REVIEW ARTICLE

Limb Salvage Surgery and Wound Treatment in the Establishment of Globally Standardized Diabetes, Amputation, and Limb Salvage Centers to Address Lower Extremity Morbidity and Mortality in Thailand

Gerit Mulder, DPM, MS, FRCST, FAPWCA, FACCWS,* Daniel K. Lee, DPM, FACFAS

School of Medicine, University of California San Diego, San Diego, CA 92103-8869, USA

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Abstract Diabetes and its consequences, particularly diabetic foot ulcerations and amputations, are increasing exponentially on a global level. Universal interest exists in the establishment of educational programs, clinics, and patient materials. However, the availability and skills needed to develop, implement, and consistently manage diabetes and related problems are lacking. This article reviews problems related to care of the diabetic foot, with a focus on Thailand as a model. Recommendations are made to assist with the development and implementation of limb salvage centers for the treatment of the at-risk diabetic foot. The guidelines presented may be applied to any countries where diabetic foot care is in the initial stages of development.

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Introduction

Extensive information, publications, and recommendations are available in the medical literature emphasizing the importance of standardized protocols and care,¹ yet no internationally accepted and applied protocol is available. The closest published materials are national and international consensus documents and recommendations from groups of experts, particularly emphasizing care in the diabetic foot.^{2,3,4} The information provided by available literature, while valuable, appears to have minimal daily application in the standard wound care clinic and hospital setting.

Each country and region in a country has unique medical, financial, and cultural needs. Published protocols may not approximate individual considerations. Medical and pharmaceutical device companies marketing their products may find significant variation in sales, and success is affected directly by the lack of understanding of national differences.

International documents, including the consensus meeting on the diabetic foot, need to be customized for each nation. If this were done, a government-supported complete protocol could then be implemented in all government hospitals, with the option available for privately funded clinics.

Both authors are PhD Candidate, Chulalongkorn University, Bangkok, Thailand.

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* Corresponding author.

E-mail address: gmulder@ucsd.edu

The Diabetic Problem

Neuropathy eventually becomes associated with development of ulcers leading to foot and lower extremity

amputation.⁵ A multicenter study that evaluated diabetic neuropathy revealed the seriousness and urgent level of this problem.⁶ The study included 4,875 patients (women, 63.8%) with a mean (SD) duration of diabetes of 12.8 (8.2) years. The prevalence of diabetic neuropathy was 42.9% (microalbuminuria 19.7%, and overt nephropathy, 23.2%). There were 373 patients (7.7%) with renal insufficiency and 24 (0.47%) with end-stage renal disease. Prevalence of ischemic heart disease and cerebrovascular disease in these patients was 11.5% and 6.6%, respectively. Mean (SD) hemoglobin A_{1C} in patients with nephropathy was 8.2% (2.6%). Only 25% of patients had hemoglobin A_{1C} of less than 7%, 46% had blood pressure above 140/90 mm Hg, and 84% received at least one antihypertensive drug. The target blood pressure of less than 130/80 mm Hg could be achieved in only 18% of these patients.

Factors contributing to the continued growth of the disease include sedentary lifestyle; diabetes-prone diets; and poor education on disease prevention, treatment, and control. Once a patient is diagnosed with diabetes and neuropathy, absence of comprehensive, standardized, and centralized care serves to synergistically increase morbidity and mortality. Childhood obesity has been common and accompanied by an increase in the prevalence of type 2 diabetes mellitus and metabolic syndrome among children and adolescents in Thailand.⁷ With uncontrolled diabetes on the rise in that country, along with coronary heart disease, a recent study in Thailand compared the quality of life of these individuals with that of a control group. The findings of this study have shown self-management education to be useful and effective.⁸ Another study used computers and e-learning techniques to disseminate diabetic prevention education in the Chiang Mai province and showed how well these methods were received in overall diabetic education in Thailand.⁹

Analyses of Need

The rapid rise in diabetes around the globe, particularly in Africa, the Asia-Pacific Rim region, and the Middle East, has coincided with growth in the incidence and prevalence of diabetic foot problems.^{10–12} The latest International Diabetes Federation estimates suggest that 380 million people will be affected by diabetes by 2025, with 1 person dying every 10 seconds.¹³ More than 2.9 million deaths yearly are attributed to diabetes worldwide. This is compounded by a decrease in life expectancy of 10 years in young people, and more than 75% of deaths occurring in the population younger than 35 years. In fact, diabetes is on track to surpass the 3 million deaths from diabetes attributable to the human immunodeficiency virus annually.¹⁴ It has been stated that every 30 seconds, somewhere in the world, a limb is lost as a consequence of diabetes.¹⁵ As many as 82% of diabetic amputations have an ulceration that is the primary contributing factor to morbidity.¹⁶

