensate for the start-up costs of $950 per location. Subsequent screenings at $30 would yield a profit of $13.74.

Discussion

This study successfully demonstrated the feasibility of implementing a pharmacist-initiated PAD screening program in the community setting and the ability of this screening to increase the number of patients identified with PAD. Of screened patients, 23% were found to have an ABI indicative of PAD. This rate of detection is similar to other studies.[5–7] Based on these results, the number of at-risk patients needed to screen to identify one person with PAD was four patients 70 years or older and six patients 50–69 years of age.

A PAD screening program can be integrated into a community pharmacy setting reasonably and affordably. Although a cost was associated with purchasing the Doppler device, this was a one-time cost and other supplies were less expensive. One barrier was lack of space for massage tables. We had the opportunity to provide PAD screenings to a local senior center, where adequate private space for massage tables was not an issue, unlike many pharmacies. In this senior population, many of the patients used nicotine and 43.4% had an ABI indicative of PAD. As the profession of pharmacy continues to expand clinical services, adequate facility design for additional private space should be considered.

The current study demonstrated that community pharmacists can successfully implement programs that improve disease detection for patients at risk for PAD. By increasing early detection of PAD, pharmacists can encourage early treatment of the disease.

Limitations

This study had several limitations. The sample population was small. A total of 43 patients were eligible for but not offered the PAD screening, primarily because of difficulties scheduling appointments within the time frame of the study. This time constraint was artificially imposed by the study timeline in order to complete this project by the end of the residency year. After the completion of the project, Kroger pharmacy continues to provide PAD screenings as part of their clinical pharmacy services. No willingness-to-pay assessment was completed, and the time needed to schedule appointments

was not included in the breakeven analysis. Also, although a patient or pharmacist satisfaction survey was not part of this project, anecdotally, pharmacists found that the Doppler was easy to use, even in patients with diabetes who were more inclined to noncompressible veins. Another limitation was that the ICQ was not validated or pilot tested. Although the questionnaire used was a combination of questions used in previous studies, it could have falsely elevated or improperly determined claudication. Also, the study did not follow patients beyond the screening date or faxed physician referral to ensure proper diagnosis or medication changes. Future plans could include continued monitoring of these patients for diagnosis or therapy changes.

Conclusion

This study successfully demonstrated the feasibility of implementing a pharmacist-initiated PAD screening program in the community setting. The implementation of this screening program included the acquisition of affordable equipment, training of pharmacists, and access to the appropriate population. This study also was effective in increasing the recognition of PAD in at-risk patients screened in the community setting.

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