



## Research Paper

# Outcomes of hospitalized diabetic foot patients in a multi-disciplinary team setting: Thailand's experience<sup>☆</sup>



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## ABSTRACT

**Aims:** The aims of this study were to evaluate the outcomes of treatment among hospitalized patients with diabetic foot ulcers, the risk factors for non-healing ulcers, and the rate of major amputation among Thai patients.

**Methods:** A retrospective study of hospitalized diabetic foot patients treated at Theptarin Hospital during the period of 2009–2013. The complete healing rate was assessed at 12 months after admission.

**Results:** During the study period, 232 patients (123 males and 109 females) with 262 admissions were included (mean age  $65.6 \pm 11.9$  years, mean duration of diabetes  $17.2 \pm 9.9$  years) with a mean follow-up of  $17.5 \pm 16.7$  months. Major amputations were performed in 4.2% of the patients and peripheral vascular disease (PVD) was a predictive factor (OR 5.25; 95% CI [1.43–19.29];  $p$ -value 0.006). Complete healing (including minor amputations) was achieved in 82.1% of the admissions. Only DFU of the heel was a statistically significant (OR 3.34; 95% CI [1.11–10.24];  $p$ -value 0.041) predictor of non-healing ulcers. Three patients (1.1%) died during hospitalization.

**Conclusions:** Management of diabetes-related foot ulcers with a multidisciplinary approach resulted in a limb salvage rate that was greater than 90% and a complete healing rate that was greater than 80%. Successful management of diabetic foot ulcers might be possible in Thailand utilizing this approach.

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## Introduction

Diabetic foot problems are the most common cause of hospitalization among patients with diabetes and often require long-term hospital admissions. Such problems have been estimated to affect 25% of all diabetic individuals during their lifetime [1]. These problems represent considerable patient morbidity and are associated with substantial health-care costs. Over 85% of lower limb amputations are preceded by foot ulcers and diabetes remains the most common cause of non-traumatic amputation in Western countries [2].

In the developed countries, the amputation rate has been reduced by 50% via proactive management with a multidisciplinary approach [3]. A multidisciplinary approach provides

meticulous wound care, debridement, adequate vascular supply, metabolic control, improvement of nutritional status, appropriate antibiotic treatment, and non weight-bearing, which are the cardinal features of the treatment of diabetic foot syndrome. Patient education and, in some cases, assisted self-care for patients provided by family member are also crucial for the prevention of diabetic feet in high-risk patients [4]. Evidence from a tertiary care unit in Thailand revealed that a multidisciplinary approach that focused on clear guidelines and collaboration between specialists resulted in a 70% decrease in the incidence of major amputation and a 60% decrease in the incidence of minor amputation [5]. Therefore, diabetic foot ulcers should be managed under the care of a multidisciplinary team with expertise in the many facets of care.

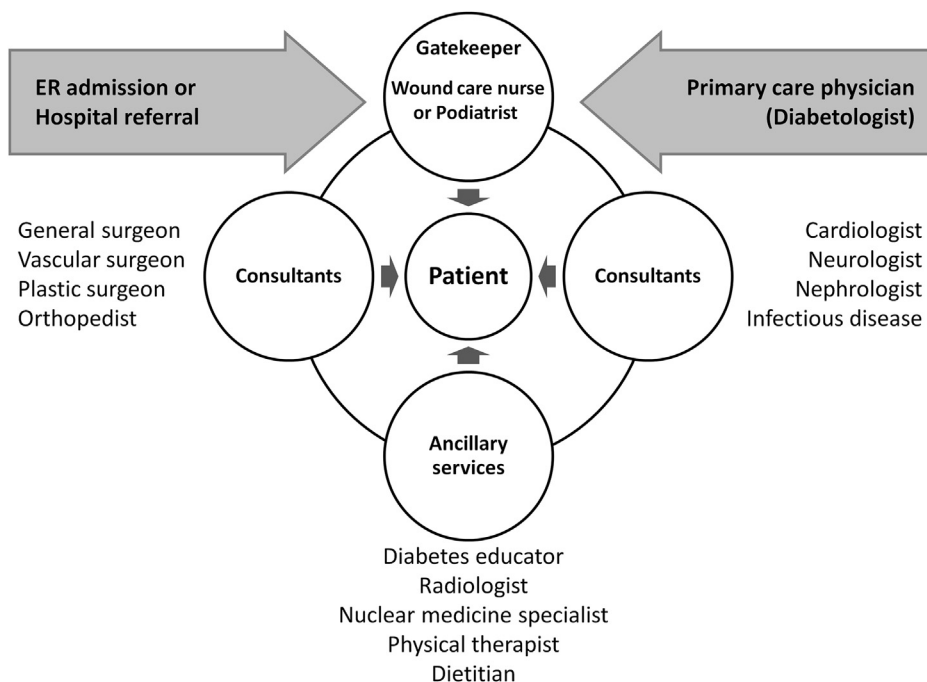
In our center, diabetologists take the lead role in foot care within the multidisciplinary team outlined in Figure 1. The advantage of this system is the emphasis on optimal glycemic control over the course of diabetic foot ulcer treatment. Furthermore, because patients with diabetic foot problems are also likely to harbor other associated complications of diabetes, such as nephropathy, retinopathy, ischemic heart disease, and cerebrovascular disease, the