International Comparative Figures

Asian regions have the highest number of deaths among all regions and the highest number of affected people in the young to middle-aged groups. Countries such as India, China, Korea, Japan, Pakistan, Philippines, and Bangladesh are among the top 10 in terms of numbers of people with diabetes. It is predicted that from 2005 to 2030, the number of people with diabetes will rise from 35 million to 71 million.¹⁷ In a separate study, however, India alone, with a 2010 population of 1,179,365,000 people, is predicted to have a diabetic population of more than 80.9 million by the year 2030.¹⁸ Financial figures may vary based on variations in the medical system in Thailand; however, the financial burden will remain significantly high. These estimates exclude the economic, social, and psychological burdens resulting from problems related to diabetes, including but not limited to renal failure, vascular disease, ophthalmic problems, angiopathies, and obesity. Lower extremity amputations, limb salvage, and functional reconstruction are key issues in saving the lives of our patients. Of patients with diabetes, 25% can develop foot ulcers in their lifetime.¹⁹ Diabetic foot ulcers lead to amputations in 85% of cases.²⁰ It is also known that more than half of these ulcers will become infected during their ulcer cycle.²¹ Infection and critical limb ischemia are major risk factors for lower extremity amputation.²²

Approximately 27% of the population of the Kingdom of Saudi Arabia is estimated to be diabetic, with about 20% experiencing amputations.²³ Up to 82% of these diabetic amputations have been associated with an ulceration, which is the primary contributing factor to morbidity.¹⁶ The growth of diabetes in the middle east and surround gulf countries has been projected to be 97% by 2025, translating into almost 50% of the population of the Kingdom of Saudi Arabia being diabetic by that time.²⁴

In Africa, the problem of diabetes is escalating, threatening the viability of many African economies.^{17,25} In both studies, the International Diabetes Federation predicted that by 2010 the prevalence of diabetes in Africa would increase by almost 100%. It is therefore predicted that by 2025, the prevalence of diabetes in the continent will increase to 18.7 million people. The life expectancy of a person diagnosed with type 1 diabetes can be as low as 7 months in some African countries, and with the impact of type 2 diabetes set to continue, the risk of related complications, such as blindness, amputations, and kidney disease, is increasing, placing additional burden on countries already stretched to the limit by common life-threatening infections.²⁶

The current figures in the United States are staggering. The unprecedented increased rates of diabetes growth and diabetes-related diagnoses in the United States are cause for alarm and crisis. It is estimated that approximately 24 million people suffer from diabetes in the United States, with a projected increase to 50 million by 2040.^{27,28} The

financial cost directly related to diabetic foot ulcers and amputations in 2007 was \$31 billion.²⁹ All associated health care costs are alarmingly high, and the total annual cost of diabetes treatment in 2002 (including direct and indirect costs) has been estimated at \$132 billion, or 1 out of every 10 health care dollars spent in the United States.³⁰ Other studies have suggested that diabetes-related amputations cost approximately \$3 billion per year (approximately \$40,000 per amputation procedure).^{31,32} With the rise in diabetes diagnoses, there is also an expected rise in the number of amputees. In a recent study from Brazil, almost 46,300 (8,500-80,900) limb amputations and 12,400 (range 2,300-21,700) deaths occur as a result of diabetic foot disease each year.³³ The annual cost associated with these hospital admissions is estimated to average almost US \$264 million. The estimated annual cost for patients with amputation averages nearly US \$128 million.

Thailand

The value of customization of protocols in an individual country can be demonstrated by using Thailand as an example. Thailand has a population of 63,525,062 (estimated census, 2010; ranked 20th in the world in population), in a territory of 513,120 km² (198,115 sq mile; ranked 50th in the world), with a gross domestic product of \$547.060 billion,³⁴ at purchasing power parity (ranked 24th in the world) and average per capita income of \$8,239 (ranked 86th in the world).³⁴

In 2000, a study reported that diabetes was common in Thailand.³⁵ By studying Thai adults 35 years of age and older in relation to the prevalence and management of diabetes and the associations of diabetes with cardiovascular risk factors, the researchers found that the estimated national prevalence of diabetes in Thai adults was 9.6% (2.4 million people), which included 4.8% previously diagnosed and 4.8% newly diagnosed. Moreover, half of all cases are undiagnosed.³⁵ Based on these figures, there is, conservatively, a diabetes rate of 10% in the total population, or approximately 6.3 million people with diabetes. If one considers the incidence of diabetic foot ulcers at 25% in a lifetime,¹⁹ then the point prevalence of diabetes would be approximately 15.8 million people. Estimating that 85% of amputations are caused by diabetic foot ulcers,²⁰ then 13.4 million people would eventually have some form of lower extremity amputation.

