Journal of Rehabilitation Research and
Development Vol. 31 No. 4, November 1994
Pages 357–362

CLINICAL REPORT

Who Is At Risk of Limb Loss And What To Do About It?

An Invited Presentation at the VA Rehabilitation Conference, sponsored by Prosthetics and Sensory Aids Services, VACO, Frederick Downs, Director, April 28, 1994, Las Vegas, NV

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Abstract—Lower limb amputations were performed on over 105,000 individuals in United States short-stay hospitals between 1989 and 1992. Additional amputations were performed in VA, military, Indian Health, and charitable orthopaedic hospitals. Half of all lower extremity amputations occurred in individuals with diabetes. When the causal chain leading to diabetic amputations was examined in 80 consecutive patients at the VA Medical Center, Seattle, WA, 23 unique pathways were identified. Multiple pathway components were identified for 96% of patients, while in 4% a single ischemic pathway was sufficient in itself to require amputation.

The majority of the scenarios leading to amputation began when patients with absent peripheral sensation sustained a pivotal event that initiated the causal chain to amputation. In nearly half the patients, this event was footwear-related. The pivotal event was followed by ulceration and faulty wound healing in 73% of patients.

Each year thousands of individuals with diabetes undergo amputation in VA facilities, resulting in substantial cost to the Department of Veterans Affairs and to themselves. If the VA is to address the prevention or delay of limb loss, the causal pathway information indicates that attention to the footwear of diabetic patients is necessary.

Key words: *amputation, causal pathway, diabetes, footwear, ulcer prevention.*

INTRODUCTION

On average, 109,411 individuals underwent amputation in United States (US) short-stay hospitals between 1989 and 1992. Approximately 96 percent of these individuals amputations were lower limb and 4 percent were upper limb. Thousands of additional amputations were performed at military, Department of Veterans Affairs (VA), Indian Health, and charitable orthopaedic hospitals. Indications for amputation corresponded with the age of the individual, such that younger individuals experienced more congenital-, malignancy-, and trauma-related amputations, compared to older individuals whose amputation codes reflected multiple pathophysiologic mechanisms (e.g., diabetes, ischemia, and infection). During 1989–1992, 51 percent of the lower limb amputations in US short-stay hospitals occurred in individuals with diagnosed diabetes, yet persons carrying the diagnosis of "diabetics" represent only 2.5 percent of the US population (1). Be-

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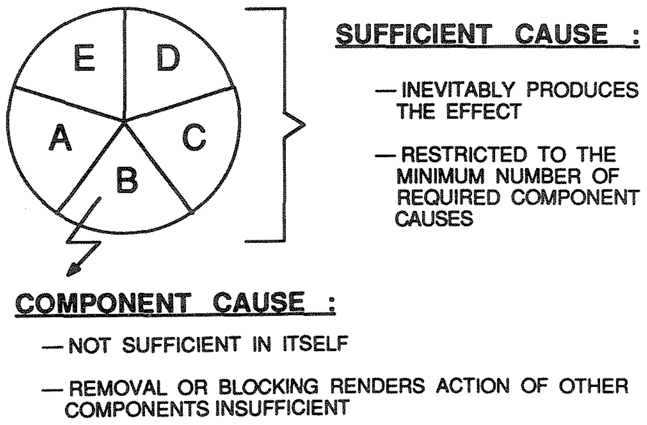
This work was supported by the Department of Veterans Affairs Health Services Research and Development, Rehabilitation Research and Development Service and the Diabetes Research and Education Foundation.

tween 1980 and 1990, a 29 percent increase in the age-adjusted diabetic amputation rates was noted. These amputation rates were uniformly higher in males than in females, in blacks than in whites, and increased with advancing age. The length of hospitalization for amputation fell from 35.8 days to 20.6 days during this interval (2).

Causal Pathways and Risk Factors For Diabetic Amputation

To determine why individuals with diabetes experience excessive lower limb loss, important pathophysiologic factors and other events leading to amputation need to be identified. The causal pathway model described by Rothman has been used for this purpose (3,4). The two major components of the model, "sufficient" and "component" causes, are illustrated in **Figure 1.** A sufficient cause is a set of minimal conditions and events that inevitably produce the outcome with no superfluous conditions or events. In disease etiology, when the components assembled form a sufficient cause, the onset of disease occurs. A component cause is not sufficient in itself to cause disease but is one of several components or pieces that must be assembled for the disease to occur. The Rothman model allows assimilation of empiric information from representative cases and considers different contributions along a disease course from the time of the initiating event to the addition of the final component cause. The critical public health message imparted by this model is that preventing the occurrence of a component cause stops its entry into the pathway and thus renders other components unable to produce the outcome (3,4).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SUFFICIENT CAUSE :
— INEVITABLY PRODUCES THE EFFECT
— RESTRICTED TO THE MINIMUM NUMBER OF REQUIRED COMPONENT CAUSES
COMPONENT CAUSE :
— NOT SUFFICIENT IN ITSELF
— REMOVAL OR BLOCKING RENDERS ACTION OF OTHER COMPONENTS INSUFFICIENT

