



TITLE: Foot Care for Patients with Peripheral Vascular Disease: A Review of the Guidelines

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CONTEXT AND POLICY ISSUES:

Peripheral vascular disease increases the risk of developing foot ulcers and contributes to poor healing.¹ Peripheral vascular disease is common among patients with diabetes who may also suffer from peripheral neuropathy and foot deformities which increase the risk of developing ulcers.¹ Foot ulcers worsen physical, psychological, and social quality of life and may lead to amputation.¹

Information on screening tools and guidelines on the prevention and treatment of foot ulcers are required when developing foot care services.

RESEARCH QUESTIONS:

1. What are the evidence-based guidelines for preventing or managing foot ulcers in patients with peripheral vascular disease?
2. What are the evidence-based screening assessments for preventing or managing foot ulcers in patients with peripheral vascular disease?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including OVID Medline and Embase, the Cochrane Library (Issue 3, 2009), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between 2004 and August 2009. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, and guidelines. Reference lists were hand searched for other relevant articles.

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Guidelines, systematic reviews, or health technology assessments were included if they focused on the screening, prevention, or management of foot ulcers in patients with peripheral vascular disease, peripheral neuropathy, or diabetes. The population of interest was expanded because peripheral vascular disease, peripheral neuropathy, and diabetes are interrelated conditions that contribute to an increased risk of foot ulcers. Systematic reviews or health technology assessments of individual treatments for foot ulcers were excluded.

SUMMARY OF FINDINGS:

Two systematic reviews evaluating screening tools to identify patients at risk for diabetic foot ulcers were found. No relevant health technology assessments were identified.

The search identified 11 guidelines focused on foot care in patients with peripheral vascular disease, diabetes, or peripheral neuropathy (Table 1). Appendix 1 lists guidelines focused on the management of diabetes which include some recommendations regarding foot care. Appendix 2 lists other reports that may be of interest.

Systematic reviews

Crawford et al.² conducted a systematic review to determine the predictive value of diagnostic tests, clinical signs, and patient's history in estimating the risk of diabetic foot ulceration. The report included five case control and 11 cohort studies. Patients were followed from 12 weeks to four years. The incidence of foot ulcers varied from 8% to 17%. High peak plantar pressures and high vibration perception thresholds were a statistically significant risk factor for ulceration. Poor cutaneous sensation (assessed using a monofilament) and the absence of ankle reflexes were also statistically significantly associated with future ulceration. Patients with a past history of ulceration, amputation, or lower limb bypass surgery were more likely to develop diabetic foot ulcers. The predictive value of transcutaneous oxygen tension, hemoglobin A_{1c}, ankle brachial indices, fasting blood glucose, serum creatinine, or duration of diabetes were unclear. The predictive value of clinical signs such as pedal pulses, skin color, skin texture, hairlessness of lower legs, or condition of the toenails were not assessed. The authors concluded that diagnostic tests and physical signs (biothesiometry [vibration perception], monofilaments, plantar pressure, and ankle reflexes) are helpful in predicting the risk of diabetic foot ulcers.²

Singh et al.¹ systematically reviewed the evidence of screening methods to identify patients at risk for diabetic foot ulcers. The complete methods used to conduct the systematic review were not reported. The total number and description of included studies were not reported. Screening for loss of protective sensation, elevated plantar pressure, and peripheral vascular disease were evaluated. In three prospective cohort studies, monofilament testing identified patients at risk for foot ulcers with a sensitivity of 66% to 91% and specificity of 34% to 86%. Positive predictive values (PPV) were 18% to 39% and negative predictive values (NPV) were 94% to 95% (see Appendix 3 for a guide to summary statistics for diagnostic tests). In two prospective cohort studies, a biothesiometer (vibration perception threshold >25 V) had a sensitivity of 83% to 86% and specificity of 57% to 63% in predicting foot ulcers (PPV 20% to 32%; NPV 95% to 97%). The authors reported that tuning fork results were less predictive of ulceration than a monofilament (sensitivity 55% to 61%; specificity 59% to 72%). In a case control study, a pressure mat device to test for elevated plantar pressure had a sensitivity of 70% and a specificity of 65% for predicting ulceration at a peak barefoot dynamic pressure threshold of 70 N/cm². Depending on the pressure threshold used, the PPV varied from 17% to 49% and the NPV from 82% to 90%.¹ The review authors reported that patients with previous foot ulceration or amputation, low ankle brachial index, duration of diabetes >10 years, poor glycemic control,