Financially, Thailand is a rapidly growing country with annual advances in industry, technology, and education, although large percentages of the populations in cities and rural areas are neither financially secure nor highly educated. This results in greater disparity in care-related needs in different sectors of the population. Care for a financially successful businessperson in a city may be significantly different from care for a rural diabetic farmer, who may not even wear shoes or understand the importance of

specialized foot care and shoes in avoiding a lower extremity amputation. The rural population may not be able to afford the more costly dressings, treatments, and devices often used in countries such as the United States. This disparity in understanding and care contributes to the high amputation rate, associated high costs of care, and high rate of morbidity and mortality in the diabetic population. The question then becomes how this situation can be modified with a standardized national protocol.

First and foremost, an evaluation of the entire country's medical system, including financial considerations, patient access to care centers, available treatment resources, physician training, and availability, as well as unmet needs, must be made. Once this task has been accomplished, an international protocol for the diabetic foot may serve as a broad template that can be modified entirely to the country's needs. Included in this modification would be resources that are readily available and affordable based on the average national income. This may mean that the protocol and resource guide may recommend the use of home-type inexpensive remedies, basic dressings, and standard procedures that, while considered antiquated in other countries, may nonetheless successfully address the diabetic foot ulcer. Expensive shoes that are imported may be replaced by locally available footwear that is less expensive, or appropriate footwear may be contracted to local shoe manufacturers at more reasonable prices than foreign-made shoes. The economy benefits medically as well as financially when as many products as possible are procured locally.

A protocol and guide to care can be designed and implemented through local physicians with an interest in wound care, guided by perhaps one or two international experts. This allows for a combination of established expertise and local insights, in contrast to the large financial sum paid by many countries to purchase an internationally known hospital "name brand," which may provide recognition but not needed care.

The final step in implementation is government approval. Once this has been obtained, a national effort may be launched to ensure that all government-supported hospitals have access to the protocol. A protocol is only as valuable as the clinicians using it, so the launch must include training of physicians at each site. To allow for local variations in customs and care patterns, the protocol must not be restrictive.

There is no lack of well-trained physicians and clinicians in Thailand, nor is there an absence of technologically advanced and well-equipped medical centers and educational institutions. The deficiency lies in minimal centralized and specialized centers with standardized protocols, training, and approaches to treatment. Physicians and surgeons with specific training in the treatment of problematic wounds, especially the diabetic foot, are grossly lacking. Care is currently scattered at various locations, with variation in treatment approach enhanced by the absence of an educational foundation to ensure not only

the most optimal care but also to the proper training of physicians and maintenance of evolving treatment approaches to address changes in medical technology and cultural and social needs. Internal research of epidemiologic trends, clinical treatment options, and new technology is not well developed. Care is currently provided by varying medical specialties, which, because of their differences in practice and hospital location, may not interact.

The Diabetes Solution

Diabetes is rapidly becoming the No. 1 disease globally, soon to surpass the human immunodeficiency virus in numbers of deaths, incidence and prevalence of disease. Diabetes is associated with various problems resulting in morbidity and mortality, one of the most significant being lower extremity amputation. The International Diabetes Federation has estimated that as a result of diabetes-related complications, approximately 1 amputation occurs somewhere in the world every 30 seconds. The majority of amputations worldwide are done on diabetic patients, with the predominant medical cause of the amputation being diabetic foot ulcers. Diabetic foot ulcers are better described as ulcers resulting from prolonged pressure on and/or neuropathy in the insensate diabetic foot, although other factors, including impaired vascular status, injury, and infection, may also contribute to the final outcome. When amputation occurs, personal, social, and financial burdens are incurred. In countries with limited resources and limited employment, amputation may place individuals in a position in which they are no longer able to work, be productive, or sustain themselves financially or physically. Creating centers for diagnosis, treatment, and prevention of diabetic foot complications would significantly impact the life of the individual while helping society and the country as a whole. The barriers to attaining this goal are lack of structured diabetic foot treatment centers, limited physician education materials, unavailability of organized country-specific protocols, patient education materials that are culture and lifestyle specific, and finally, the small number of individuals willing to dedicate their career and time to the establishment of country-specific centers globally.

An education exchange program with US universities and centers of excellence could enhance clinician training but would not solve the internal fragmentation of care. While training of physicians is essential, it is most effective when conducted in the country where the problem exists, thereby allowing for integration of local culture and social considerations.