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**Figure 1.** Outline of hospitalize diabetic foot management which diabetologists take the lead role in the foot care multidisciplinary team.

management of foot ulcers should incorporate these associated comorbidities during the selection of treatment.

A retrospective study from Thailand revealed that a history of foot ulcer among Thai diabetic patients was associated with a three-fold increase in mortality rate compared to those without such history and that the average age of death was earlier than that of Caucasian patients (64.8 years versus 74.2 years) [6]. Unfortunately, there are no national diabetes outcome indicators, particularly outcomes of hospitalized diabetic foot patients, that are routinely collected in Thailand. Therefore, the aim of this study was to evaluate the outcomes of treatment among hospitalized patients with diabetic foot ulcers, the risk factors for non-healing ulcers, and the rate of major amputation in a multi-discipline diabetes center that was facilitated and led by diabetologists.

## Materials and methods

This retrospective study was approved by the institutional review board (IRB) committee of Theptarin Hospital, Bangkok, Thailand. The medical histories of all hospitalized diabetic foot patients who were treated at Theptarin Hospital during the period from 2009 to 2013 were analyzed. Theptarin Hospital is one of the most comprehensive diabetes centers in Bangkok, and over 4000 registered diabetic patients were treated at this hospital during the study period.

Diabetic foot ulcer (DFU) was defined as a full thickness wound below the ankle in an individual with diabetes. Acute DFUs were defined by a duration of DFU less than 14 days, and chronic DFUs were defined by a duration of DFU greater than or equal to 14 days. The commonly used Wagner classification defines wounds by the depth of ulceration and the extent of gangrene [7]. However, the University of Texas system (UT classification) grades wounds according to the depth and then stages the wounds according to the presence or absence of infection and ischemia [8]. In this study, the wounds were classified with both systems. The end point of this study was “complete wound healing,” which refers to the complete epithelialization of the overlying soft-tissue wound. Non-healing

ulcers were defined as wounds that had not healed by 12 months after admission. Amputations were divided into minor (up to below the ankle level) and major amputations (above the ankle level). The limb salvage rate was defined as the percentage of patients who avoided major amputations. Peripheral vascular disease (PVD) was classified according to revised Trans-Atlantic Inter-Society Consensus (TASC II) classification [9].

The patient profiles, types of diabetic wounds, gradings of the DFUs, co-morbidities, methods of treatment, and final outcomes were collected. The complete healing rate was assessed 12 months after admission. The risk factors for non-healing ulcers and major amputations were also determined.

## Statistical analyses

Continuous values are given as the mean  $\pm$  SD and categorical variables are given as proportions. Unpaired *t*-tests were performed to compare the numerical values between two groups when the data were normally distributed. When the data were not normally distributed, Mann–Whitney tests were used for comparisons. The chi-square test was used to compare the factors that were associated with non-healing ulcers and major amputations. *p*-Values  $<0.05$  were considered statistically significant. All statistical analyses were conducted using the Statistical Package for the Social Sciences (version 17.0; SPSS, Chicago, IL, USA).