and impaired visual acuity were all associated with a statistically significant increased risk of foot ulceration.¹ The authors concluded that there was substantial evidence to support screening all diabetic patients to identify those at risk for foot ulcers.¹

Guidelines

The guidelines included in this report are listed in Table 1. Three guidelines contained specific recommendations for foot care in patients with peripheral vascular disease.³⁻⁵ The other eight guidelines focused on the prevention and management of foot ulcers in patients with diabetes or peripheral neuropathy.⁶⁻¹³ Two of the guidelines were Canadian.^{7,9} All but one guideline⁸ reported on the methods used to develop the recommendations. Ten guidelines conducted a systematic review of the literature.^{3-5,7,9-14} Methods for peer review were not clearly reported by six guidelines.^{3,5,11,15-17}

The three guidelines for patients with peripheral vascular disease covered a similar scope focusing on assessment and treatment of ulcers.^{3,5,16} The guidelines recommended assessing causative and contributing factors for ulceration, documenting the patient history and prior treatments, relevant laboratory tests, and conducting diagnostic tests. A comprehensive lower extremity evaluation with documentation of the wound characteristics and evidence of infection or osteomyelitis was suggested.^{3,5,16}

Recommendations on treatment of ulcers covered cleansing, debridement, dressings, and use of antiseptics or topical antibiotics.^{3,5,16} Management of pain, edema and infection; adjunctive therapies; exercise programs; and surgical options were also discussed.^{3,5,16} Recommendations for monitoring and referral were also listed.^{3,16} One guideline also addressed nutritional support³ and two discussed patient education.^{3,16} One guideline discussed interventions to prevent ulcer recurrence.⁵

Table 1. Evidence-Based Guidelines for the Screening, Prevention, and Management of Foot Ulcers

Organization	Year	Title	Quality assessment				
			Objectives and population stated	Methods to develop stated	Based on systematic review of literature	External peer review conducted	Level of evidence stated for recommendations
Peripheral vascular disease							
Wound, Ostomy and Continence Nurses Society ³	2008	Guideline for management of wounds in patients with lower-extremity arterial disease	Yes	Yes	Yes	NR	Yes
Wound, Ostomy and Continence Nurses Society ⁵	2005	Guideline for management of wounds in patients with lower-extremity venous disease	Yes	Yes	Yes	NR	Yes
American Society of Plastic Surgeons ^{4,17}	2007	Evidence-based clinical practice guidelines: chronic wounds of the lower extremity	Yes	Yes	Yes	No	Yes
Diabetes or peripheral neuropathy							
International Working Group on the Diabetic Foot ^{6,14,16}	2008	Practical guidelines on the management and prevention of the diabetic foot	Yes	Yes	Yes	No	No
Registered Nurses' Association of Ontario ⁷	2007	Reducing foot complications for people with diabetes 2007 supplement Reducing foot complications for people with diabetes (2004)	Yes	Yes	Yes	Yes	Yes
American College of Foot and Ankle Surgeons ^{8,15}	2006	Diabetic foot disorders: a clinical practice guideline	Yes	NR	No	NR	No
Registered Nurses' Association of Ontario ^{9,18}	2005	Assessment and management of foot ulcers for people with diabetes	Yes	Yes	Yes	Yes	Yes
Infectious Diseases Society of America ^{10,19}	2004	Diagnosis and Treatment of Diabetic Foot Infections	Yes	Yes	Yes	Yes	Yes
Wound, Ostomy, and Continence Nurses Society ¹¹	2004	Guidelines for management of wounds in patients with lower-extremity neuropathic disease	Yes	Yes	Yes	NR	Yes