Currently, two primary approaches have been taken by Thailand in an attempt to curb and address morbidities and comorbidities of the diabetic foot, both of which have significant limitations. One has been to train a limited number of individual physicians abroad, primarily in the United States and Europe, through brief internships and

fellowships allowing exposure to diabetic foot and wound treatment centers. This approach allows for a very small number of individuals to be trained per year. Those who receive training may vary in specialty, including vascular surgeons, general surgeons, podiatrists, plastic surgeons, and others. These individuals receive different emphasis within their training period and return to Thailand to provide a limited amount of care within their specialties without focusing on only the diabetic foot problem.

The second approach has been to pay internationally recognized hospitals and institutions exorbitantly high sums of money to open foreign hospitals affiliated with their US institution names. An erroneous assumption may have been that simply giving a hospital the same name as its US affiliate and providing a few US staff members (very few of whom have extensive training in diabetic foot and diabetic foot ulcers) will make a complex and stratified problem disappear.

Neither of the above approaches has resulted in any significant decrease in amputation numbers, complications, and morbidity of the diabetic foot. The most rapid and effective means of creating change is to provide a small number of experienced and well-educated experts in diabetic foot care to coordinate key leaders throughout the country to assist with building the foundation of diabetic foot care. The introduction of a large foreign hospital, doctors inexperienced in foot care, and a top-heavy administration only serves to burden and slow, rather than expedite, the creation of needed centers and education, and it also results in an expensive system providing minimal positive outcomes. Two or three efficient and skilled coordinators would rapidly infiltrate and assist with the building of a customized and managed system within Thailand to address their own country's needs.

Summary

It is evident that Thailand, like many countries in the Asia and Pacific Rim region, is experiencing a staggering increase in diabetes and related complications, particularly amputations related to diabetic foot problems. The affected countries all need to initiate the creation of diabetic foot clinics in suitable geographic locations. Health care providers will need to receive clinical protocols, guidelines, and patient education materials because established medical institutions providing lower extremity care or wound care curricula are not available. Ongoing training will be needed to ensure high-quality, affordable care.

References

1. Hellman S, Baker L, Flores D, Lehman H, Bacon J: Effect of ethnicity on adherence to diabetic regimen. *Ethn Dis.* 1997;7(3):221–228.