## Results

During the study period, 232 patients (123 males and 109 females) with 262 admissions were included (mean age:  $65.6 \pm 11.9$  years, mean duration of diabetes:  $17.2 \pm 9.9$  years), and the mean follow-up time was  $17.5 \pm 16.7$  months. The median length of stay was 7 (range 1–63) days. The reasons for admissions included uncontrolled infection (38.9%), PVD (17.6%), severe hyperglycemia (15.4%), worsening of renal function (14.3%), co-morbidity (12.2%), and other (1.6%). The mean body mass index (BMI) was  $25.4 \pm 4.2$  kg/m<sup>2</sup>, and the average HbA<sub>1c</sub> was  $8.9 \pm 2.4\%$  (74 mmol/mol). The

**Table 1**  
Baseline characteristics of the hospitalized DFU patients according to wound type

Baseline characteristics	Neuropathic wound (N = 149)	Ischemic wound (N = 36)	Neuro-ischemic wound (N = 77)	Total (N = 262)
Age (years)	60.8 ± 11.1	70.9 ± 10.8	72.4 ± 9.3	65.6 ± 11.9
Male (%)	53.0%	50.0%	53.2%	52.7%
BMI (kg/m <sup>2</sup> )	26.2 ± 4.5	24.7 ± 4.0	23.7 ± 3.1	25.4 ± 4.2
Duration of DM (years)	15.9 ± 9.1	16.0 ± 9.7	20.7 ± 10.8	17.2 ± 9.9
HbA <sub>1c</sub> (%)	9.4 ± 2.5	8.2 ± 2.0	8.1 ± 1.9	8.9 ± 2.4
Diabetic nephropathy (%)	39.5%	50.0%	49.4%	44.0%
Diabetic retinopathy (%)	60.6%	33.3%	40.0%	53.0%
Previous DFU (%)	49.0%	44.4%	53.2%	49.6%
Smoking (%)	21.4%	21.9%	22.4%	22.0%
Wagner ≥ grade 3	36.2%	66.7%	50.7%	44.7%
Length of stay (days)	8.0 ± 8.5	13.6 ± 12.1	14.6 ± 11.6	10.7 ± 10.5

prevalences of ischemic heart disease and chronic kidney disease were 21.0% and 44.0%, respectively. Twenty-two percent of the patients had histories of current or previous smoking. One hundred fifteen patients (49.6%) had prior histories of foot ulcers. Major and minor amputations were performed for 11 and (4.2%) and 49 patients (18.7%), respectively. The details of the baseline characteristics are shown Table 1.

The diabetic foot ulcers (DFUs) were classified into neuropathic wounds (56.9%), ischemic wounds (13.7%), and mixed-type wounds (29.4%). Among all ulcers, 89.3% were localized to the toe and forefoot areas, 6.9% were localized to the heel and 3.8% were localized to the ankle area. Acute DFUs were present in 31.7% of the patients. The distribution of the ulcers according to the Wagner classification was as follows: Wagner 1 (22.5%); Wagner 2 (32.8%); Wagner 3 (32.1%); Wagner 4 (11.8%); and Wagner 5 (0.8%). Application of the UT classification revealed that UT stages C and D comprised 56.5% of the admissions. Charcot joints were presented in 8.8% of the cases.

Open surgical bypass revascularizations were mandatory for six patients during the study period and including two aortobifemoral bypasses, one femorofemoral bypass, two femoropopliteal artery bypasses and one femorotibial vessel bypass. Primary angioplasties were performed in 55 patients (48.7% of the PVD patients) from 2009 to 2013. Limb salvage was achieved in 83.3% of these patients. TASC type C and D lesions were present in 84.0% of the patients who underwent angioplasty.

Regarding the bacteriologies of the DFUs, a total of 224 bacterial isolates were obtained from 170 DFUs (64.9%). Gram-negative bacilli were more prevalent (58.8%) than were gram-positive cocci (41.2%). The most commonly isolated organism was *Escherichia coli* (18.7%), followed by *Pseudomonas* spp. (12.6%) and *Staphylococcus aureus* (11.8%). Mixed organisms were found in 33.6% of the DFUs and were most prevalently a combination of gram-negative organisms. Regarding the acute DFUs, methicillin-sensitive *S. aureus* (MSSA) was the most commonly isolated organism (20.8%),

followed by mixed gram-positive and negative organisms (19.4%). Regarding the chronic DFUs, mixed gram-positive and -negative organisms were most commonly found (22.9%), followed by *Pseudomonas* spp. (8.4%). The antibiotic sensitivity profiles of the bacteria were studied, and 6.5% of the gram-negative bacilli were found to be extended-spectrum β-lactamase ESBL producers, and 3.5% of the gram-positive cocci were methicillin-resistant *S. aureus* (MRSA).