Figure 1.
Diagram of sufficient and component causes. A–E represent causes that are not sufficient in themselves but that are required components of a sufficient cause that inevitably produces effect. Adapted from Rothman (3). (Reprinted, with permission, from Diabetes Care, Vol. 13, No. 5, May 1990.)

METHOD

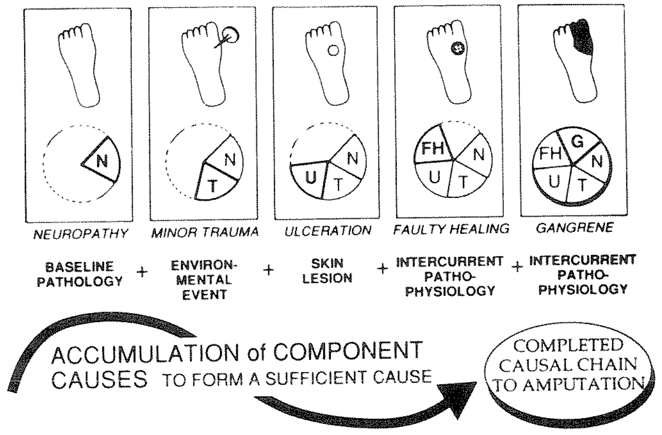
The causal pathway methodology was applied to diabetic amputations. The components included four major pathophysiologic mechanisms: neuropathy, ischemia, infection, and wound-healing failure; two common soft tissue complications, cutaneous ulceration and gangrene; and an environmental initiating event, (e.g., minor trauma, trauma from repetitive mechanical pressure or footwear). These components were selected based on historical and quantitative data and the diabetic amputation literature.

For this study, extensive health, physical and laboratory measures, medical history, and lesion photographs were uniformly collected and compiled into a standard patient work sheet. These measures were applied to the 80 consecutive diabetic male veterans, ages 30–85, who required their first amputation of an affected lower extremity for nontraumatic indications between 1984 and 1987 (5). Similar data were collected from a concurrent control population of 236 diabetic male veterans who underwent elective surgical procedures, not related to diabetes, performed by surgeons from eight subspecialty services. Cases and controls were jointly analyzed to control for age, race, diabetes type, duration, severity, and socioeconomic status; the results of this case-control study are described elsewhere (6).

The three causal pathway investigators independently assigned component and sufficient causes for the amputation based on guidelines that had been agreed upon in advance.

RESULTS

Final consensus was achieved among investigators using a modified Delphi process (7). The analysis identified 23 unique amputation causal pathways among the 80 cases. In 77 amputations, multiple components were reflected in the causal pathway; while in one pathway, which accounted for three cases, an ischemic pathway was sufficient in itself to require amputation. In eight pathways, which accounted for 73 percent of the amputations, the combination of minor trauma, ulceration, and faulty wound healing was present. **Figure 2** diagrams a causal pathway that includes baseline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INTERCURRENT PATHO-PHYSIOLOGY
ACCUMULATION of COMPONENT CAUSES TO FORM A SUFFICIENT CAUSE
COMPLETED CAUSAL CHAIN TO AMPUTATION

Figure 2.
Representation of causal pathway to individual amputation, which includes essential contributions from underlying diabetes-related pathophysiology (neuropathy), initiating environmental event (minor trauma), formation of foot lesion, and subsequent healing complications. Eventual occurrence of gangrene is terminal event of this causal chain, which requires participation of all preceding components before becoming sufficient to cause amputation. Theoretically, amputation could have been avoided by elimination of any one component cause before convergence of causal chain. (Reprinted, with permission, from Diabetes Care, Vol. 13, No. 5, May 1990.)

neuropathy, a minor traumatic pivotal event, ulceration, and faulty healing; the final component cause, which completed the causal chain, was gangrene.