2. Brem H, Sheehan P, Rosenberg HJ, Schneider JS, Boulton AJ: Evidence-based protocol for diabetic foot ulcers. *Plast Reconstr Surg.* 2006;117(suppl 7):193S–209S.
3. Jones KR, Fennie K, Lenihan A: Evidence-based management of chronic wounds. *Adv Skin Wound Care.* 2007;20(11):591–600.
4. Margolis DJ, Kantor J, Berlin JA: Healing of diabetic neuropathic foot ulcers receiving standard treatment: a meta-analysis. *Diabetes Care.* 1999;22(5):692–695.
5. International Diabetes Federation. Position statement: the diabetic foot. Available at: http://www.idf.org/Position_statementsdiabetic_foot. Accessed September 27, 2010.
6. Ngarmukos C, Bunnag P, Kosachunhanun N, et al: Thailand diabetes registry project: prevalence, characteristics and treatment of patients with diabetic nephropathy. *J Med Assoc Thai.* 2006;89(suppl 1):S37–S42.
7. Panamonta O, Thamsiri N, Panamonta M: Prevalence of type II diabetes and metabolic syndrome among overweight school children in Khon Kaen, Thailand. *J Med Assoc Thai.* 2010;93(1):56–60.
8. Wattana C, Srisuphan W, Pothiban L, Upchurch SL: Effects of a diabetes self-management program on glycemic control, coronary heart disease risk, and quality of life among Thai patients with type 2 diabetes. *Nurs Health Sci.* 2007;9(2):135–141.
9. Sranacharoenpong K, Hanning RM, Sirichakwal PP, Chittchang U: Process and outcome evaluation of a diabetes prevention education program for community healthcare workers in Thailand. *Educ Health (Abingdon).* 2009;22(3):335.
10. Tantisiriwat N, Janchai S: Common foot problems in diabetic foot clinic. *J Med Assoc Thai.* 2008;91(7):1097–1101.
11. Elhadd TA, Al-Amoudi AA, Alzahrani AS: Epidemiology, clinical and complications profile of diabetes in Saudi Arabia: a review. *Ann Saudi Med.* 2007;27(4):241–250.
12. Fatani HH, Mira SA, el-Zubier AG: Prevalence of diabetes mellitus in rural Saudi Arabia. *Diabetes Care.* 1987;10(2):180–183.
13. International Diabetes Federation fact sheet: Did you know? 2008.
14. World Health Organization. Resolution WPR/RC51.R5: prevention and control of noncommunicable diseases. Available at: http://www.wpro.who.int/rcm/en/archives/rc51/rc_resolutions/wpr_rc51_r05.htm. Accessed September 27, 2010.
15. Every thirty seconds a limb is lost somewhere in the world as a consequence of diabetes. *Lancet.* 2005;366(9498):1719–1724.
16. International Consensus on the Diabetic Foot and Practical Guidelines on the Management and the Prevention of the Diabetic Foot. International Working Group on the Diabetic Foot. 2003. Available at: <http://www.iwgdf.org/>.
17. International Diabetes Federation: Diabetes Atlas. 3rd ed. Brussels, Belgium: IDF; 2006.
18. Bjork S, Kapur A, King H, Nair J, Ramachandran A: Global policy: aspects of diabetes in India. *Health Policy.* 2003;66(1):61–72.
19. Singh N, Armstrong DG, Lipsky BA: Preventing foot ulcers in patients with diabetes. *JAMA.* 2005;293(2):217–228.
20. Pecoraro RE, Reiber GE, Burgess EM: Pathways to diabetic limb amputation: basis for prevention. *Diabetes Care.* 1990;13(5):513–521.
21. Lavery LA, Armstrong DG, Wunderlich RP, Tredwell J, Boulton AJ: Diabetic foot syndrome: evaluating the prevalence and incidence of foot pathology in Mexican Americans and non-Hispanic whites from a diabetes disease management cohort. *Diabetes Care.* 2003;26(5):1435–1438.
22. Nather A, Bee CS, Huak CY, et al: Epidemiology of diabetic foot problems and predictive factors for limb loss. *J Diabetes Complications.* 2008;22(2):77–82.
23. Al-Tawfiq JA, Johndrow JA: Presentation and outcome of diabetic foot ulcers in Saudi Arabian patients. *Adv Skin Wound Care.* 2009;22(3):119–121.
24. Farah N. UAE among top ten countries where diabetes is widespread. *Gulfnews.com.* March 12, 2010. Available at: <http://gulfnews.com/news/gulf/uae/health/uae-among-top-10-countries-where-diabetes-is-widespread-1.595625>. Accessed September 28, 2010.
25. Focus on Africa [special issue]. *Diabetes Voice.* 2006;51(3). Available at: <http://www.diabetesvoice.org/en/issues/06/09/01/volume-51-issue-3>. Accessed September 28, 2010.
26. Diabetes Declaration and Strategy for Africa: a call to action and plan of action to prevent and control diabetes and related chronic diseases. Retrieved March 2009. Available at: www.idf.org/webdata/docs/IDF-Africa-Action-Plan-FINAL.pdf.
27. Narayan KM, Boyle JP, Geiss LS, Saaddine JB, Thompson TJ: Impact of recent increase in incidence on future diabetes burden: U.S., 2005–2050. *Diabetes Care.* 2006;29(9):2114–2116.
28. Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates on diabetes. Available at: http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf. Accessed February 3, 2010.
29. Rogers LC, Lavery LA, Armstrong DG: The right to bear legs—an amendment to healthcare: how preventing amputations can save billions for the US health-care system. *J Am Podiatr Med Assoc.* 2008;98(2):166–168.
30. Hogan P, Dall T, Nikolov P: Economic costs of diabetes in the U.S. in 2002. *Diabetes Care.* 2003;26:917–932.
31. Shearer A, Scuffham P, Gordoia A, Oglesby A: Predicted costs and outcomes from reduced vibration detection in people with diabetes in the U.S. *Diabetes Care.* 2003;26:2305–2310.
32. Gordoia A, Schuffham P, Shearer A, Oglesby A, Tobian JA: The health care costs of diabetic peripheral neuropathy in the U.S. *Diabetes Care.* 2003;26:1790–1795.
33. Rezende KF, Ferraz MB, Malerbi DA, et al: Predicted annual costs for inpatients with diabetes and foot ulcers in a developing country: a simulation of the current situation in Brazil. *Diabet Med.* 2010;27(1):109–112.
34. International Monetary Fund. Available at: <http://www.imf.org/external/country/THA/index.htm>. Accessed January 10, 2009.
35. Aekplakorn W, Stolk RP, Neal B, et al: The prevalence and management of diabetes in Thai adults: the international collaborative study of cardiovascular disease in Asia. *Diabetes Care.* 2003;26(10):2758–2763.