Organization	Year	Title	Quality assessment				
			Objectives and population stated	Methods to develop stated	Based on systematic review of literature	External peer review conducted	Level of evidence stated for recommendations
National Institute for Clinical Excellence ^{12,20}	2004	Type 2 diabetes: Prevention and management of foot problems	Yes	Yes	Yes	Yes	Yes
Royal Melbourne Hospital ¹³	2004	Creation of a multidisciplinary, evidence based, clinical guidelines for the assessment, investigation and management of acute diabetes related foot complications	Yes	Yes	Yes	Yes	Yes

NR=not reported or incomplete reporting

Limitations

Three guidelines were specific to patients with peripheral vascular disease; however, none of these were developed in Canada. Therefore, these guidelines may not be generalizable to the Canadian healthcare system.

There are numerous guidelines on the prevention and management of diabetic foot ulcers. Although peripheral vascular disease is common among diabetic patients, some recommendations from these diabetic foot care guidelines may not be relevant to non-diabetic patients with foot ulcers. This may also be true for screening methods evaluated in the two systematic reviews.^{1,2}

One of the systematic reviews did not report their methods fully.¹

It was not possible to thoroughly assess the methods used to develop the guidelines, and the guideline content, due to the volume of guidelines identified in the HTIS search.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

There are several guidelines for the screening, prevention, and management of foot ulcers in patients with peripheral vascular disease and related co-morbidities (diabetes or peripheral neuropathy). The three guidelines which included specific recommendations for patients with peripheral vascular disease covered a similar scope. These guidelines provided recommendations on patient assessment, lower extremity examination, laboratory and diagnostic tests. Management of the wound, edema, pain, and infection were discussed. The guidelines also covered adjunctive treatments, surgical options, preventative interventions, and patient follow-up. The identified systematic reviews indicated that diagnostic tests and screening of diabetic patients were helpful to predict risk of foot ulcers. Clinical signs and patient's history may be useful to predict those at risk for foot ulceration.

PREPARED BY:

Gaetanne Murphy BSc Pharm, Research Officer
Emmanuel Nkansah, MLS, MA, Information Specialist
Health Technology Inquiry Service
Email: htis@cadth.ca
Tel: 1-866-898-8439

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APPENDIX 1: Guidelines for the Management of Patients with Diabetes

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APPENDIX 2: Other Studies of Interest

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APPENDIX 3: Guide to Summary Statistics of Diagnostic Tests²¹

In order to test the accuracy of an experimental test, comparison to a reference standard test is required. The results of the experimental test are then compared to the reference test to determine the number of true and false, positive and negative results. The results of the reference standard test must be reliable or the performance of the experimental test will be poorly estimated.

	Patients with disease (positive reference test)	Patients without disease (negative reference test)	
Positive experimental test	True positive	False positive	Total positive
Negative experimental test	False negative	True negative	Total negative
	Total with disease	Total without disease	Total patients

Sensitivity = number of true positives / total number with the disease (ie. the proportion with the disease that has positive test results)

Specificity = number of true negatives / total number without the disease (ie. the proportion without the disease that have negative test results)

Diagnostic accuracy = (number of true positive and true negative)/total number of patients

Positive predictive value = number of true positives/total positive

Negative predictive value = number of true negatives/total negative

Example:

	Number of patients with disease (positive reference test)	Number of patients without disease (negative reference test)	
Positive experimental test	60	5	65
Negative experimental test	7	28	35
	67	33	100

Sensitivity = 60/67 or 90%

Specificity = 28/33 or 85%

Diagnostic accuracy = (60+28)/100 or 88%

Positive predictive value= 60/65 or 92%

Negative predictive value = 28/35 or 80%