

The Development and Application of Diabetic Foot Protocol in Chiang Mai University Hospital With an Aim to Reduce Lower Extremity Amputation in Thai Population

A Preliminary Communication

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Lower extremity amputation is a frequent complication of diabetes, and the authors' region does not have effective strategies to minimize it. There are devices to reduce pressure and educate. After healing, there are custom fabricated orthoses and footwear, and monitoring of progressive ambulation. From August 2005 to July 2006, a diabetic foot protocol (DFP) for out-patient management based on a multidisciplinary team approach was tried at the local teaching hospital. This report compares the amputation rate in patients receiving DFP care from August 2005 to July 2006 with those who had standard care from August 2003 to July 2005. Sixty-one and 110 diabetic foot ulcer

patients received DFP and standard foot care, respectively. Their sex distribution and mean age were similar. The incidence of major amputations in the DFP and standard care groups was 3.3% and 13.6%, respectively (P = .03). The incidence of minor amputations in the DFP and standard care groups was 3.4% and 15.8%, respectively (P = .02). DFP was associated with improved diabetic foot care outcomes. It may be used by clinical teams with a view to improve outcomes for patients with diabetes.

Key words: *diabetic foot, clinical management protocol, amputation*

A mputation is one of the most common complications of diabetes. It is believed that every 30 seconds a lower extremity is lost somewhere in the

world as a consequence of diabetes.¹ This is because the diabetic foot tends to be numb, ischemic, and deformed, and these changes are likely to lead to sepsis and necrosis of the foot.^{2,3} In our hospital, during 2002 to 2004, ischemia and infection have been the causes of 55% of amputation.⁴ The global incidence of amputations in patients with diabetes mellitus continues to be high, despite growing evidence that it is preventable and treatable with early intervention and staged management.⁵⁻⁷ This begs the question whether local training should be modified.

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It is widely accepted that care of the diabetic foot calls on the time of several specialists at the same time.^{8,9} A study of primary care clinics in southern Sweden reported a 22% reduction in overall amputations 10 years after improvement in access to multidisciplinary diabetic foot care services.¹⁰

Previously in the authors' center, specialists were accustomed to working independently rather than in a multidisciplinary team. For instance, surgeons treating diabetic patients with a foot ulcer focused on surgical debridement alone without much reference to others managing the glycemic status of the patient or indeed thinking about the appropriateness of footwear to achieve offloading. In early August 2005, a dedicated diabetic foot team was set up in our center and a diabetic foot protocol (DFP) was developed based on our reading of contemporary literature such as the Staged Management Diabetes Foot program in the Louisiana public hospital system.⁵ The purpose of our study was to determine whether DFP, compared to earlier interventions, affects the rate of lower extremity amputation (LEA).

METHODS AND MATERIALS

The DFP was used from August 1, 2005, to July 31, 2006. Guidelines for practice were developed to address criteria for diagnosis, risk factor assessment, treatment options, therapeutic targets, monitoring, and follow-up.⁵ A formula was developed to identify 2 risk criteria: simple ulcers and complex ulcers. Specific decision pathways were created to guide foot examination in terms of sensitivity to a 10 g Semmes Wienstein monofilament, specification of foot abnormality, application of an ischemic index (Ankle Brachial Pressure Index), and diameter and depth of ulcers. Additional algorithms developed included treatment options and follow-up schedules.

A foot-care team was formed consisting of endocrinologists, a rehabilitation physician, a family doctor, nurses, and plastic and vascular surgeons. This team met on a monthly basis to develop coordinated strategies for improving access to and utilization of appropriate foot care services. Flow sheets based on DFP algorithms were developed. Standing orders and standardized ulcer assessment and management protocols for each risk category were implemented. The consultation between specialists was carried out in flow sheets only without any formal consultation form. Preventive services were provided routinely according to the flow chart used, including self-care education, routine palliative foot care, and the provision of protective footwear.

Foot care education was offered. Education of each patient took 10 to 20 minutes and included verbal and written instructions, depending on participants' risk factors and foot care knowledge and self-efficacy and self-care behavior reported by a research nurse. Foot care education topics include individual risk factors, washing and drying feet, toenail care, footwear, moisturizing feet, and when to report foot problems.¹¹

From August 2003 to July 2005, diabetes patients with foot ulcers received standard care such as debridement. For the patients with both ischemia and neuropathy, consultation was done on the interdepartmental consultation forms. Preventive measures were taken at the discretion of the attending physician. There were no detailed guidelines or flow sheets for these specific services.

Throughout the 2 periods, amputation rate was defined as the loss of any part of a lower limb. All patients in both groups who had not been visited by our team recently would be contacted either by letter or telephone to collect data accurately. The Clinical registrar recorded all known amputation cases. Multiple amputations on the same limb during a single hospitalization, or repeat amputations on the same limb within 1 month of a previous amputation, were considered as a single amputation at the highest level on the leg. A major amputation was defined as either a "below-knee amputation" or an "above-knee amputation." Average LEA incidence rates for the standard care and DFP period were calculated by dividing the number of LEA cases on the registries for each period by the sum of diabetes cases with foot lesions. This was a part of a project named "Health Promotion Capacity Development of Thai Medical Schools," which was supported by the Consortium of Thai Medical Schools and the Thai Health Foundation.