The component causes present in the causal pathways leading to amputation included ischemia, 46 percent; infection, 59 percent; neuropathy, 61 percent; faulty wound healing, 81 percent; ulceration, 84 percent; and gangrene, 55 percent. The major risk factors identified for diabetic lower limb amputation from the case control-study were lack of vibratory perception on either lower extremity, low levels of cutaneous circulation, a history of peripheral vascular disease, low levels of high density lipoprotein subfraction 3, and lack of outpatient diabetes education (6). The population at attributable risk related to absence of vibratory perception was 72 percent and suggests the percent of disease incidence in the population of diabetic individuals due to this risk factor. A pivotal antecedent event or component cause that triggered the series of events ultimately leading to amputation was identified by 86 percent of the cases. For nearly half, the pivotal event either was shoe-related (42 percent) or might have been averted had the patient been wearing appropriate footwear (8 percent).

DISCUSSION

The Frequency of Amputation Risk Factors and the Magnitude of the VA Amputation Problem

In a study of risk factors for diabetic foot ulcers in the General Internal Medicine Clinic at the Seattle VA Medical Center (VAMC), the reported annual foot ulcer incidence was 5.7 percent[1]. **Table 1** shows interim self-reported findings on the prevalence of lower limb symptoms and procedures from a multi-site VA Cooperative Health Services Study of 732 diabetic individuals (8). Numbness of the feet or legs was reported by 60 percent, while over 40 percent reported no pain sensation in their feet. In **Table 2,** these patients identified their educational needs relevant to prevention of limb loss by indicating they had been taught nothing, a little bit, or that they wanted to know more about a topic (8).

Table 1.
Self-reported frequency of lower limb symptoms and procedures.

Symptom	Frequency (%)
Numbness of the feet or legs (sometimes, often, all the time)	59.7
No pain sensation in feet (sometimes, often, all the time)	41.5
Thigh/calf pain when walking (sometimes, often, all the time)	62.3
History of sores on feet/legs	28.0
Prior foot/leg blood vessel surgery	8.4
Prior amputation of toe, foot, or leg	7.0

Subjects: 732 diabetic patients attending three VA General Internal Medicine clinics.
Source: Cooperative Study in Health Services #7, Hines Center for Cooperative Studies in Health Services, Edward Hines Jr. VA Hospital, Hines, IL.

There are several hundred thousand diabetic veterans now receiving VA care. The lack of pain sensation results in many of these patients having no indication of lower limb pain, pressure, or trauma. Thus, these individuals are more likely to develop skin ulcerations in traditional shoes due to unperceived repetitive mechanical and shear stress. This lack of sensation, coupled with other complications, such as vision loss and limited dexterity for foot exams, may limit many patients in their ability to perform adequate self-care.

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[1] E. Boyko: Personal communication, 1993.

Table 2.
Self-reported frequency of educational needs.*

Educational Need	Frequency (%)
Checking feet regularly	27.5
Selecting proper shoes	38.6
When to call a provider	41.5
Whom to call for an urgent problem	39.6

Subjects: 732 diabetic patients attending three VA General Internal Medicine clinics.
Source: Cooperative Study in Health Services #7, Hines Center for Cooperative Studies in Health Services, Edward Hines Jr. VA Hospital, Hines, IL.
*Educational need is defined as knowing nothing, a little bit, or would like to know more.

The frequency of nontraumatic lower limb amputations in the VA was assessed for fiscal years (FY) 1986–1990[2]. **Table 3** shows a decline in diabetic and nondiabetic amputations during this interval. These data were used to estimate the economic impact of diabetic foot ulcers and amputations in VA. Direct and indirect costs for outpatient and inpatient ulcer care reflect current costs at the Seattle VAMC. Private sector diagnostic related group (DRG) reimbursement figures were used to estimate amputation and revision cost since VA is a "non-priced" setting (9). The frequency of serious foot pathology progressing to amputation was estimated at 15 percent. To extrapolate backward, the reciprocal of 15 percent, or 6.667, was multiplied by the average number of diabetic amputations (9,000) to yield an estimated 60,000 annual "pathologic lesions." Of the serious foot pathology, which includes foot ulcers, 20 percent were estimated to require inpatient care and the remainder required outpatient care averaging 4.5 visits per veteran. Although private length-of-stay figures were used for amputations and revisions, it is noteworthy that in statewide California data, the average amputation length-of-stay was 21 days in 1984 and 18 days in 1987 (10). This contrasts with the VA FY 1984 figure that 64 percent of amputation hospital stays exceeded 30 days and 6 percent surpassed 180 days[2]. Cost assumptions for **Table 3** would be modified by changes in amputation frequency, length-of-stay, and the addition of other diagnostic and surgical procedures (e.g., revascularization). Unique VA costs such as changes in pension, relocation to VA-supported extended care facilities and extended rehabilitation, equipment, and services are not included. Based on the above assumptions, an estimate of the annual VA diabetic foot ulcer and amputation costs is shown in **Table 4** and indicates that annual costs now exceed one-third billion dollars.