Major amputations were performed in 6.0% of the patients, and peripheral vascular disease (PVD) was a predictive factor (OR 5.25; 95% CI [1.43–19.29]; *p*-value 0.006). Complete healing (including minor amputations) was achieved in 82.1% of the patients. Only DFU in the heel was found to be a statistically significant (OR 3.34; 95% CI [1.11–10.24]; *p*-value 0.041) predictor of non-healing ulcers as shown in Table 2. This association occurred independently of the presence of PVD. Three patients (1.1%) died of cardiac arrests that were likely due to the development of ischemic heart disease during hospitalization. The mortality rates across the entire cohort at one and three years after discharge were 5.7% and 9.5%, respectively. Among the patients who underwent major amputations, the mortality rates at one and three years after discharge were 27.3% and 45.5%, respectively.

## Discussion

Diabetic foot ulcers (DFUs) have been neglected in health-care research and planning, and DFUs are often accompanied by other diabetic complications. It is not uncommon to observe cardiovascular or cerebrovascular events during the management of diabetic feet [10]. Globally, diabetic foot complications remain the major medical, social, and economic problem for all types of diabetes. Without early and optimal interventions, wounds can rapidly deteriorate and lead to unnecessary amputations. Following amputations, patients not only suffer the clinical and psychological consequences of limb loss, but amputation itself is predictive of a

**Table 2**  
Comparison of the clinical characteristics of the healed (including minor amputations) and non-healed patients

Baseline characteristics	Healed ulcer (N = 232)	Non-healed ulcer (N = 30)	<i>p</i> -Value
Age (years)	65.1 ± 11.6	67.5 ± 12.9	0.071
HbA <sub>1c</sub> (%)	8.8 ± 2.3	9.0 ± 2.8	0.119
Serum creatinine (mg/dL)	1.6 ± 1.7	2.4 ± 2.6	0.699
Duration of ulcer (days)	60.0 ± 104.2	41.2 ± 42.9	0.540 <sup>a</sup>
Wagner ≥ grade 3	36.2%	66.7%	0.212
Location of ulcer (%)			
Toe	50.5%	33.3%	0.613
Forefoot	40.9%	40.0%	0.845
Heel	5.6%	16.7%	0.041
Ankle	3.0%	10.0%	0.093

<sup>a</sup> The data were not normally distributed, so Mann–Whitney tests were used for the comparisons.

five-year mortality that is higher than those of breast cancer in females and prostate cancer in males [11].

Data from the Thailand diabetes registry (TDR) project, which is a cross-sectional study of 9419 diabetic patients from 11 tertiary care hospitals across Thailand, has revealed that the prevalence of lower extremity amputation among Thai diabetic patients is 1.5% and that patients with histories of ulcers, peripheral vascular disease, diabetic retinopathy and insulin injection are at higher risks [12]. These observations clearly indicate the need for regular screening to identify such high-risk individuals. The inpatient management of DFUs also has a significant financial affect, and DFUs are associated with prolonged lengths of hospitals stays. The EURODIABE study examined total direct and indirect costs over one year across several European countries [13]. The average total cost based on 821 patients was approximately 10,000 euros, and hospitalization representing the greatest direct cost. In Thailand, a study from a provincial hospital revealed that the median cost of hospitalization was USD\$ 190 for patients with diabetic feet compared to USD\$ 101 for patients without complications [14].

To achieve best outcome in terms of amputation reduction due to diabetes, the multidisciplinary team concept must be adopted for both the general management of diabetes and the management of associated complications including foot ulcers [15]. In this study, we achieved a limb salvage rate greater than 90% and a complete healing rate greater than 80% via a multidisciplinary team approach involving diabetologists as leaders and center coordinators. Therefore, these data reaffirm that the organization of care is one of the main determinants of the outcome of diabetic foot ulcers.

Patients with diabetic foot ulcers suffer from multi-organ disease. A large prospective study in Sweden that was conducted in both out- and in-patient settings revealed that nearly one-fifth of the patients with unhealed ulcers died from co-morbid conditions and that the severity of PVD was associated with healing rate and amputation [16]. The factors that are related outcome are complex due to the variation in the definitions of outcome across studies [17]. It is difficult to perform long-term studies on this patient group because the time to heal can be very long. Unfortunately, no other studies of the outcomes of DFU among patients hospitalized in Thailand are available. In the present study, our patients were comparable in terms of co-morbidities and demographic data, but they were younger than the patients who were included in a Swedish series (65 years versus 75 years). Our study revealed that the presence of PVD increased the risk of major amputation by more than 5-fold. PVD tends to occur at a younger age among patients with diabetes and is more likely to involve distal vessels. Although current report of PVD among Asians have reported low rates that range between 3 and 6%, while these rates are 25–45% among Westerners [18], the prevalence of PVD increases with age. Consequently, it is expected that the prevalence of PVD among Asians will significantly increase in the near future.