This project received prior approval of the Research Ethics Committee, Faculty of Medicine, Chiang Mai University (Reference No 121/2006).

Differences between data were tested for statistical significance using the chi-square test.

RESULTS

Sixty-one and 110 diabetic foot ulcer patients received DFP and standard foot care respectively; their sex distribution and mean age were similar for both periods (Table 1). Patients in the DFP group had more hypertension but less hyperlipidemia than patients receiving standard care alone. Only 1 patient in the DFP group had end-stage renal disease

Table 1. The Number of Risk Factors for Vascular Disease in Each Group

Item	DFP N = 61	Standard Foot Care N = 110
Males (%)	20 (32.8)	37 (33.6)
Mean age (years)	57.8	60.6
Patients with hypertension (%)	42 (68.9)	49 (44.6)
Patients with history of smoking (%)	26 (42.6)	55 (50.0)
Patients with hyperlipidemia (%)	27 (44.3)	73 (66.4)

DFP = diabetic foot protocol. Percentages in parentheses.

Table 2. The Number of Lower Extremity Amputations in Each Group

Type of Amputation	DFP N = 61	Standard Care N = 110
Toe	2 (3.4)	10 (10.5)
Transmetatarsal	0	4 (4.2)
Syme	0	1 (1.1)
Below knee	2 (3.3)	12 (10.9)
Above knee	0	3 (2.7)

DFP = diabetic foot protocol. Percentages in parentheses.

and needed chronic hemodialysis. In the DFP group, the rate of major amputations was statistically significantly lower than those in the standard care group (3.3% and 13.6%, respectively, $P = .03$). The incidence of minor amputations in the DFP and standard care groups was 3.4% and 15.8%, respectively, and this was also statistically significant ($P = .02$).

DISCUSSION

The aim of this study was to develop a protocol to manage DFP. This protocol was tested against existing practice. In the group of patients with diabetic foot ulcers treated using the protocol and a multidisciplinary approach, lower rates of LEA were observed compared to the group receiving standard care, the difference being statistically significant (INSERT P VALUES FOR BOTH GROUPS ED). The DFP appeared to work well. It was a simple proposition without the need of sophisticated logical instruments. Guidelines and collaborative practice between specialists were the main components of this experiment.

We did not seek to determine whether a specific element of DFP was associated with the improved outcomes and suggest several likely explanations could be correct. Among these is considered the collaborative practice rather than independent clinical approaches.^{9,11-14} We consider that by working in collaboration, clinical complications such as foot sepsis, a common problem in diabetic patients when treatment is delayed may be avoided. Second, members of our DFP team were encouraged to innovate. Family physicians in charge of patients' education proposed a combination of group therapy family counseling and home visits that was much more effective than the standard approach. This technique meant that patients were spoken to rather than merely handed a printout of care information. Third, the DFP laid down clear instructions for trainee clinicians to consult with specialists.¹⁵

We also observed some unique problems in Thailand based on social and cultural practices.¹⁶ Despite patients with diabetic foot lesions receiving education to wear footwear (shoes) always in the home and outside, patients from a religious order (Buddhist monks) refused to follow these instructions as these were in violation of their rules of conduct. Such monks are accustomed to visiting places of worship barefoot. They pray frequently in the kneeling posture, which can create abnormally high pressures on the toes. One patient had chronic hemodialysis for end-stage renal failure and had received a femoro-posterior tibial distal bypass. In 2 months following surgery, the foot ulcer healed.

Interestingly, relatives often fed patients with sweet fruit despite our education and instructions to abstain from such food. This indifference to medical supervision is based on the cultural notion that indulging patients (by relatives) helps them to cope. Evidence suggests that patient education may reduce foot ulceration and amputation, especially in high-risk patients.¹⁷

Another finding of this study was that the public transportation is not easy in Thailand. For this reason, we had to extend our follow-up period to 2 to 3 weeks in order to make it possible to obtain collaboration from patients and other medical centers. We recognize the importance of more frequent follow-up for patients when the ulcer is frank.

We plan to extend our protocol to district hospitals. The developed DFP is amenable to being run by nurses, which reduces the workload on busy medical doctors. We consider it necessary to try this protocol in district hospitals in Thailand based on simple stratification and low costs. Horswell et al

reported that the multidisciplinary approach reduced emergency department and hospitalization utilities and charges in a statewide public hospital system, and we would like to emulate this success after carefully designed studies.⁵

LIMITATIONS OF THE STUDY

There are limitations to this study, the first being the use of historical cohorts against which the DFP group was compared. This approach lacks rigor and limits the value of our findings, though it does not invalidate them. A rigorous study preferably based on a randomized control design is indicated before such a protocol is pursued vigorously.

In conclusion, we needed to initiate the program somewhere. These results would indicate that we have taken the correct first steps and are on track to develop a protocol-based treatment plan for patients with DF problems to eventually reduce the number of amputations and to prevent them.

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