Table 3.
Nontraumatic lower limb amputations,* in Department of Veterans Affairs Hospitals, for fiscal years 1986–1990.

Fiscal Year	Diabetes, ICD 84.10–84.18	Diabetes, ICD 84.3 Revision	No Diabetes, ICD 84.10–84.18	No Diabetes, ICD 84.3 Revision
1986	9,944	1,384	8,516	1,322
1987	8,942	1,367	8,407	1,354
1988	8,910	1,323	8,296	1,288
1989	8,638	1,229	7,997	1,190
1990	8,551	1,159	7,899	1,128
TOTAL	44,985	6,462	41,115	6,282
Average	8,997	1,292	8,223	1,256

* = Number of procedures, not individuals.
ICD = International Classification of Disease Codes.
Source: Compiled from VA Patient Treatment File.

Table 4.
Estimated annual costs of diabetic foot ulcers and amputations in the Department of Veterans Affairs.*

Estimated Number	Procedure	DRG	Estimated Cost ($)
60,000	Foot ulcers and other pathology		
12,000	20% inpatient care,* 8 days @ 1,078/day**	271	103,488,000
48,000	80% outpatient care,* 4.5 visits @ 95/visit		20,520,000
10,300	Amputations and revisions***		
3,600	Toe/Foot @ 15,124	114	54,446,400
5,400	BK, AK @ 33,444	113	180,597,600
1,300	Amputation revisions @ 18,495	213	24,043,500
TOTAL			383,095,500

*FY 1994 direct and indirect cost estimates from the Seattle VA cost accounting system for ulcers.
**This estimate does not include the cost of operative procedures.
***Medstat private sector reimbursement figures.

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[2] Personal communication: J. Taylor, Biometrics Division, Management Sciences Services, Office of the Assistant Secretary for Plans and Policy, Department of Veterans Affairs, Washington, DC 1992.

Preventing Limb Loss in the Department of Veterans Affairs

The widespread prevalence of peripheral neuropathy, the 7.5 percent incidence and 28 percent prevalence of prior foot sores, and the frequency of prior revascularization and amputation suggest a large VA population at high risk for diabetic amputation. Available clinical trial data describe several effective foot care interventions. These include a randomized trial showing the effectiveness of outpatient diabetes education in decreasing diabetic lower limb amputations (11), the reduction in foot ulcer healing time with total contact casts (12), and studies that evaluated patient, health care provider, and system interventions related to foot care. The group of patients who were randomized to intervention received patient education and contracts, while their providers received education, guidelines, and prompts. Over the 1-year study, results showed a decreased prevalence of serious foot lesions, increased frequency of foot examinations, and increased podiatry referrals (13).

CONCLUSIONS

The causal pathway data suggest that footwear is an important component cause of amputation and deserves further attention. This finding is consistent with reports from other investigators that indicate that 39–76 percent of amputations in their diabetic clinical and research populations were similarly initiated by ill-fitting footwear (14–16). No experimental trials have been conducted to establish the efficacy of therapeutic footwear in preventing ulcers and/or amputations. Related research includes a cross-over study of patients allocated to intervals of running shoes and their own footwear. Results suggest a reduction in callus formation while wearing the running shoes (17). No conclusions on therapeutic footwear efficacy could be drawn from the Health Care Finance Administration's Therapeutic Shoe Demonstration which reported in 1993, "no evidence that providing therapeutic shoes for diabetics with severe foot disease was not a cost neutral benefit" (18). This study was not designed to test clinical effectiveness of therapeutic footwear and in a subsequent population the authors concluded a more orderly approach to the trial would have been to first determine the conditions for clinical effectiveness before assessing their effects on Medicare costs (19). A descriptive study following ulcerated patients over 2 years found that reulceration occurred in 72 percent of patients who resumed wearing their own footwear compared to 26 percent of patients who continued wearing prescribed footwear (15). In a Swedish cohort study, individuals with prior healed foot ulcers reported 1-, 3-, and 5-year reulceration rates at 34 percent, 61 percent, and 70 percent, respectively (16).

Available therapeutic footwear is limited and patients complain because it is expensive, unattractive, not a covered benefit, and wears out quickly. Shoe requirements based on the foot geometry of diabetic patients with foot insensitivity suggest that many patients belong in therapeutic shoes with extra width across the metatarsal heads and extra depth in the toe box, while only a small percentage of patients have such extensive foot deformities that a custom shoe is required.

In VA, many medically needy diabetic veterans are denied footwear because they do not meet the service connected or other "mandatory care" requirements. Health care organizations such as VA should test footwear in prospective intervention trials to determine the appropriateness of providing this benefit to the high risk service recipients and the achievable cost savings from this action.

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