Recently, primary angioplasty has been regarded as the primary therapeutic strategy for diabetic patients with critical limb ischemic ulcers because it is considered to be a less invasive and effective method to restore the distal flow toward the ischemic tissue zones [19]. One study showed that, when endovascular revascularization techniques were utilized, only 10 of 191 patients (5.2%) later required major amputations [20]. In the present study, the results from the patients who underwent angioplasty revealed a limb salvage rate of 83.3%. Traditionally, primary infra-inguinal angioplasty is the established treatment modality for infra-inguinal arterial occlusive disease; however, supra-inguinal (aorto-iliac) disease might be amenable to angioplasty, and good long-term results have been achieved at low risk as compared to open bypass surgery [21,22]. The trend of revascularization procedures in our center has shifted from open bypass surgery to primary

angioplasty due to the co-morbidities of open bypass surgery and the limited availability of experienced vascular surgeons. Consequently, primary angioplasty might be considered to be an acceptable option for some patients with severe limb ischemia and, when technically feasible, might be the favored initial option.

The interesting data from our study revealed that the risk of non-healing was more than three times higher among patients with heel ulcers than among patients with ulcers at other sites. This finding is consistent with previous reports that heel ulcers are associated with the poorest prognoses among all diabetic foot ulcers [23,24]. Diabetic heel ulcers are particularly challenging to treat because flap reconstruction of the heel area is difficult. Moreover, significant debridement or amputation of the heel rarely leaves a functionally walking patient. Several classification systems for DFUs had been devised over the years and include the Wagner classification system, the University of Texas system, and the more recent PEDIS classification. The International Working Group on the Diabetic Foot (IWGDF) has proposed the PEDIS classification, which grades ulcers based on Perfusion (arterial supply), Extent (area), Depth, Infection, and Sensation [25]. However, none of these classifications account for measurements of neuropathy or ulcer location. The problem of heel ulcers will increase in conjunction with the increase in the diabetic and aging populations. Heel ulcers in patients with diabetes have the potential to deteriorate rapidly, and therefore frequent re-evaluations are necessary.

In the present study, major amputations were required for the patients with advanced foot infections, the medically compromised patients, and occasionally patients with severe Charcot deformities. Although lower extremity amputation (LEA) is regarded as a marker of the quality of foot care among diabetics, LEA rates among patients with diabetes vary by country, healthcare system, cost, and payer [26]. Amputation is not only a marker of disease but also of disease management. The decision to operate is based on by many factors. Primary amputation might be the best option for some patients, and the early identification of these patients might obviate the use of inappropriate, potentially dangerous, and costly procedures. Whenever a major amputation is planned, the option of revascularization should be considered first. All patients who have undergone a major amputation are at a high risk of subsequent contralateral amputation, and thus surveillance programs for the remaining feet are crucial.

The occurrence of DFU is a pivotal event in the life of a person with diabetes and a marker of serious disease and co-morbidities. Other high-risk patient include those with end-stage renal disease based on previous data that revealed that up to two-thirds of people on dialysis will die within two years of amputation [20]. Therefore, these high-risk patients also need to be evaluated thoroughly regarding medical conditions and particularly renal failure [27].

The strengths of this study include its relatively large sample size and that it is the first comprehensive report of hospitalized Thai DFU patients for whom a multi-disciplinary approach was employed. However, several limitations also exist. First, the retrospective nature of the study resulted in relatively incomplete data and missing data regarding some aspects such as foot deformities and complete vascular assessments. Second, the bacteriological profiles in our study were derived primarily from patients who received prior antibiotic treatment from previous hospitals, which limits the generalizability of the findings. Finally, as discussed earlier, the amputation rate might not be a good marker of the quality of clinical care, and better indicators are required for future studies.

In conclusion, the successful management of diabetic foot ulcers requires a dedicated team of multiple specialists and a well-defined referral pattern within each community. Our data demonstrated that the use of multidisciplinary approach resulted in the achievement of limb salvage rate above 90% and a complete

healing rate above 80%. However, this level of care is not yet accessible to all patients with diabetes in Asia. Reductions in the numbers of amputation that result from diabetes can be widely achieved if proper strategies, such reimbursement systems, referral systems, preventive policies, and medical personnel training, are executed at the national level.

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